### **Technology Licensing Office**

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Our vision is to be a leader in innovation management that creates value for the University of Utah, its stakeholders and society.

## Letter from the President

Innovation is a cornerstone of our mission at the University of Utah, and the achievements in this report are proof of our thriving entrepreneurial spirit. As a catalyst for innovation, the Technology Licensing Office plays a key role in realizing the visionary ideas of our faculty, researchers, students, and industry partners. The Technology Licensing Office not only facilitates the transfer of cutting-edge technologies but also supports an environment where ideas are nurtured, refined, and transformed into practical applications.

The Technology Licensing Office diligently safeguarded 145 patents in 2023, ensuring that our intellectual capital is transformed into economic and societal value through licensing and strategic alliances.

Looking forward, we are excited about the opportunities that lie ahead. Our strategies are geared toward enhancing the technology transfer process, strengthening industry partnerships, and amplifying the recognition of the U as a leader in innovation.

As we navigate the evolving landscape of academia, industry, and technology, I extend my deepest appreciation to each member of our U community. Your passion, dedication, and relentless pursuit of knowledge have been instrumental in achieving the milestones recounted in this report.

Together, we will continue to push the boundaries of what's possible, and we will continue the essential work of transferring our discoveries beyond campus in our commitment to improving lives and changing the world.

**Taylor R. Randall** President University of Utah





patents in 2023, ensuring that our intellectual capital is transformed into economic and societal value

## Letter from the VPR

Together, we will continue to push the boundaries of innovation and transform ideas into solutions that shape the future.

It's been an exciting year in commercialization and innovation at the University of Utah. With the move of the U's Technology Licensing Office to the VPR Office, this report shares the remarkable journey we have undertaken in advancing innovation, fostering collaborations and translating groundbreaking research into real-world applications that drive economic and societal progress.

I'm delighted to share that the U's research funding has reached \$768M in FY23—the highest in U research history. Congratulations to all for another record-breaking year in research.

As we reflect on the achievements and milestones of the past year, it is evident that our commitment to bridging the gap between academia and industry has yielded inspiring outcomes. The Technology Licensing Office has not only facilitated the transfer of cutting-edge technologies but nurtures a culture of entrepreneurship and knowledge dissemination among our faculty, researchers and students.

In this report, we highlight 25 license agreements of technologies originating from various disciplines. These technologies have found their way into startups, existing companies and industries, creating a tangible impact on society. I invite you to explore the report, engage with our success stories and envision the limitless potential that lies ahead. Together, we will continue to push the boundaries of innovation and transform ideas into solutions that shape the future.

I extend my gratitude to the brilliant minds within our university, our dedicated partners, and the entire U community for their unwavering support in making these achievements possible. Our success is a testament to the power of collaboration, determination and the pursuit of knowledge for the greater good.

Erin Rothwell Vice President for Research University of Utah

## **Embracing Change** Rebranding for the future

Since 1965, our organization has undergone several name changes to align with the evolving trends in academia and the global landscape. We started in 1965 as the Product and Patent Development Office before changing to the Tech Transfer Office in 1986, Tech Commercialization Office in 2006, and Technology & Venture Commercialization Office in 2013. Most recently, in 2020, we adopted the name PIVOT Center. These changes underscore our unwavering commitment to faculty and our impact on discoveries at the University of Utah.

Under the leadership of Vice President for Research Erin Rothwell, we are expanding our teams and enhancing our services related to licensing and translation. The Technology Licensing Office, in collaboration with the AVPR of Innovation and Translation, is now responsible for all aspects of licensing and translation.

For you, this means you will benefit from our streamlined processes, ensuring prompt assistance with your disclosure, market opportunities, commercialization strategy, risk mitigation, intellectual property protection, and licensing. We extend our gratitude to you for being a part of our entrepreneurial research community, and we eagerly anticipate the future as the Technology Licensing Office.

The Technology Licensing Office, working in collaboration with the AVPR of Innovation and Translation, will now be responsible for all aspects of licensing and translation, symbolizing our renewed dedication to supporting faculty.

