VANDERBILT

CTTC

Center for Technology Transfer
& Commercialization

DRIVING *INNOVATION* FORWARD

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INSIDE:

03 **Operating in Times of Crisis**
Letter from the Director

04 **CTTC Performance Metrics**
FY20 Snapshot & More

06 **Impactful Transactions**
Acadia, Moderna, Sandia

07 **Inventor Spotlight**
Scott Smith

10 **Startup Spotlight**
Meru, SkyNano, IDBiologics

11 **Where Are They Now**
AI Biomed, nPhase, PathEx

12 **Supporting Research**
MTAShare

13 **Ancora Innovation**
Bringing Discoveries into the Clinic

14 **Partnership Spotlight**
CET & the Life Sciences Center

15 **Innovating in Times of Crises**
Novel Molecules, Ventilators, Screening Tools

OPERATING IN TIMES OF CRISES

This edition of Driving Innovation Forward was prepared during the coronavirus pandemic. As such, it seems reasonable to discuss innovation and technology transfer efforts through the lens of crisis management. And it seems reasonable to address the normal issues of operational successes, customer service, and the innovation and entrepreneurship ecosystem in the same manner. So let's take a moment to review how technology transfer operations have evolved in response to the temporary halt of on-campus research activities, and focus on how some of our researchers deployed their talents toward tackling emergent needs in this time of crisis.

Now that we all have been hardened by the working conditions beset upon us by the coronavirus pandemic, it is safe to say that many have acquired new expertise in performing in crisis mode. Communicate often. React rapidly. Prioritize. Create to-do lists. Download Zoom updates.

The lines of separation between work time and personal time have blurred - I am walking my dog at noon and editing contracts at midnight. I am using a Mac instead of a PC, and cannot for the life of me figure out why there is no forward-delete button on the keyboard. I have learned to affix my signature to any document in any format - but I am saving all my documents to a single file folder – something which I will pay dearly for when I start working again from the office. All-in-all, a center such as ours can admittedly do almost all it needs to do from home, and for that, we are very fortunate. Our normal course of business has not changed – we evaluate, protect, market, license and monitor the development of technologies created in VU and VUMC laboratories. We generate revenue for these institutions and for our inventors. We assist with forging relationships with industry partners. And we help create new companies to develop and commercialize new Vanderbilt innovations. But first and foremost, in these times, our primary responsibilities are two-fold:

- Do ANYTHING and EVERYTHING we can to support VU and VUMC and their employees.
- Help position VU and VUMC innovations related to COVID-19 for development, rapid deployment and use.

This means routine items such as processing Material Transfer Agreements that ordinarily may take a week or two must be completed same day – perhaps in a few hours. This means weighing in on evaluations of new COVID-related research activities on campus to identify needs and hurdles to overcome – removing impediments to progress. This means introducing researchers to companies that can help with funding, development or rapid deployment of COVID-related technologies. And this means understanding and learning from other universities' efforts for efficiently making COVID-related products available broadly in this time of great need.

We have also been fortunate in being able to witness a renewed sense of insight and innovation among our researchers and clinicians. Scientists, engineers and clinicians that have put existing research effort on hold have refocused their efforts on ideas and concepts that can make a difference to patients and front-line healthcare providers embroiled in fighting the spread and impact of SARS CoV-2. There are some incredible members of the Vanderbilt community doing some heroic and groundbreaking work to develop novel solutions. And we think it is worth highlighting a few such efforts here for posterity and for inspiration. The projects outlined on the inside of the back cover below are but a few of the many important efforts undertaken by our researchers, but exemplify what can be accomplished in the face of adversity (please see page 15). Stay safe and innovate.

