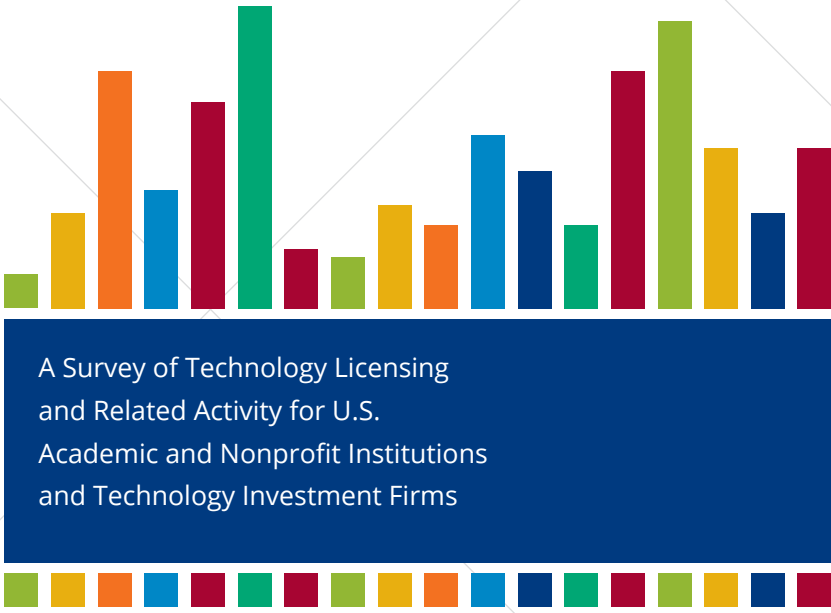
FY2016

AUTM U.S. Licensing Activity Survey



A Survey of Technology Licensing
and Related Activity for U.S.
Academic and Nonprofit Institutions
and Technology Investment Firms

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EXECUTIVE SUMMARY

Academic Research Commercialization Is an Economic Engine But Beware Attacks on Patent Rights

More than ever, academic technology transfer is driving economic development. It's evident in the formation of 1,024 startup companies in 2016 alone, and a significant increase in non-U.S. patent applications, which reflects a more international approach to the protection of intellectual property. These are some of the findings from the Association of University Technology Managers (AUTM) in the latest U.S. Licensing Activity Survey of 195 universities, hospitals and other research institutions across the country.

The annual survey also shows that U.S. research institutions continue to develop and invest in intellectual property arising from academic research. The number of federally funded invention disclosures (8,208) grew 6.2 percent from 2015, while new provisional applications filed in the United States (12,114) increased 5.2 percent and the number of U.S.-issued patents (7,021) rose 5.1 percent.

The 2016 survey revealed impressive double-digit gains in several areas. In addition to a 33.6 percent increase in non-U.S. patent applications, clinical trial expenditures were up nearly 14 percent from the previous year.

Driving the Innovation Economy

A recent study from AUTM and the Biotechnology Innovation Organization (BIO) shows that academic-based research boosts local, national and global economies. Technology transferred from research institutions to the marketplace helps create jobs through new startups and product sales, and contributes to the evolution of new industries. That's why it's particularly important to note that the number of new startups (1,024) based on academic inventions continues to grow.

Of these startups, research institutions received equity from 495, an increase of 5.1 percent compared with data from 2015. This equity component, often in lieu of cash payments from a financially strapped new company, highlights the continued support of startups by their licensing institutions for years to come. More than 7 out of 10 startups reported their primary place of business in the home state of their licensing institutions, creating opportunities within their local economies.

AUTM's U.S. Licensing Activity Survey reveals the impressive work being performed by technology transfer offices across the nation. In 2016, total research expenditures were up only 0.45 percent, after being effectively flat for five years. Meanwhile, the survey shows that on average, a single licensing officer executed 6.9 licenses and options, an increase of 6.3 percent from 2015 and an increase of 16.3 percent from five years ago.

Is everything rosy? No.

The Perils of Eroding Patent Rights

The report shows a slight decrease in option and exclusive license agreements compared with nonexclusive agreements. That's likely due to the concerns of company licensees. They worry about the increased risk of bringing inventions to market in the face of eroding U.S. patent rights, which have suffered at the hands of recent court rulings and legislation. For example, in 2016, the number of option agreements decreased 7.0 percent and exclusive licenses dipped 2.1 percent. These declines may indicate that the risk appetite of potential licensees is changing. It warrants careful observation. By contrast, nonexclusive licenses, which don't rely on market exclusivity, continue to rise (4,201, up 2.1 percent over 2015).