## UNIVERSITY OF UTAH® INNOVATION AWARDS

Dedication, creativity and commitment to advancing the knowledge and pushing the boundaries of innovation.

The University of Utah hosted its first Innovation Awards in October 2023, celebrating U researchers who are going above and beyond to translate their research into solutions to today's problems.

The highlight of the program was recognizing the recipients of the eight Innovation Awards, but we also recognized those contributing to the U's innovation culture in fiscal year 2023 (July 1, 2022-June 30, 2023) by patenting technologies, receiving commercialization specific grants (the Ascender Grant and SBIR/STTR), learning how to form companies in the I-Corps program and forming a National Academy of Inventors chapter.

### **Innovation Awards recipients**

Excellence in Innovation Undergraduate Student – James Walker

Excellence in Innovation Graduate Student – Jack Silcox

Investigator on the Rise - Mei Yee Koh

Advancement of EDI in Research – Keke Fairfax

Innovator of the Year – Jacob George

Innovation Impact – Jared Rutter and Kevin Hicks

Breakthrough of the Year – Bone Bolt OIC

Lifetime Achievement – Gregory Hageman

### **Ascender Grant recipients**

One of our favorite resources at the Technology Licensing Office is the Ascender Grant. The grant helps U researchers bridge the gap between the academic lab and potential commercialization. We recognized seven PI's who completed their Ascender Grant milestones in the fiscal year:

Massood Tabib-Azar	Himanshu Sant
Jay Kim	Matthew Rondina
Marc Porter	Jesse Rowley
Ling Zang	

I-Corps<sup>™</sup> helps entrepreneurs take their revolutionary technology from the lab to the market, so they can become a leader in innovation, commercialize their tech and make a direct impact.

The University of Utah is a proud member of the I-Corps<sup>™</sup> program, and we are excited to provide regional programming for our students, faculty, community and state. To date, I-Corps<sup>™</sup> Hub West has 10 Partner Institutions (including the U), 700+ participants and 50+ NSF Team Grants. The hub is a network of universities dedicated to helping researchers successfully take their research and translate it into viable deep technology in the marketplace.

After our teams have refined their value proposition and gained a greater understanding of where their deep tech can fit in the marketplace through our regional programming, they are invited to submit their application for Hub sponsorship to the National Science Foundation (NSF) I-Corps program. While the final decision rests with the NSF, once teams are accepted to the national program, they will receive a \$50,000 grant from the NSF to support the commercialization of their deep technology.



### I-Corps teams

The University of Utah is proud to support our team of faculty and students as they progress through the program and learn more about entrepreneurship.

The following teams successfully completed the first and second phases of the I-Corps program and are working toward Nationals.

### Electronic Grip Gauge (EGG)

Marta Iversen Jacob George Michael Adkins Monika Buczak Brenda Mann

### Unimer Technology

Dmitri Kapitonov

### PhenoTx

Tarek Moustafa Tom Zangle Phil Bernard Vinberg Labs Frans Vinberg Jordan Allen

### НерВТ

Kuby Balagurunathan Ishan Capila

## Ascender Grant 11 awards, \$880,213 awarded

## **Faculty First**

I am pleased to report on the significant progress that my team has made in achieving our key objectives at the Technology Licensing Office (TLO) over the past year, largely by listening to faculty needs and proactively facilitating our office's evolution. We embraced accountability by striving to be more proactive, seek out gaps and inefficiencies, and improve our day-to-day operations. Under the guidance of our Vice President for Research, Erin Rothwell, we successfully restructured our office, refined workflows and optimized operations. As part of these efforts, our office rebranded including a name change to highlight TLO's "faculty first" approach.

Each functional team within TLO generated a report related to its workflow processes. We designed the reports to include relevant performance indicators that are crucial to TLO's core competencies. Some of these include CDA/MTA/DTAs, assessments of new invention disclosures, faculty engagement, periodic reviews of technologies, and marketing efforts. Based on these reports, we identified and implemented several process changes that improved response time and customer service.