-- Alan Bentley

FY20 SNAPSHOT

168 Invention Disclosures

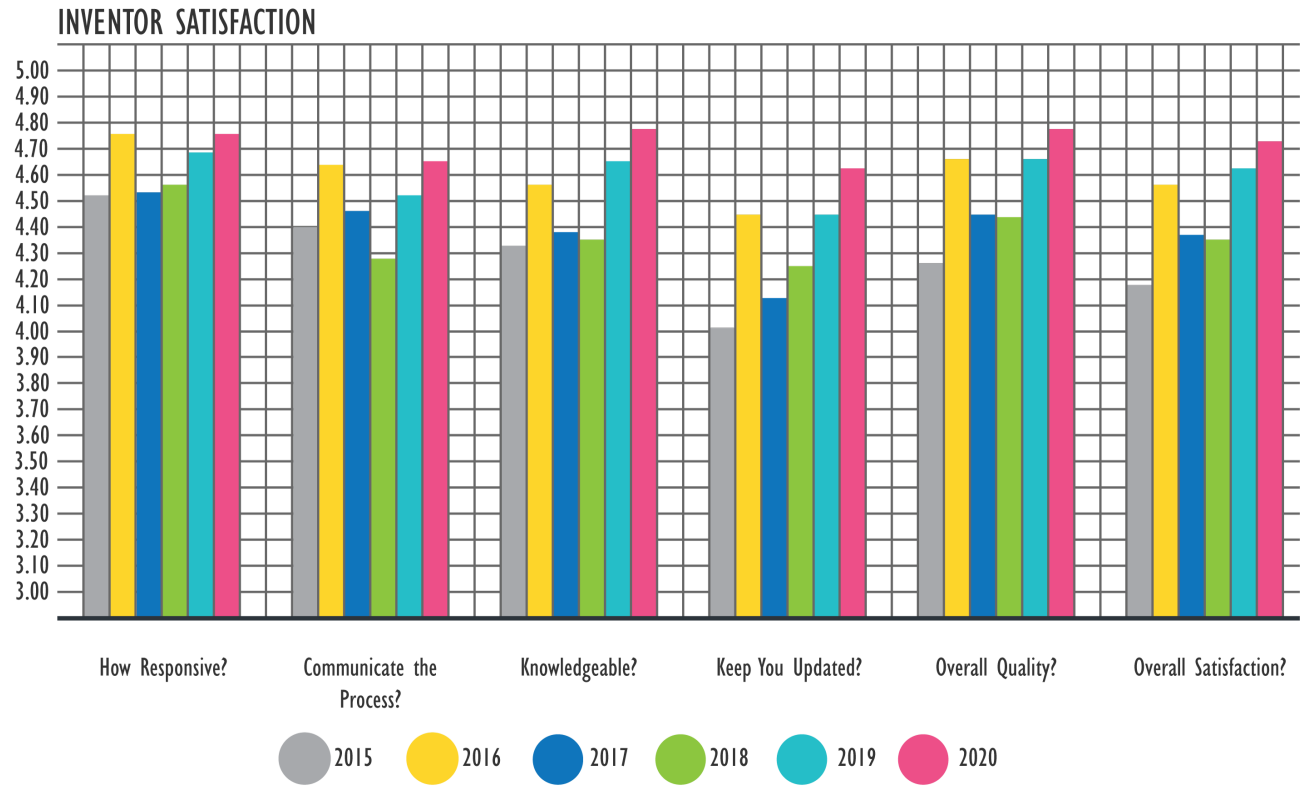
5 New Startup Companies

$22.5M Licensing Revenue

94 Licenses & Options

301 U.S. Patent Applications Filed

76 U.S. Patents Issued



10YR Snapshot

1791 Inventions
Representing 2,030 Vanderbilt inventors

459 U.S. Patents Issued

763 Licenses
Including 109 exclusive licenses

$111.9M Licensing Revenue

FY10-FY19

Vanderbilt Research

$6.20B Total Research Expenditures

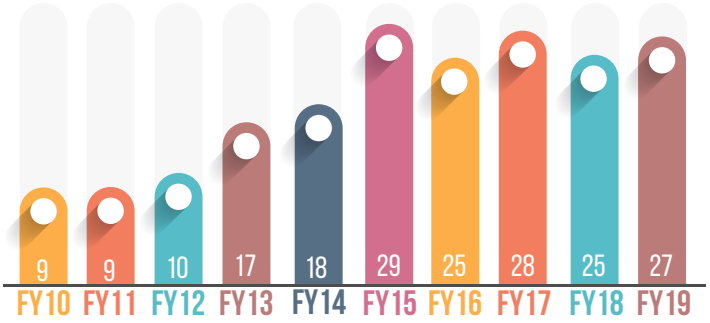
$4.39B Federal Research Funding

$339M Industry Sponsored Research

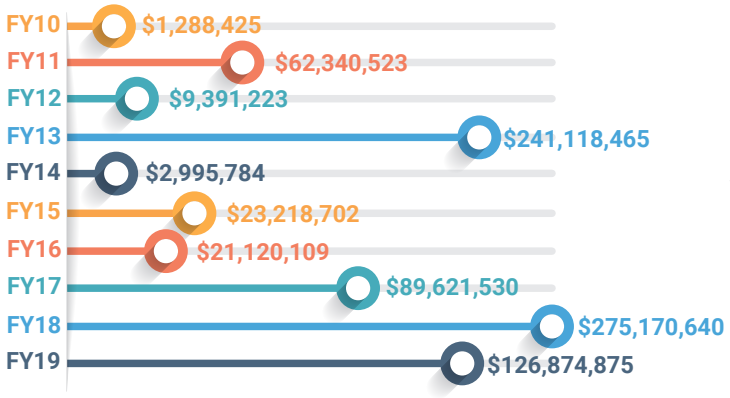
2010-2019

In addition to the formal metrics that CTTC reports to leadership (see previous page), CTTC tracks many other metrics and statistics that provide insight into how the center is performing, and into areas ripe for improvement. For instance, because we track the average time to process transactions, we have noticed that the recent increase in MTA requests during the pandemic have taxed our capacity to timely keep up with demand, leading us to restructure operations and work flows. And we track metrics, such as "Technologies First Transferred", to understand the average length of time it takes to license a new technology from disclosure to execution of a license agreement, and how this metric varies by type of technology (software vs medical device vs educational system vs therapeutic, etc). The metrics highlighted below are examples of data not generally reported publicly, but essential for us to understand CTTC's operations.

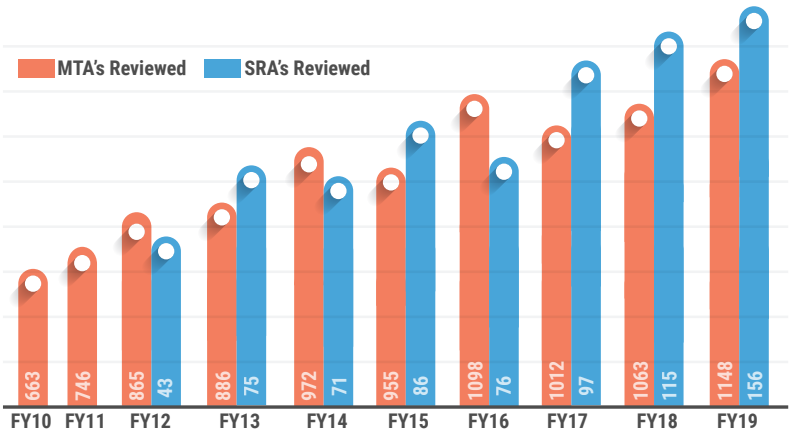