Such concerns are further underscored by our survey data that show 331 startups ceased operation in 2016, up 37.4 percent over the previous year and an ominous trend. Academic technology transfer is predicated on the ability of academic institutions to protect their nascent intellectual property to allow for licensees to invest and bring the invention to market. Recent patent rights erosion is tilting this balance and has resulted in fewer companies licensing academic inventions.

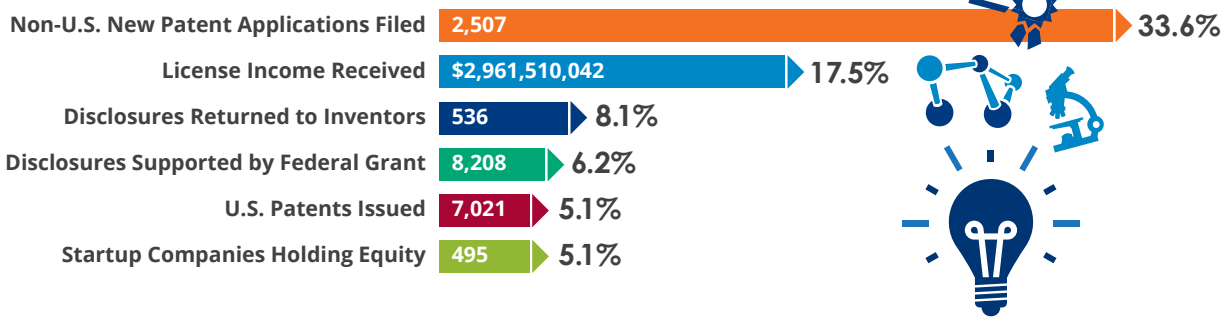
What does it all mean?

Technology transfer continues to be an important driver of impressive gains for local, state and national economies. Without this work, as supported by the Bayh-Dole Act, innovations would linger on lab shelves, their life-changing impacts never realized. It's a better world because of academic research commercialization. The 2016 U.S. Licensing Activity Survey bears that out.

Ragan Robertson
Cabinet Chair
AUTM Metrics and Surveys Portfolio

TECHNOLOGY TRANSFER GROWTH

Percentage Increases over 2015



The BetterWorld Project

Removing Arsenic from Drinking Water

Lehigh University

Tens of millions of people in Bangladesh and the eastern Indian state of West Bengal are poisoned by drinking water laden with toxic levels of arsenic, according to the World Health Organization. In the United States, the Environmental Protection Agency estimates that more than a third of wells in Arizona and California have excessive levels of the chemical.

"Arsenic is a natural contaminant of groundwater found throughout the Earth's crust," said Arup K. SenGupta, Ph.D., a professor at Lehigh University. "In some places arsenic levels are quite high, and it's become a very serious public health problem."

Exposure to arsenic can cause acute reactions including nausea, heart failure or even death within just a few hours. Although some individuals can tolerate large doses without ill effect, for most people, arsenic poisoning produces chronic and sometimes fatal diseases including diabetes, cardiovascular disease and cancer.

SenGupta began working on arsenic removal in the 1990s, winning several international awards for a well-based filtering system he developed for villages in India. As he continued researching novel filtering mediums, he found a way to impregnate tiny polymeric beads, known as anion exchange resins, with ferric hydroxide nanoparticles to create an effective mechanism for separating arsenic from the water in wells and public water supplies.

Massachusetts-based Solmetex Inc., a specialist in industrial arsenic remediation, was searching for a way to reduce arsenic in U.S. drinking water when it learned of SenGupta's work. The company quickly licensed and commercialized the patented technology, using the technique as the basis for an advanced filtering system called the LayneRT.

"The beauty of Arup's approach is that by embedding iron oxide into a polymeric structure, he's created a very durable product that lasts a long time and generates very little waste," said Solmetex CEO Owen Boyd.

In addition to installing the LayneRT in water systems throughout the United States, Sometex (later acquired by Layne Christensen Co.) began working with companies in India to install and maintain similar filtration systems there.