The Pivot Center was strategically restructured by creating two specialized units to enhance efficiency and better cater to the diverse facets of technology commercialization at the U. The first unit, TLO, is dedicated to streamlining the process from disclosure to licensing, ensuring a seamless transition for technology transfer. Simultaneously, the second unit, which is led by the Associate Vice President for Research Innovation and Translation (AVPRIT) James Hotaling, is focused on fostering and supporting startups, aiming to provide a dedicated and comprehensive approach to nurturing entrepreneurial initiatives within our

technological landscape.

As we move forward, we are excited about the positive momentum that our new leadership and restructuring brought to TLO. We anticipate further progress and success as we continue to collaborate and drive technology licensing and commercialization at the U.

Bruce Hunter Interim Chief Innovation Officer University of Utah



The Ascender Grant program is one of the ways the Technology Licensing Office advances technologies for the University of Utah. The program helps inventors bridge the funding gap between research and commercialization by providing support for technology development, proof of concept and preparations for additional investment by entrepreneurs, investors and potential licensees.

"Often, the funding provided in research grants does not cover all the development and de-risking necessary to prepare an innovation for investment from entrepreneurs, investors and industry," said Kyrsten Woolstenhulme, the Technology Licensing Office director of innovation management.

Researchers can use the grant in a variety of ways to support their efforts. "The program facilitates technical development, market research and other de-risking activities—such as validating scalability or performance verification—to advance an innovation to a licensable and investable stage," Woolstenhulme said.

### Jan Kubanek

Mental and neurological disorders are the world's leading cause of disability, according to University of Utah biomedical engineering professor Jan Kubanek. Over the years,

treatments have been developed for some of these disorders, but oftentimes these treatments are inadequate.

"It's a major issue because in about one in three cases across the board, when you look at mental and neurological disorders, people are resistant to current treatments," Kubanek said.

Kubanek and his lab at the U have looked for ways to treat this patient population. A solution they have converged on is "neuromodulation," where the doctor would directly modulate the regions of the brain that are malfunctioning. While their approach has shown promise in earlier trials involving monkeys, Kubanek and his team are now focused on proving it will work for human use.

Kubanek's team has received funding from the National Institutes of Health and Focused Ultrasound Foundation, and they recently made use of the Ascender Grant.

Kubanek and his team are using the grant "to fund clinical testing of the approach and device in patients with major depression," he said. "That helps us to speed up the patient recruitment and collect the data faster than we could otherwise without this help."

## Minna Roh Johnson

### Translating fundamental science for impact

Every university researcher is introduced to technology transfer at some point. Scientists might have a knee jerk, negative reaction to commercialization, but University of Utah biochemistry assistant professor Minna Roh-Johnson said pursuing basic science and translating research out of the lab is not an either-or situation.

"I think they think about it as sort of icky. It makes them feel uncomfortable because they're not trying to monetize their findings. They're trying to just discover the truth, and it feels like commercialization goes against sort of the inherent principles of a scientist," she said. "You can be interested in the fundamental aspects of science, and you can really want to help people and that's OK."



Recently, Roh-Johnson realized a project in her lab had potential to impact people but it was too risky for traditional funding sources. "What we needed was more data, but it takes so much money and time to generate those data, and we had no funding streams coming in," she said.

Stuck in this seemingly impossible situation, Roh-Johnson decided to diversify the lab's funding streams just like she had diversified the projects and people in her lab, so she reached out to the Technology Licensing Office.

In her lab, <u>researchers</u> are looking at the potential to use macrophages, a type of immune cell present in tumors, to prevent metastasis in solid tumors. "When you think about immune cells, you probably think of them as protecting the host by fighting off infections, for example," Roh-Johnson said. "That certainly is something that macrophages do. But in many solid tumors, macrophages have this very different role, where they instead help promote cancer progression."

The Roh-Johnson lab is now developing a technology to teach the macrophages to defeat the cancer cell instead of promote metastasis. After disclosing the technology—Roh-Johnson's first disclosure—she applied for and received Ascender Grant funding.

