

Tech transfer industry shows gains

in patents filed and granted,
university-created startups,
commercial products
—but slippage in federal research funding cited



Highlights of AUTM's U.S. Licensing Activity Survey
FY2013



Association of University Technology Managers®
Advancing Discoveries for a Better World®

Things weren't looking good for Valerie Esposito ...

... Long Island resident, government clerical worker and single mother of three who, at age 41, had been struggling with metastatic melanoma for four years and now had tumors throughout her body, including a large one on her lung and others pressing excruciatingly on her spine and spleen. Her condition, which had begun with a mole discovered during pregnancy, was now, in the early spring of 2011, considered end-stage.

But a new protocol combining recently approved immunotherapy drug Yervoy with radiation not only halted the metastases—it dramatically shrank her existing tumors in a matter of a few weeks.

Valerie Esposito today is healthy and enjoying her first grandchild. Her life was saved and prolonged by the practice of technology transfer, through which discoveries move from university and other research laboratories to commercial partners capable of transforming the inventions into beneficial products and services. The results of tech transfer can be seen all around us: in dramatic therapies and cures, in productivity advances that connect the world more closely and in clean technologies that offer a brighter path forward for future generations.



The story of Valerie Esposito is just one example of how technology transfer practices conducted by universities and other nonprofit entities span the globe and yet facilitate work at the microscopic level to improve the human condition. At the same time, academic tech transfer powers the innovation economy, creating jobs, improving productivity and offering solutions to environmental challenges.

And although tech transfer is a complex and time-intensive process, its ultimate value is simply that it makes the world a better place.

The Association of University Technology Managers (AUTM) plays a key role in the process by highlighting the public value of tech transfer; promoting important intellectual property protections, including ongoing benefits of the pivotal Bayh-Dole Act; and supporting its members and other technology transfer professionals through education, advocacy and industry engagement.

Each year, AUTM conducts its *Licensing Activity Survey* to quantify tech transfer.

For more than two decades, AUTM has been the leader in collecting, synthesizing and disseminating academic technology transfer data as a valued resource for all aspects of the industry. In recent years, AUTM's survey data have continued to show impressive gains in several categories, including the number of university technology startups launched and employment at those fledgling companies.

The numbers reported in these *Highlights* of the survey are drawn from FY2013 as a measure of those U.S. institutions reporting (approximately 200 of a 300 total population) and therefore do not represent the composite activities comprising tech transfer. They do, however, reflect the major role tech transfer plays in transforming our society and our economy.

And yet, in attempting to assess the impact of tech transfer and determine future investment in its practice, can we really put a number on the benefits to society? By demonstrating significant growth over time, through metrics ranging from licensing income to new products, can statistical results quantify actual improvements in the human condition? Can numbers reflect the creative research achievements of individual institutions, while highlighting the need for continued support of intellectual protections and efforts to advance tech transfer globally?

"While we are a numbers-driven society," says Jane Muir, president of AUTM and director of the Florida Innovation Hub at the University of Florida, "it is important to note that some of the most important numbers are not actually captured in this survey. It is difficult to quantify the impact of the many people whose cancer is in complete remission as a result of immunotherapy research started in a university lab."

But when coupled with the compelling human stories behind them, metrics can indeed start to sum up the human impact of technology transfer.



When coupled with the compelling human stories behind them, metrics start to sum up the human impact of technology transfer.