RESEARCH FUNDING

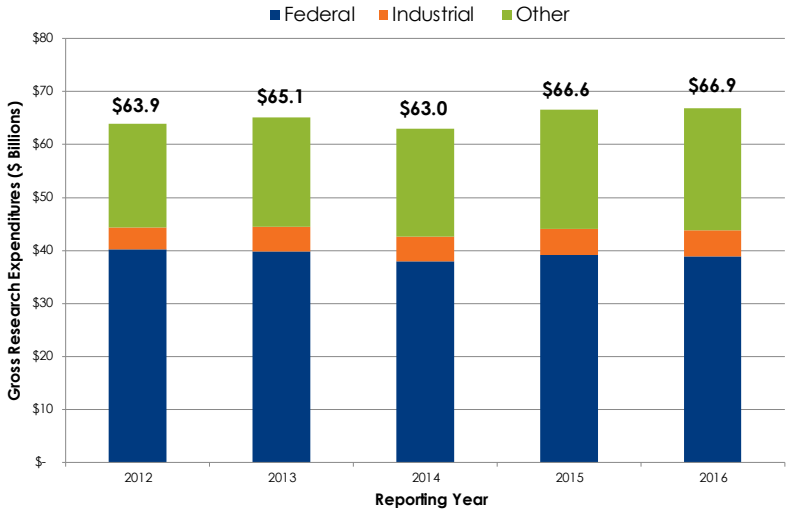
Research conducted in academic institutions provides the foundation underlying the innovation economy in the United States — leading to groundbreaking technologies and lifesaving medical treatments. Studies show that U.S. taxpayers receive a sizable return on their investment in federally funded research. Since 1996, academic patents and the subsequent licensing to industry have boosted U.S. industry gross output by up to $1.3 trillion and U.S. gross domestic product by up to $591 billion, and supported up to 4.3 million person-years of employment.

Total research expenditures in fiscal 2016 were up only 0.45 percent over the previous year, continuing a trend of virtually flat funding over the past five years.

Key Findings

- Federal and overall funding of research was effectively flat.
- Industry-sponsored research is growing, but it remains just a small fraction of research funding.
- Significant increases in research funding from other sources imply that institutions are finding creative solutions to obtain research support.

RESEARCH FUNDING RELATIVELY FLAT



The BetterWorld Project

Converting Mango Waste to Valuable Products

University of San Carlos

Although the mango is a nutrient-rich fruit, its peels and seeds actually offer more antioxidants and health compounds than the pulp.

Knowing that made it hard for University of San Carlos (USC) professor Evelyn Taboada, Ph.D., to watch tons of mango peels and seeds head to open dumpsites every day in her home province of Cebu in the Philippines. Left to rot, the mango waste released foul odors and attracted disease-carrying insects — a problem that was compounded by local residents scavenging in the dumpsites, creating a significant health hazard.

To tackle the problem, Taboada led a team of researchers from USC's BioProcess Engineering and Research Center in developing biochemical processes to convert the organic waste to commercially viable ingredients. Taboada turned to USC's newly created Innovation and Technology Support Office for help in patenting the mango waste conversion processes.

"This project has become the model for tech transfer success," said Danilo B. Largo, Ph.D., ITSO manager, who also licensed the technology across a wide range of applications to startup company Green Enviro Management Systems (GEMS), a joint venture between USC and a local investor.

Today, seven Cebu mango producers divert their mango waste to the GEMS processing facility, where peels and seeds are separated and converted to saleable products. The peels are ground into naturally gluten-free flour, which is exclusively licensed to a local bakery for making cookies, energy bars and bread. The mango husks are sold as low-cost fuel, and from the dried peels, high-value pectin and polyphenols are extracted and sold as ingredients for food and nutraceuticals.

During the peak of the mango season, GEMS processes up to 30 metric tons of mango waste per day with the help of 100 employees, including many of the people who used to scavenge at the dumpsites.