Her team is using the grant to fund experiments and provide the data needed to prove the impact of their technology.

"With the Technology Licensing Office we can really change the way we do our science and change the speed at which we do it," Roh-Johnson said. "I sort of card carry in terms of being a basic scientist. I'm really proud of it. But at the same time, if our work actually saves people, yeah, I'm not going to lose sleep over that."

In her lab, researchers are looking at the potential to use macrophages, a type of immune cell present in tumors, to prevent metastasis in solid tumors.

## **Jared Rutter & Kevin Hicks**

### 'A challenge we should face'

University of Utah Department of Biochemistry professor Jared Rutter's research has touched everything from cancer, diabetes, fibrosis, cardiovascular disease and more, but the common thread connecting his work has always been metabolism.

The work Rutter and his team do in his lab isn't directly related to clinical care, he said. "But I would hope that we are working on topics that are disease relevant, and that our science is solid and good enough that it can then serve as a foundation from which either we or someone else will try to use it to impact patients."

Rutter has used this foundation to create three companies, but pursuing commercialization wasn't always part of his plan when he joined the university in 2003.

"It's been a great experience, and I think it has really also informed my academic lab," Rutter said of his experience in founding and interacting with companies. "How I think about science has been very much informed by the experiences I've had in the private sector."

This year, Rutter and his colleague Kevin Hicks received the Innovation Impact award at the 2023 Innovation Awards for the MIDAS platform that led to one of Rutter's three startups, Atavistik Bio.

MIDAS (mass spectrometry integrated with equilibrium dialysis for discovery of allostery systematically) gives scientists insights into never-before-seen interactions between environmental cues and cell metabolism, while opening the door for better drug discovery.

Being both an academic and an entrepreneur gives Rutter a valuable perspective into the world of drug development and research. "I feel like it's helped me to understand what the important problems are from a drug development perspective," he said. "There's no point in going down a drug development path if at the end of the day the private sector will not pick that up and carry it into clinical trials."

His insight into the business aspect of drug development hasn't been the only benefit to his lab that he's seen so far. He also said his work in the private sector has "turned into collaborators in some cases or consultations in other cases" that have helped his lab do better science.

Even with all the benefits he's seen from commercialization, Rutter recognizes that it can be a challenge to take on, in addition to his other duties at the university. "Our day job is hard, and it takes a lot of time. So, thinking about doing other things can be overwhelming," he said. "It makes sense that it would be a challenge, but I think it's a challenge we should face."





## "

How I think about science has been very much informed by the experiences I've had in the private sector.



Featured Faculty

## By the Numbers

## Patents Issued

Patents Filed

## 7 Startups

# Disclosures 265

## Licenses



## Vanessa Redecke & Hans Haecker

## **Jacob George**



Patients are

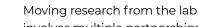
take more

now far more

responsibility

of their health.

educated, they



**Partnering for success** 

Moving research from the lab to the market isn't always a linear path and often involves multiple partnerships to reach the end goal. While some might get discouraged by setbacks, a team of motivated collaborators and a mission to solve a global problem can result in success.

For University of Utah immunology and microbiology professors Vanessa Redecke and Hans Haecker, that magic formula led to the creation of a COVID-19 antibody test that uses artificial intelligence to give faster, more accurate diagnoses in a point of care setting.

Once Redecke and Haecker knew their test idea worked, they approached the Technology Licensing Office for assistance. The office connected the team with ARUP, a national nonprofit and academic reference laboratory started by a group of U pathologists in 1984.

A very productive collaboration between the teams developed, leading to the identification of a key problem with the test: the readout needed to be more objective.

What could have been a stumbling block turned into the development of a key aspect of Redecke and Haecker's test. ARUP connected the team with another U startup, Techcyte. Techcyte develops AI-based image analysis solutions for the diagnostics industry-a perfect fit for the test.

With the perfect set of collaborators, the test fell into place. Together they took the test and figured out a way to give a clear, objective diagnosis using something most people have in their pocket—their cellphone. All the user needs to do is open the app, conduct the test and scan the test card through the app. The test image uploads automatically to Techcyte for AI-based analysis and the results are returned to the cellphone within seconds.