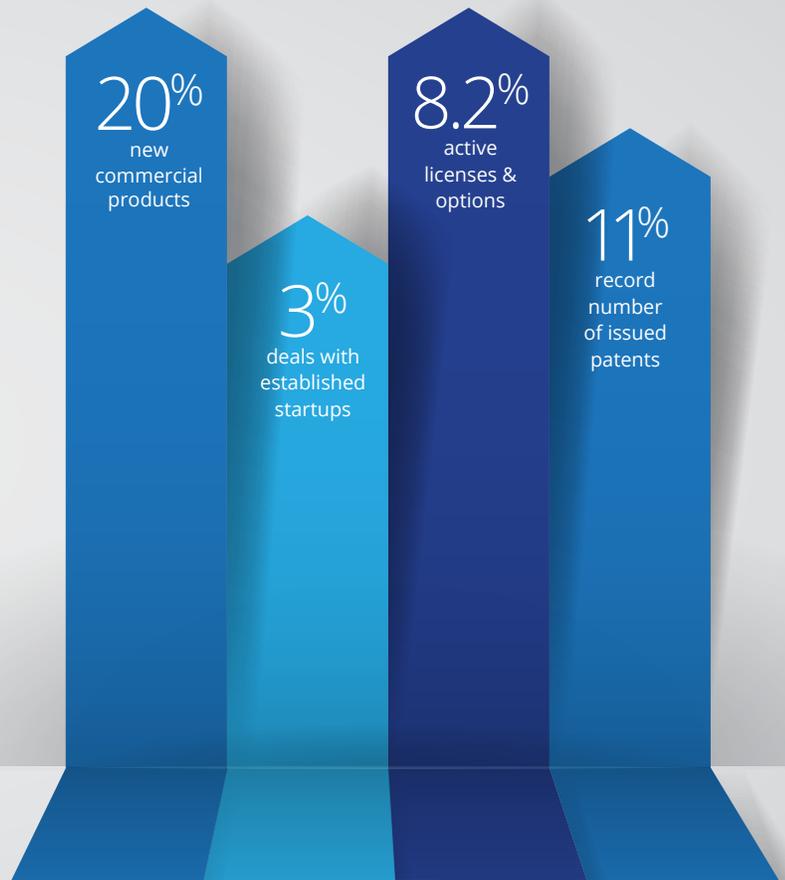
This AUTM *U.S. Licensing Activity Survey* FY2013 *Highlights* provides a preview of the data found in the fiscal year 2013 report and offers a glimpse into the current state of the tech transfer field. The comprehensive AUTM *Licensing Activity Survey* FY2013 will be published later this year. That data will be supplemented with additional stories about the true impact of technology transfer and its substantial social impact as measured by products that transform lives—like Valerie Esposito's—improve its quality and increase the competitiveness and productivity of our global society.

And this edition of the *Highlights* shows that, despite reductions in federal research funding, academic and research institution licensing and startup activity are very strong and continue to play an important role in the economy. But that strength won't be sustained without ongoing investment into research by government.

Healthy increases

The survey reveals that the combined number of executed licenses and options by the reporting institutions showed healthy increases over FY2012, as did the number of startups formed and those that were active at the end of the fiscal year. FY2013 saw a modest gain in total research expenditures, due in large part to a stronger contribution from industry. The number of issued patents topped last year's record numbers. Patent and legal expenditures increased, while legal reimbursements were essentially flat. Deals with established startup companies rose 3%. The total number of active licenses and options through the close of 2013 also increased. The number of new commercial products that were created grew more than 20%.

University-based research generates a significant return on investment for national and global economies. In addition to jobs created by startup companies, product sales for companies and new industries, research creates jobs directly through the hiring of principal investigators, research teams, lab technicians and others who help support the work. Indirectly, research creates jobs through innovations leading to new technologies, new companies and new industries.



After a period of steady growth in federal research funding driven by stimulus money, federal research dollars remained relatively flat (-0.7%) last year, and there are signs that additional headwinds can be expected. A study by the American Association for the Advancement of Science found that overall federal research and development funding could be reduced by \$57.5 billion or 8.4% if federal sequestration remains in place through 2017. Research grants funded by the National Institutes of Health (NIH) have declined every year since 2004.