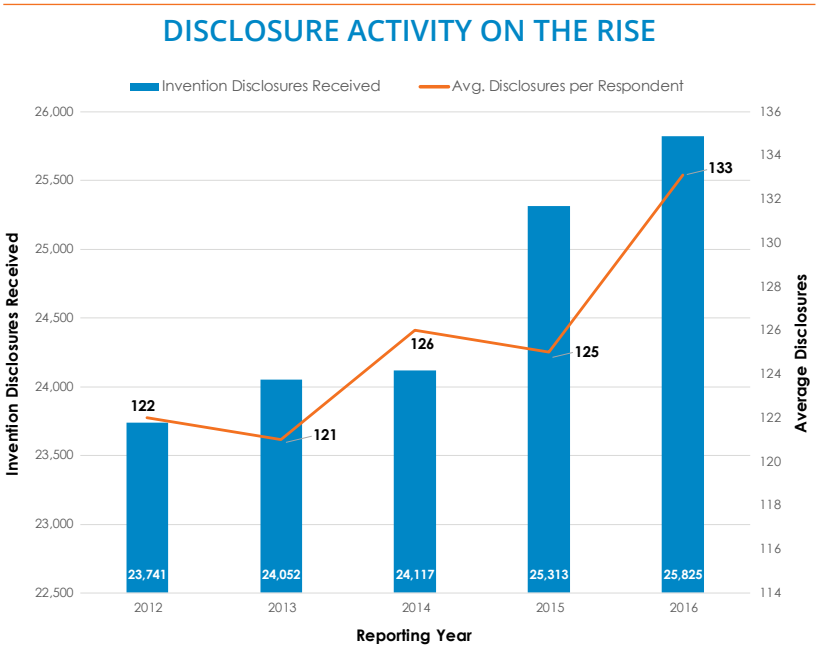
DISCLOSURES

Discoveries born out of research can lead to more impactful applied research, new commercial products and new companies. The movement of those discoveries and knowledge from the university to benefit the public is technology transfer, a collaborative process that begins when the inventor discloses an invention to the university. The invention disclosure is the launching pad for evaluating the technology, analyzing the market and developing strategies for protecting the intellectual property.

Disclosure activity, a key indicator of the levels of innovation, continued its upward trend in 2016.

Key Findings

- Disclosure activity has been on the rise in the past five years, increasing 8.7 percent since fiscal 2012.
- The average number of disclosures per respondent increased by 8 from 2015, the largest annual increase over five years.



The BetterWorld Project

Harnessing Patient's Immune System to Combat Cancer

St. Jude Children's Research Hospital

For patients with leukemia and lymphoma, today's treatments can fall short. If a patient's cancer recurs, the disease may be more aggressive and difficult to treat. Even when treatments are successful, there are often dangerous side effects with long-term consequences, particularly in children.

To develop a more effective treatment, Dario Campana, M.D., Ph.D., and Chihaya Imai, M.D., Ph.D., researchers at St. Jude Children's Research Hospital, looked to immunotherapy, a method that uses immune cells (known as T-cells) to attack cancer cells. By modifying the T-cells to target proteins expressed on the surface of cancer cells, these fighter cells can be genetically engineered to attack cancer.

Infusions of donor T-cells had helped a few leukemia patients, but in some cases the foreign cells attacked the patient's tissues and organs. Campana and Imai needed a way to control the T-cells' search-and-destroy activity while leaving healthy cells intact.

The researchers modified an existing T-cell therapy, called chimeric antigen receptor or CAR, using the patient's own cells instead of donor cells and adding a molecule called 4-1BB. The results were encouraging: The therapy not only induced T-cells to kill the targeted cancer cells, but also caused the fighter cells to proliferate.

"I was amazed by how powerful they were," said Campana, who now works at the National University of Singapore. "This incredible capacity to eliminate target cells within minutes was something that I had never seen before."

Biopharmaceutical company Juno Therapeutics licensed the patented CAR T-cell therapy in 2013 and began clinical trials to test its effectiveness in treating specific leukemias and lymphomas.

"Hopefully, as similar methods are being developed, patients with other forms of cancer will also benefit from these technologies," said Campana.