### **Finding impact**

Test in hand, the team pivoted their focus to ensuring the product would find itself in the hands of the people who could use it. The team's research was spun out to form a new company, Nanospot.ai.

Even after forming Nanospot.ai, Haecker said the Technology Licensing Office continues to offer guidance when needed. "It's not a one time thing that you get in contact with the office and they tell you what to do. It's more like a collaboration that develops over sometimes an extended period."

The team is now looking for ways to ensure the product will continue "democratizing health," as Redecke said. "Patients are now far more educated," she said regarding the impact of the COVID-19 pandemic. "They take more responsibility of their health."



### Getting tech into people's hands

Much of University of Utah professor Jacob George's work sounds like stuff straight out of a science fiction novel: prosthetic hands that can bring back a user's sense of touch. exoskeletons that restore movement, wristband devices that can turn the lights off by thought, and more. This technology has become reality in the Utah NeuroRobotics Lab that George directs.

The impacts of these technologies are vast. For example, technology like the Luke Arm—a prosthetic, robotic hand that an amputee can move using their thoughts and also restores their sense of touch-provides more benefits than a regular prosthesis.

It "allows an individual who's lost a hand to have direct impacts on their well-being and improving their dexterity, but also brings psychological benefits associated with the sense of touch that we can restore," George said.

George and his lab are working to expand this technology into the broader field of human computer interaction, assistive technology and even virtual reality. These technologies have resulted from both successful interdisciplinary research and academic-corporate partnerships.

George said one of the perks of being at the U and in the state of Utah is the spirit of collaboration. He has worked with researchers from the University of Utah hospital, the engineering department and more. "People want to collaborate and make cool things happen. That's really where our strength comes from."

Add that collaboration to Utah's entrepreneurial spirit and you can see why the state consistently ranks as <u>one of the</u> top states to start a business. "At the U, we can patent technology, get it out there, and then create startups really easily in this environment," George said.

For George, his commercialization journey started by disclosing an invention to the Technology Licensing Office. From there he has been able to tap into the office's resources and connections to partner with groups beyond campus, resulting in sponsored research agreements and funding for George's lab.

George is actively working with a company that is interested in integrating his lab's wristband device with smart home technology. After receiving an Ascender Grant to produce a prototype, the company began supporting his lab's ongoing research by providing letters of support and donating equipment.

That's only one of many companies and organizations that George is working with to further his research. and this kind of assistance is available to all U researchers with innovations and ideas that could provide real impact. Since starting at the U a few years, George and the Technology Licensing Office have been able to receive hundreds of thousands of dollars for his budding lab.

"I think the barrier to entry is actually lower than most people would think," George said. "It can be a good relationship that all really needs to happen is just invest a little bit of time."



## **Creating the link between** human and artificial limb

Almost 30 years ago, Florian Solzbacher shared a dream with his childhood friend Marcus Gerhardt. "I want to create the link between human and artificial limb."

Solzbacher's initial vision—to create advanced medical technologies for patients with disabilities-has now grown into one of the leading brain computer interface (BCI) companies in the world—Blackrock Neurotech, a company based on groundbreaking research done at the University of Utah.

Today, Blackrock is in the process of bringing to market the world's first implantable BCI device for patients with paralysis.

"Our long-term vision is that Blackrock's implants will become more widely available to the millions of people who need them, much like pacemakers are easily accessible to people with heart issues," Solzbacher said.

Since 2004, over three dozen patients have received Blackrock's neural implants in braincomputer interface trials. With their BCIs, these patients—all with some form of paralysis—have controlled computers, moved robotic limbs and even regained control of their own paralyzed arm just by thinking.

### The birth of Blackrock Neurotech

The core of much of Blackrock's work is the Utah Electrode Array that was invented by Richard Normann at the University of Utah in the late 1980s and early to mid-1990s. Solzbacher, who joined the U as an electrical and computer engineering professor in 2004, built upon this foundation to advance and refine the device, by increasing reliability, scalability and long term stability.