This level of disinvestment occurs at the risk of diminishing the various benefits of technology transfer that AUTM and the industry overall have worked to achieve. As a result, universities have explored expanding their relationships with industry collaborators. This trend is reflected in a significant increase in industry-sponsored research expenditures, as follows:

\$65.1 billion

total research expenditures ▲2.3%

\$39.9 billion

federally funded research expenditures ▼-0.7%

\$4.58 billion

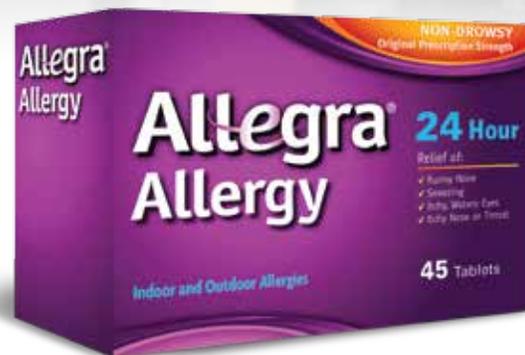
industry-sponsored research expenditures ▲11%



John Ritter, vice president of Metrics and Surveys for AUTM and director of the Office of Technology Licensing at Princeton University, says the association is working hard to introduce new measures of societal impact through the data it collects.

“We’re finding better ways of asking questions and capturing answers that provide a more nuanced understanding of how technology transfer benefits society,” Ritter says. “We hope that our surveys help communicate the benefits of our work to university leaders, policymakers, scholars, alumni, industry and the general public.”

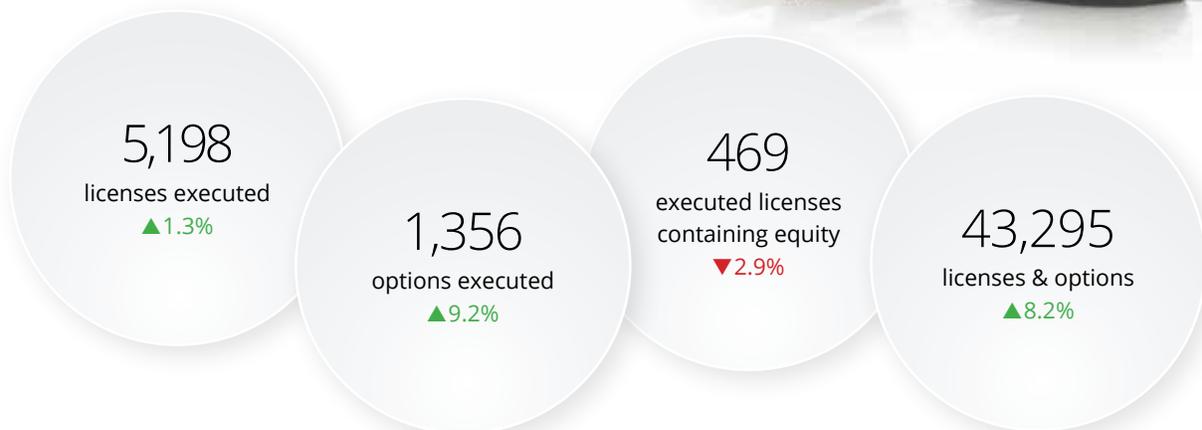
One facet of the effort includes working more closely with AUTM members, who are on the front lines, to learn of successful products arising from campus labs and progressing into the marketplace. Survey data show there are close to 10,000 patented products currently being sold that originated in academic research laboratories.



These products include blockbusters such as Allegra, which resulted from the efforts of a Georgetown University researcher to understand the role of fexofenadine in reducing symptoms of seasonal allergies. One out of 5 in the U.S.—a total of 60 million people—suffers from asthma and allergies. The Georgetown discovery was commercialized by Sanofi-Aventis and has helped allergy sufferers everywhere breathe more easily while avoiding the risks associated with earlier allergy medications.