PATENTS

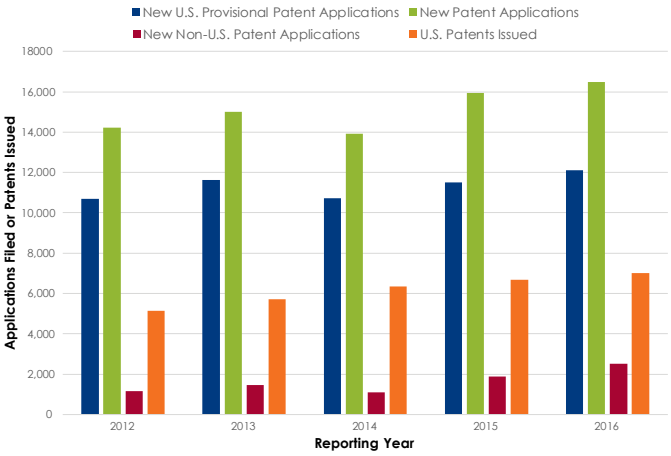
A key step in the transfer of technology is the protection of potentially useful ideas as intellectual property. Patent protections provide economic incentive for entrepreneurs and companies to invest in new technologies. This is especially important for inventions that require the commitment of significant financial and technical resources over a long period to develop into marketable products.

Protecting the intellectual property begins with the filing of a patent application with the U.S. Patent and Trademark Office and, when appropriate, foreign patent offices. New patent applications have been steadily increasing year over year.

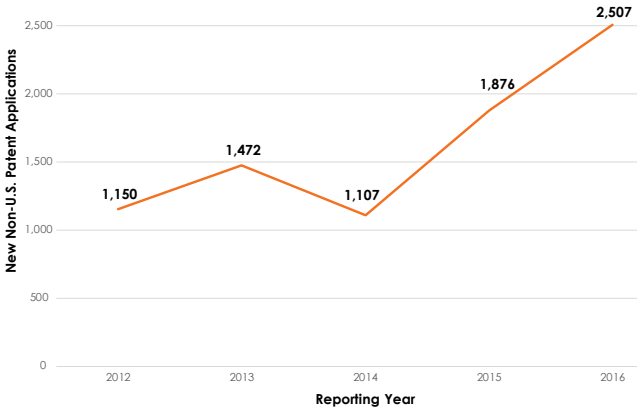
Key Findings

- Provisional applications filed in the United States (12,114) increased 5.2 percent over 2015.
- The number of U.S.-issued patents (7,021) grew 5.1 percent from 2015.
- Non-U.S. patent applications increased 33.6 percent.

U.S. PATENT ACTIVITY



INTERNATIONAL APPLICATIONS CONTINUE TO GROW



The BetterWorld Project

New Variety of Sweet Potato Takes Root

North Carolina State University

The sweet potato, once relegated to a supporting role in the traditional Thanksgiving dinner, has become a popular vegetable, showing up in pancakes, in salsa and on the menus of fine dining restaurants.

So when crops of the Beauregard sweet potato began to fail in North Carolina — the nation's No. 1 producer of the crop — farmers were desperate for a hardier variety of the vegetable.

"After growing successfully for years, the Beauregard was giving way to disease and just wasn't growing well," explained Kenneth V. Pecota, M.S., a researcher in the sweet potato breeding program at North Carolina State University (NCSU).

Pecota and G. Craig Yencho, Ph.D., quickly went to work on a new cultivar, combining sweet potato plant parents with other plant parents to identify an ideal progeny. The multiyear process involved growing seeds produced by cross-pollination by the tens of thousands in a greenhouse, and then transferring cuttings to fields.

"In a breeding program, the goal is to find a needle in a haystack: the plant that will withstand all of our testing," said Yencho. "It takes up to 2 million seeds to establish a major cultivar."

When a fledgling plant thrived through a tough growing season, the breeders knew they had found their new cultivar. Named the Covington, it became the first commercially successful plant-patented sweet potato variety in 2005. In addition to patenting the Covington, NCSU's Office of Technology Commercialization and New Ventures also helped structure a nonexclusive licensing agreement for farmers and seed growers that included an annual fee plus a royalty.

Today, the Covington represents about 20 percent of all sweet potatoes grown nationwide and is the No. 1 sweet potato export.

"The Covington is one of the crown jewels of the plant breeding program," said Kultaran Chohan, Ph.D., licensing associate at NCSU. "Over the years, it has consistently been one of NCSU's highest royalty earners."