Solzbacher and his colleagues at the U had developed an excellent invention and a growing portfolio of intellectual property, thanks to the very business and startup friendly environment at the University of Utah. In 2007, he decided it was time to translate his research to real-world applications. He reached out to his old friend Gerhardt, who had extensive experience in company creation, to help him move the array out of the academic setting.

Gerhardt recommended that rather than build a company from scratch, they build upon an existing team or business. Their timing was perfect. At the time another company (Cyberkinetics Inc., which had acquired Richard Normann's startup Bionic Technologies in 2002) was attempting to commercialize the Utah Electrode Array, but its funding was drying up.

Discussions with the company about licensing and commercializing the technology soon shifted from the possibility of joining and re-structuring to the possibility of purchasing the company outright—exactly the idea Gerhardt had suggested.

Ultimately, Solzbacher's development contracts, patent portfolio and improvements he made in the university lab to the Utah Electrode Array and electrode technology were merged with the company's former Utah Bionic Technologies team. This, in combination with Gerhardt's entrepreneurial expertise and network, led to the founding of Blackrock Neurotech.

The new startup now had to figure out how to legally use and continue developing the Utah Electrode Array. This required licensing the technology from the University of Utah since it was developed using the U's resources.

The resulting licensing agreement with the University of Utah turned out to be extremely supportive of the startup's conditions and needs, allowing the company to develop as it has. "The university has consistently supported Blackrock," Solzbacher said. "Throughout the years and development of the company, the university has always been a steadfast supporter and often extended assistance in times of crisis."

As for Solzbacher's experience as both a U professor and an entrepreneur, he said, "Your success is seen as the university's success. Very few places truly support translation and commercialization the way that I have experienced it at the University of Utah when I needed their support."

### **Developing an accessible BCI**

There are many challenges of commercializing a medical device, everything from navigating the regulatory process and interfacing with insurers to ensure these devices are accessible to patients through insurance. Now add on top of those challenges the fact that the human brain is more complex than any other structure in the known universe.

Blackrock has faced these challenges head-on because of its commitment and mission to develop better technologies for the benefit of patients.

"We know from talking with patients, caregivers and advocacy groups that many assistive technologies are antiguated, cumbersome and oftentimes impractical. It doesn't need to be this way; we have the ability—and the obligation—to create cutting-edge technologies that restore function for these patients," Solzbacher said.

The ability to directly interface with the brain safely and effectively has advanced to the point where BCIs can leave the lab and produce practical, real-world benefits for patients with paralysis. "Getting BCI technology into the hands of patients will be life-changing for them, their caregivers and their communities," Solzbacher said.

Until now, patients could only access this technology through multimillion-dollar research studies, but that is changing: Blackrock expects its first commercial BCI device—and the first commercially available implantable BCI in the world—to be available soon.

In the years to come Blackrock hopes to commercialize products that restore hearing and vision, lessen depression and anxiety, mitigate pain and more.

"We are at the beginning of an explosion in novel treatments that will fundamentally change the way we treat neurological disorders, and the patient impact will be profound," Solzbacher said.



## **Mingnan Chen**

### 'These are real people'

University of Utah molecular pharmaceutics professor Mingnan Chen and his colleagues published a paper in 2019 detailing their work to develop a new treatment for autoimmune diseases that would target unhealthy immune cells while leaving normal, beneficial immune cells alone.

After publication, Chen received letters and emails from people around the world inquiring about potential clinical trials, hoping they would soon have better options to treat autoimmune diseases. "Obviously, they're not as satisfied with their current treatment," Chen said. "These are real people. They're not just some phrases on the paper."

Autoimmune diseases like Type 1 diabetes and multiple sclerosis are relatively common, and Chen has seen the diseases impact people in his life—his friend's son has Type 1 diabetes and another friend has multiple sclerosis. In the case of Type 1 diabetes, many people develop symptoms as children. "Then their whole life they are being affected by the disease," Chen said. "I just feel that maybe with the basic science of Type I diabetes and other autoimmune disorders we have, we can do something for that."