Boost in critical partnerships

Collaboration between academia and industry has increasingly become a critical component of an efficient national innovation ecosystem. The signing of a license agreement begins a long-term relationship between the university and its industry collaborator. Data pertaining to licensing activity in FY2013 shows an increase in partnerships established between academia and industry. Overall, the data revealed:



Case study: **Procysbi**

The drug Procysbi (a delayed-release prolonged-acting form of a generic drug: cysteamine bitartrate) was recently approved for treatment of a rare childhood kidney disease—nephropathic cystinosis. Although the utility for the treatment of cystinosis was discovered in the 1970s by researchers at the University of California, San Diego, the development of Procysbi is an example of the long-term diligence and collaborations often required to bring life-saving products to market.

The earliest trials of the drug eventually led to additional studies to improve its efficacy. The University of California filed patents in 2006, and clinical work, supported by the Cystinosis Research Foundation, commenced on a new drug formulation. Clinical validation helped elicit the interest of a corporate partner, Raptor Pharmaceuticals, which licensed the technology in 2007. By working closely with the inventors, Raptor was able to move Procysbi quickly into clinical trials, while continuing to fund research that may expand the indications for which this drug may be used. Although many drugs take more than a decade to get onto the market, Procysbi reached the market in 2013.

Case study: **SiNode**

Another example of town-and-gown collaboration is SiNode Systems, a minority-owned clean-tech startup developing innovative lithium-ion battery anodes that significantly boost charging speed and increase energy capacity to 10 times longer than existing anode technology, responding to an increasingly basic need of modern life. The anode could greatly enhance battery life for hybrid and electric vehicles and smartphones.

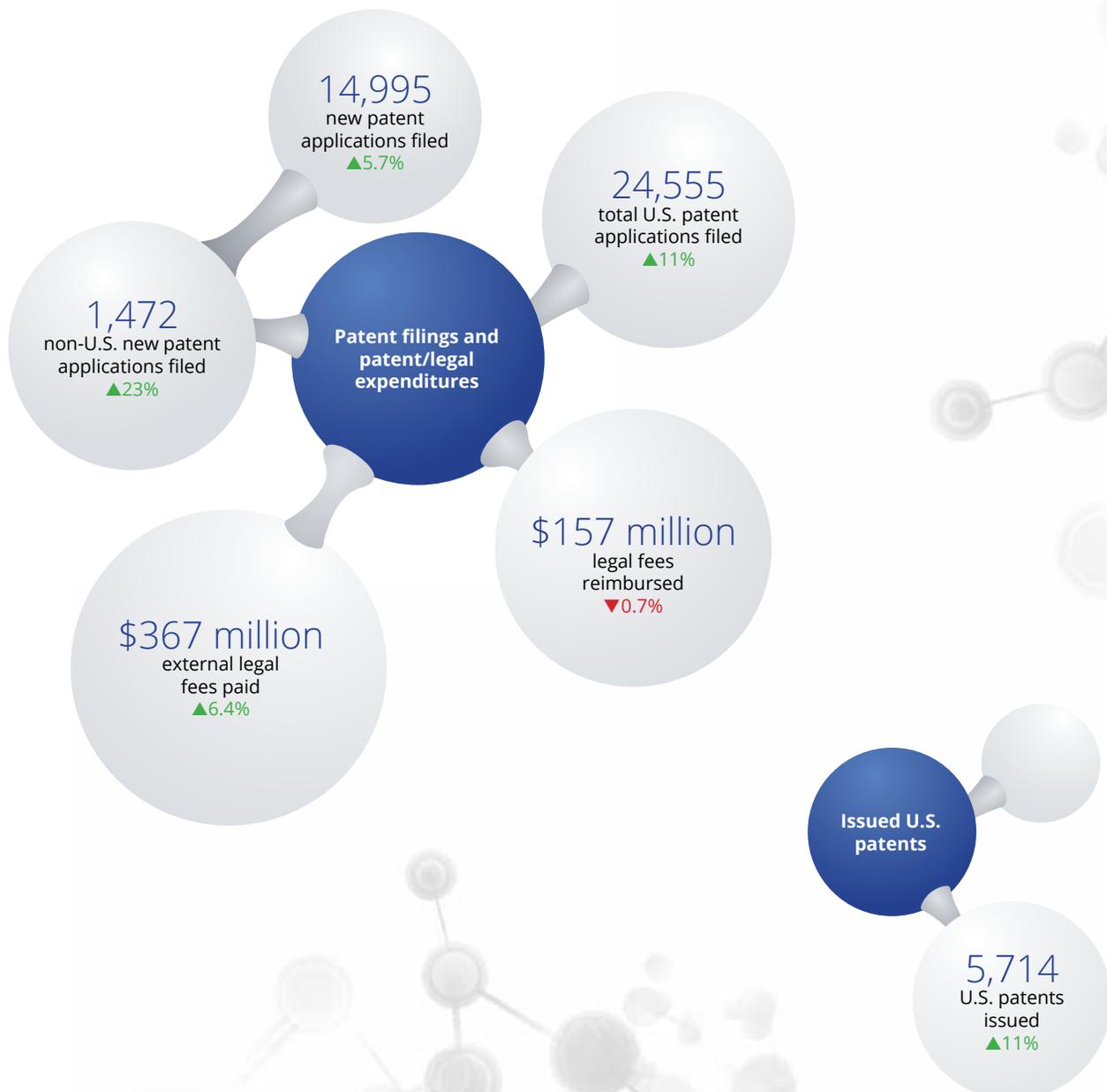
Developed, optimized and patented in collaboration with researchers at Northwestern University and Argonne National Laboratory, SiNode technology uses a composite of silicon and graphene in a layered structure. SiNode Systems recently was awarded a \$1 million Phase II SBIR grant from the U.S. Office of Energy Efficiency and Renewable Energy (EERE).