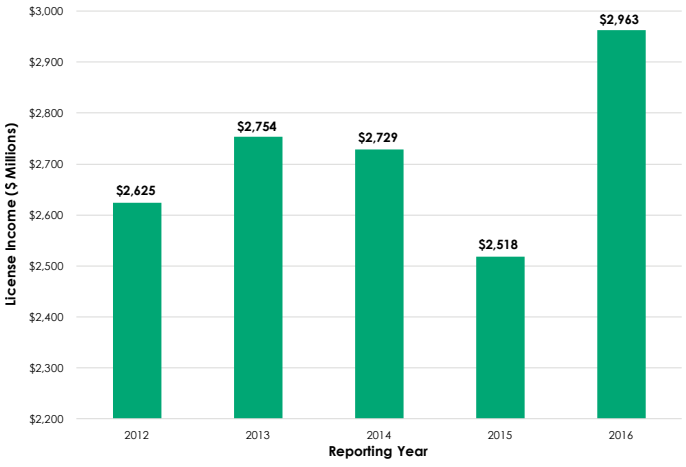
LICENSES AND OPTIONS

After the technology's intellectual property is protected, usually in the form of a patent application, the technology transfer office determines the best way to transfer that technology to the marketplace. This is often accomplished through a license to a commercial entity to either develop the technology further or get it out to the marketplace in its current state.

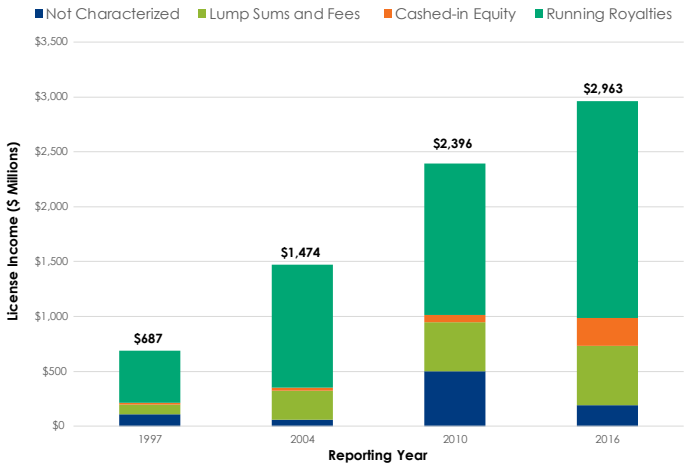
Key Findings

- In 2016, licenses issued to small and startup companies (5,013) represented the majority (70.0 percent) of executed licenses. Since most university technologies are early-stage, this trend supports the notion that large pharma companies are moving away from early-stage research. More and more early-stage research is being conducted in academic institutions, startups and small companies.
- Licenses and options to large entities (2,562) were down 16.0 percent from the prior year.
- The share of licenses generating more than $1 million remains less than 1 percent, and that share has been decreasing.
- License income increased 17.5 percent over 2015. This increase is primarily fueled by gains in royalty-based income reported by two institutions that were on hiatus from the survey. Equity cash-out also contributed to this overall gain, increasing 89.1 percent as compared to 2015. Notably, this increase does not include the reported $1.14 billion sale of royalty rights in Xtandi® to Royalty Pharma from the University of California.
- In 2016, total license income climbed to almost $3 billion, but is still below the $3.3 billion reported in 2008, of which $1 billion was from one-time events — a major litigation settlement and a major royalty monetization.

LICENSE INCOME GROWS



GROSS INCOME BY TYPE FOR SELECTED YEARS



The BetterWorld Project

‘See-through’ Technology Detects Future Sinkholes

Louisiana Tech University

How do you predict a catastrophic sinkhole event? How do you “look” underground to assess buried infrastructure without costly and destructive excavation?

Erez Allouche, Ph.D., P.E., director of the Trenchless Technology Center at Louisiana Tech University, knew storms and extensive flooding were likely causing havoc on underground pipelines that carry drinking water, storm runoff and sewage. Commercially available video inspections could offer limited information on interior pipe walls — but nothing about the surrounding soil where voids often develop.

With no technology to detect sinkholes before they break through the surface, Allouche and his colleagues set out to develop a system that could see through underground pipes to assess surrounding soil conditions. After exploring various technologies, the team settled on the newly available high frequency electromagnetic waves or ultra-wide band, also adopted by the automotive industry for use as vehicle sensors. But refining the technology and getting it into the field would require hundreds of thousands of dollars and a commercial partner.