Chen has continued to research treatments even after the successful publication in 2019. "We are passionate about developing protein-based therapeutics, antibody-based therapeutics," Chen said. "We do that by integrating the knowledge about protein engineering, pharmaceuticals and immunology together."

We are passionate about developing protein-based therapeutics, antibodybased therapeutics.

Chen's interest in translational research and therapeutics began early in his career when he asked his Ph.D. advisor what the purpose was behind their basic immunology research. and



his advisor responded that the research could help develop vaccines.

Now, Chen describes commercialization as necessary and rewarding. "The work we are doing has great purpose."

Within a few years of coming to the U, Chen disclosed his first inventions to the Technology Licensing Office and has worked with the office ever since. The office has assisted Chen's lab with patent applications, corporate connections, and even helped fund his research through the Ascender Grant.

"We now have this goal or this drive to really promote something into the clinical trial or even clinical approval," he said. "There's just so much more we can do together with the Technology Licensing Office."

Chen has found that beyond benefiting patients' lives, his work in translation and commercialization has also improved his research. "They can raise a new question for your research direction," he said.

His commercialization efforts have also opened doors for new funding opportunities—like the Ascender Grant. Companies that license technologies from the university might also contract research back to the lab to support further research, and federal funding agencies require commercialization for some grants. "It's another avenue we should not overlook," he said. "There can be rewards in the long term and short term."

## Wade Fallin

### Serial entrepreneur and innovator

Wade Fallin started his career as a "serial entrepreneur" and "serial innovator" before he came to the University of Utah. "Instead of a professor starting an innovation company, I'm a serial entrepreneur who became a professor," Fallin said.

After receiving bachelor's and master's degrees in mechanical engineering, he began working for the large medical device companies that specialized in orthopaedic devices. "Like most young people coming out of their college programs, I wanted to do something that really made an impact to the human condition in a positive way."

After seven years with these companies, Fallin knew it was time for a change. He left his job and started his first company with a college friend and an orthopaedic surgeon in northern Utah. "That was the beginning of this serial entrepreneur experience that I've enjoyed over 25 years."

Over the course of those 25 years, Fallin connected with and formed friendships with the current and two previous chairs of the orthopaedics department at the U. "That long standing relationship led to us starting to talk about how we could apply the principles I learned in industry within the Orthopaedic Department at the University of Utah."

The result of those discussions was the formation of the Louis S. Peery, MD Orthopaedic Innovation Center (LSP OIC) at the U in the spring of 2020, directed by Fallin. "We are an accelerator that takes research discoveries, unmet clinical needs or ideas for better surgical techniques and devices, and then our team conducts FDA compliant product development activities to translate those to systems that are clinically and commercially ready."

### **Guiding new innovators**

Since its formation, the LSP OIC has evaluated around 75 disclosures and has seven issued patents with more in the pipeline.

In his role, Fallin uses his expertise as a seasoned entrepreneur who has started and sold five companies to guide U faculty as they develop their research into an invention that could be used in a clinical setting.

"The first ideas that you have aren't always the best, but they get you going down the path," Fallin said. From there teams start a process where they ideate, design, build and test the new idea, evaluate it, and repeat. "From that learning, then the solution improves. It might take a few times through that cycle but each time you're getting closer and closer to the target."

Luckily faculty members don't have to go through that cycle alone. Fallin encouraged faculty to work with resources like the LSP OIC and other accelerators that have "been through the process before and can relate their experience on how to go from an idea to something that finds its way to clinical use and to commercial success."



In his role. Fallin uses his expertise as a seasoned entrepreneur who has started and sold five companies to guide U faculty as they develop their research into an invention that could be used in a clinical setting.

## 'Good medicine is good business'

University of Utah spinout company Tolero Pharmaceuticals launched in 2011 with the goal of advancing research and commercialization around an investigational anti-cancer agent discovered at the U. With a round of Series A funding, Tolero's team hit the ground running.