A KEY ISSUE

The rise in intellectual property protection

Academic research remains primarily focused on the education of the next generation of research scientists and engineers and the timely dissemination of research findings in peer-reviewed scientific journals. A portion of academic research findings may result in technologies that show commercial promise. After all, a significant portion of the U.S. economy is driven by industries that are extremely dependent on intellectual property. To encourage investment in technology that might otherwise lay dormant, research institutions file patents on these disclosures. Patents are essential to universities' role in encouraging uptake in the marketplace. Universities pursue patents so that entrepreneurs will invest and build businesses. Patents provide the basis for a company to invest substantial resources and time—five to 10 years or more—to develop the technology into commercially viable products.

Activities related to academic intellectual property management increased in FY2013, with data showing a rise in the initial expenses to academia for intellectual property protection:



A study by the Biotechnology Industry Organization estimated the economic impact of university and nonprofit patent licensing from 1996 to 2010 was as much as \$388 billion on the U.S. gross domestic product and \$836 billion on the U.S. gross industrial output, while creating as many as 3 million jobs.



Case study: **Lyrica**

Lyrica, the work of a Northwestern University chemistry professor, represents another commercial success story through its unique ability to reduce epileptic seizures and provide relief to patients suffering from chronic pain associated with fibromyalgia. Licensed by Pfizer, Lyrica has helped millions of people and exemplifies the positive human health impact of a single blockbuster invention. Many university inventions captured in the AUTM survey may never be blockbusters like Lyrica, yet they still hold promise to improve people's lives in ways both subtle and important.

Case study: **Self-de-icing pavement**

Consider the carbon fiber strips developed at the University of Alaska Anchorage. When embedded in sidewalks and paired with a low-voltage current, this invention provides a cost-effective way to avoid shoveling all winter. An additional outcome from such a product is a reduction in the number of ice-related injuries.



Case study: **Vapor Wake canines**

Another example of a real-world benefit can be found in the Vapor Wake canines being bred and trained by scientists at Auburn University. The university's technology, now under license to a startup, results in dogs with an exceptional sense of smell and the unique ability to detect and track mobile explosives, such as bombs being carried through airports or crowded urban settings.