With the help of Louisiana Tech’s Office of Intellectual Property and Commercialization, the researchers won millions of dollars in funding from the National Institute of Standards and Technology, the state of Louisiana and the National Science Foundation. Years of work followed by field testing yielded a patentable technology, which was exclusively licensed to commercial partner CUES Inc.

CUES is now working with early adopters of its radar inspection device called FutureScan. The device, which is strapped to a video inspection robot that traverses underground pipes, sends signals and processes the reflections, providing a detailed report of pipe anomalies and the likelihood of soil voids at each segment of the pipeline.

“Sinkholes are a real threat,” said Allouche. “I’m proud to be part of a team that developed a system that may potentially save lives and provide people with higher confidence that the ground will not open beneath them.”

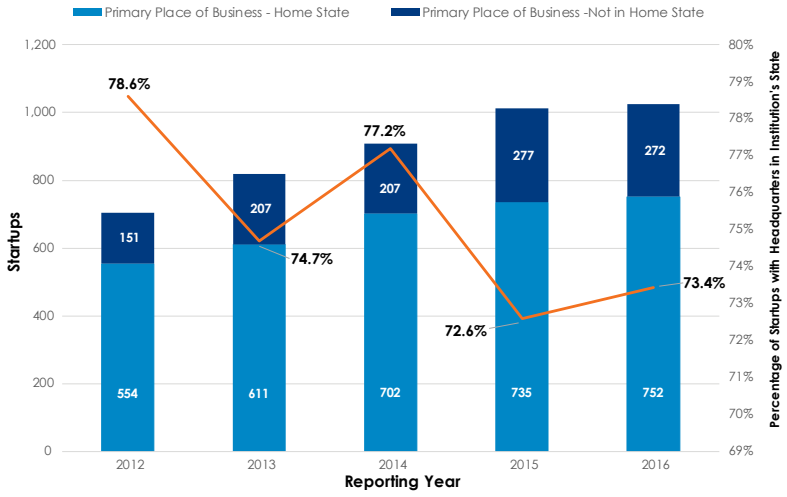
STARTUPS AND PRODUCTS

The innovations born out of academic research often lead to the formation of new companies that develop new products, create jobs and spark economic growth.

Key Findings

- The proportion of licensing to startups that are located within the state of the research institution remains high at 73.4 percent.
- 1,024 startup companies were formed in 2016 alone.
- Research institutions received equity from 495 of these startups, an increase of 5.1 percent over 2015.
- 800 new products were introduced into the marketplace in 2016.
- 331 startups ceased operation, an increase of 37.4 percent over the previous year.

STARTUPS SHOW STEADY GROWTH



ABOUT THE SURVEY

AUTM invited 309 U.S. institutions (including universities and colleges, hospitals and research institutes, national laboratories and third-party technology investment firms) to participate in the AUTM U.S. Licensing Activity Survey: FY2016. AUTM received 195 completed surveys, for a response rate of 63.1 percent. Respondents for 2016 comprised 165 universities, 29 hospitals and research institutes, and one technology management firm. The numbers from these institutions reflect the significant role played by technology transfer in today's innovation economy.

Most of the data collected in this survey is also available in AUTM's Statistics Analysis for Technology Transfer (STATT) database. To access this searchable database of more than 25 years of academic licensing data, visit **www.autm.net/statt**.

SUGGESTED CITATION

Association of University Technology Managers®, report titled ***AUTM U.S. Licensing Activity Survey: FY2016, A Survey Report of Technology Licensing (and Related) Activity for U.S. Academic and Nonprofit Institutions and Technology Investment Firms*** can also be referenced by its abbreviated title, ***AUTM U.S. Licensing Activity Survey: FY2016***, editors Shawn Hawkins, Yiorgos Kostoulas, Alice Li, Nichole R. Mercier, Matthew A. Mroz, Olivia Novac, Ragan Robertson, Nate Ruey, Ashley J. Stevens, April Turley and Karen White, with research assistance by Chrys Gwellem.

ABOUT AUTM

The Association of University Technology Managers (AUTM) is a nonprofit leader in educating, developing, promoting and inspiring technology transfer practitioners to make the world a better place through the commercialization of academic research. AUTM's global community of 3,200 members represent businesses and government organizations, and more than 350 universities, research institutions and teaching hospitals.

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