The team quickly added more compounds to Tolero's portfolio, raised a Series B round, and started clinical studies on this foundational compound, given the name TP-0903, discovered at the U. With all that progress came a rise in costs as well. Clinical studies alone can cost millions if not tens of millions of dollars; add staffing, continuing research, overhead costs and more on top of that, and it was clear Tolero would need another influx of funding.

But how should they get it? "We were looking at all the options, everything from a Series C round to an initial public offering and raising money on the public markets or pursuing a partnership with a pharmaceutical company," said Tolero cofounder Steve Warner.

Warner, along with Tolero's two other cofounders—David Bearss and Dallin Anderson decided to pursue the third option and began meeting with multiple potential partner companies around the world. "When we connected with a Japanese company now called <u>Sumitomo Pharma Co., Ltd</u>. (Sumitomo Pharma), it became apparent pretty quickly to both sides that there was an opportunity to do something even bigger," Warner said.

That "something even bigger" would not only provide the needed funds to continue Tolero's impactful work, but it would also allow the team to increase its research and reach while maintaining its connection to Utah and the U.

### From the U to startup

Let's back up. Before forming Tolero, Warner and Bearss worked at the University of Utah Huntsman Cancer Institute in the Center for Investigational Therapeutics where they were focused on drug discovery.

"There's lots of great basic research and even translational research happening at the university," Warner said. "At CIT we really tried to spin some of those ideas and understanding of biology into actual commercial products."

That's where they discovered and developed TP-0903—also known by its generic name, dubermatinib—that would lead to forming Tolero. Bearss and Warner were collaborating with multiple other scientists at the Huntsman Cancer Institute when they first synthesized and tested a compound that targets a certain protein (AXL receptor tyrosine kinase) that impacts a cancer cell's survival.

The team at CIT did as much as they could to advance TP-0903 at the university, but eventually, they knew that in order to progress the compound into a product with a potential clinical application, they would need to start a company around it.

### Thus, Tolero was born.

However, once the team left the academic setting, they had to worry about raising money and surviving on their own without the large university behind them. "We left our comfortable jobs at the university and we put ourselves in a situation where our livelihoods were dependent on Tolero being successful," Warner said.

On top of the new concerns independence brought, Bearss and Warner also found themselves spending more time out of the lab and in meetings trying to raise more capital to fund their research. Joining Sumitomo Pharma gave them an opportunity to pivot their focus back to research and away from the business side of the company. "If you look at the rate at which we were able to accelerate our pipeline by not only moving faster but moving more things forward, we would not have been able to do it without Sumitomo Pharma," Warner said.

While TP-0903 advanced into clinical studies in multiple cancer indications, including the Leukemia and Lymphoma Society Beat AML clinical study, the program was eventually discontinued when the clinical studies did not reach statistical significance for study endpoints—an outcome that happens all too often in oncology research and development.

Tolero's acquisition by Sumitomo Pharma didn't stop the team's working relationship with the state of Utah and the U at all. Warner's team is still located in Lehi, and many trials are conducted at the Huntsman Cancer Institute. In fact, three of the five agents Sumitomo Pharma Oncology is focusing on have had trials open at Huntsman.

"Whether it's a compound developed at the U or something that came from our lab, these are still things that were grown locally," Warner said. "And to be able to evaluate them in patients locally is, I think, something that really kind of resonates both with us and with the university."

### **Commercializing for impact**

The work that Sumitomo Pharma does comes down to helping patients with cancer.

"That's really what gets us up every morning," Warner said. "We're scientists. We love pursuing exciting, fascinating, innovative science, but the motivation behind all of it is benefitting the patient."

The team's ongoing impact, research and success wouldn't have been possible if Warner, Bearss and Anderson hadn't decided to start Tolero in 2011. "Our focus from the beginning of Tolero was: 'Good science is good medicine and good medicine is good business,'" Bearss said. "We tried to get the science right and let that guide the rest of the work in translating scientific discoveries into new medicines."

"Starting a company is accompanied by so many uncertainties, but it's extremely worthwhile and seeing our innovations positioned to potentially benefit patients with cancer has been very rewarding," Warner said.



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