In recognition of the potential impact of companies launched with university technology, AUTM has introduced new measures to help quantify the scope of startup activity.

So far, detailed data have been collected on close to a third of the 8,500 startups that have been reported through the AUTM survey over the years.

This year's survey revealed the following startup and product data:

818

startup companies
formed
▲16%

611

of them had their primary
place of business in the licensing
institution's home state
▲10.3%

4,206

startups in operation as
of the end of FY2013
▲5.1%

\$22.8 billion

of net product sales
were generated last year
▼38%

719

new commercial products
created by companies licensing
university technology
▲22%

Startup companies can be an effective mechanism for transferring nascent technology from the university research environment to the marketplace. In FY2013, the 818 new companies created as a result of technology transfer activities represent an increase of 16% over the prior year and an average of 2.25 new companies per day. Almost 75% of these companies remain local, stimulating economies and creating thousands of new jobs along the way. Small companies such as these are the American job creators, generating the majority of new jobs in the U.S., according to the U.S. Department of Labor's Bureau of Labor Statistics.

Another positive indicator is the total number of startups in operation as of the end of FY2013: 4,206, which is an increase of 5.1% over the prior year. According to the Science Coalition, "Companies spun out of research universities have a far greater success rate than other companies, creating good jobs and spurring economic activity."

Jane Muir emphasizes the inherent limitations of the numbers: "It is important to note here that only 70 institutions reported this startup company data, against a total population of approximately 300 institutions. Most tech transfer offices do not have the resources to track this data, so these numbers are grossly under-representative of the true impact of technology transfer on job creation."

AUTM reported more than \$22 billion in sales of products created and based on academic research. In FY2013, nearly 14 new commercial products were created each week—products based on university discoveries for which patents were typically filed five to 12 years prior. The goal of university technology transfer activities—to advance research discoveries from academia to the marketplace for society's benefit—is achieved when these new products reach the marketplace after years of development by industry collaborators.

Despite a 38% drop in net product sales, which could be largely attributable to agreements—and presumably patents—expiring and the products not being counted in the survey data, these products are still benefitting society. At Emory University, discovery of HIV antiretroviral drugs has led to significant patent agreements. More than 80% of people infected by HIV take at least one of the drugs invented by Emory professors. Some of the agreements recently expired, significantly reducing net product sales, but these life-saving drugs are still being prescribed in much of the developing world. Merck & Co. handles marketing and distribution of the first once-a-day, single-tablet regimen for adults with HIV. Merck announced it will lower the drug's cost in countries with high HIV prevalence using a sliding scale based on each country's wealth. The drug will be registered in 45 countries in the Middle East and Africa and in nine countries in Latin America, the Caribbean and Asia.

Taken as a whole, the FY2013 survey numbers, "paint a truly impressive picture of the breadth and depth of technology transfer and its economic impact," says AUTM's John Ritter. "Yet underlying all of these statistics are human examples of lives saved and lives better lived, thanks to discoveries that have arisen from basic research and reached people everywhere in the form of useful products and services."

About the U.S. survey

The 2013 U.S. survey was distributed to 299 U.S. institutions (232 universities and colleges, 61 hospitals and research institutions, three national laboratories and three third-party technology investment firms). Of the 299 U.S. institutions contacted, 202 responded, for a response rate of 68%, a slight improvement over the 2012 survey, which generated a response rate of 65%. Respondents for 2012 included 170 universities, 30 hospitals and research institutions, one national laboratory and one third-party technology investment firm.



About technology transfer

Technology transfer moves ideas from research institutions to the marketplace to improve the quality of life and benefit society. Technology transfer offices assist the efforts of researchers to identify commercially viable technologies and obtain patents or other legal protection for the intellectual property. Technology transfer offices also help promote these technologies to potential licensees, negotiate licensing agreements and manage their respective institution's portfolio of licenses and patents. Licensees—from startups to large companies—are typically responsible for commercializing the licensed technologies by integrating the technologies into products and overseeing the development, manufacture and marketing of those products.

The patenting of discoveries is fundamental to attracting companies, entrepreneurs and investors into allocating the necessary resources to ensure that these discoveries have the opportunity to reach the stream of commerce. The returns on this investment are the products that benefit the public, drive economic growth and employment, and generate state and federal tax revenues. These technology transfer efforts are pursued in concert with the research institutions' core values of sharing research results, materials and know-how for the betterment of the community and society.

About AUTM

The Association of University Technology Managers (AUTM) is a nonprofit organization with an international membership of more than 3,200 technology managers and business executives. AUTM members—the majority of whom are managers of intellectual property, with IP being one of the most active growth sectors of the global economy—work at universities, research institutions and teaching hospitals, as well as numerous businesses and government organizations.

For more information regarding the FY2013 survey—including sponsorship opportunities and past surveys—please visit the AUTM website (www.autm.net).



Immunotherapy

Among the tech transfer industry's significant latter-day focuses, immunotherapy harnesses the body's own immune system to fight tumors. Melanoma, the most dangerous form of skin cancer and that which threatened Valerie Esposito's life, is caused by uncontrolled growth in pigment-producing skin cells. Highly curable in its early stages, melanoma can often be surgically removed. But it is more likely than other skin cancers to metastasize, making treatment far more difficult. In the late stages of metastatic melanoma, the average survival rate is six months.

The American Cancer Society (ACS) reports that melanoma accounts for less than 5% of all skin cancer cases ... but it is responsible for the vast majority of skin cancer deaths. The ACS estimates that in 2014, 76,100 in the United States will be diagnosed with melanoma, and 9,710 will die from the disease.

James Allison, a professor in the Division of Immunology and director of the Cancer Research Laboratory at the University of California, Berkeley (UCB), studied immune responses to cancer, and how the disease proliferates by selectively suppressing T-cell activation.

In 1995, he showed that a checkpoint molecule called cytotoxic T lymphocyte antigen-4 (CTLA-4) puts the brakes on T-cell responses. Block CTLA-4 and the immune system could be activated, according to Allison's theory, unleashing a robust antitumor response. In preclinical experiments, he demonstrated that he could bind a special type of protein called a monoclonal antibody to CTLA-4, preventing it from interfering with T-cell activation.

Melanoma is responsible for the vast majority of skin cancer deaths.

For help in the patenting process and finding a commercial partner, Allison turned to UCB's Office of Intellectual Property and Industry Research Alliances. The road to commercialization generally is long and challenging, and Allison's immunotherapy study was no exception. His technology originally was licensed to NeXstar Pharmaceuticals, which merged with the biopharmaceutical company, Gilead Sciences Inc., which sublicensed the rights to Medarex, which developed a human monoclonal antibody and began testing in partnership with Bristol-Myers Squibb. Bristol-Myers Squibb acquired Medarex in 2009.

In clinical trials, the antibody—generically named ipilimumab—added months to the survival rates of patients with advanced melanoma, something no other drug had been able to achieve. Based on the results of a randomized, double-blind Phase III study, the drug was fast-tracked and approved as brand-name Yervoy by the U.S. Food and Drug Administration in March of 2011.

To date, well over 10,000 cancer patients—Valerie Esposito among them—have received Yervoy in clinical trials to treat advanced melanoma and other types of cancer, either alone or in combination with other drugs, with a survival rate of 17% to 22%. Bristol-Myers Squibb is testing Yervoy to treat specific prostate cancers, as well as small-cell and non-small-cell lung cancer.

Both federal dollars—through the National Institutes of Health—and, later, private funding supported Yervoy's path from the lab to the clinic.





Advancing Discoveries for a Better World®

111 Deer Lake Road, Suite 100
Deerfield, IL 60015, USA
Phone: +1 (847) 559-0846
Fax: +1 (847) 480-9282
info@atm.net



Association of University Technology Managers®
Advancing Discoveries for a Better World®