Some technology licenses have more commercial "upside" than others, and may include large milestone payments or royalty payments on product sales. To get a sense of how valuable licensing efforts may be to Vanderbilt long term, we track the number of transactions signed each year that has the potential to generate year-over-year royalties in the long term, and we track the face value of all fixed cash payments obligations included in the transaction. Our goal is to increase the number of royalty-bearing transactions annually and to increase the total fixed contract value of all transactions completed annually.

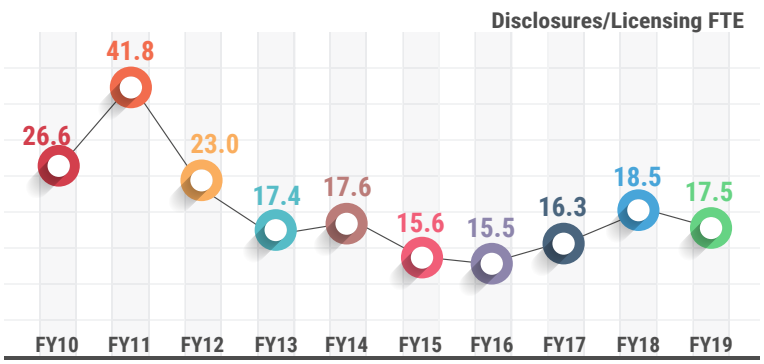


Royalty Bearing Transactions



Fixed Contract Value of Transactions





Load balancing among the licensing staff is important to ensure that the Vanderbilt community receives quality, reliable and timely service from our center. Researchers rely on CTTC not only to evaluate, protect and commercialize innovations from Vanderbilt laboratories, but to support the research enterprise by processing requests for the sharing of research tools, identify industry partners for supporting research programs, and for assisting other units such as Sponsored Programs Administration (VU) and the Office of Contracts Management (VUMC). To be effective, our staff must be 'at the ready', and we must ensure that bandwidth exists to assist as needed. And so we keep close tabs on the number of projects taken on by CTTC and by individual staff members.

IMPACTFUL TRANSACTIONS

Acadia Pharmaceuticals, Inc.

Vanderbilt has partnered with Acadia Pharmaceuticals Inc. for the development of novel drug candidates targeting the muscarinic M1 receptor with the potential to treat a range of central nervous system (CNS) disorders. These diseases include Alzheimer's disease, Schizophrenia and other neurocognitive disorders. The collaboration will focus on positive allosteric modulators (PAMs) of the M1 receptor. The M1 PAM program, developed within the Warren Center for Neuroscience Drug Discovery directed by Jeff Conn and Craig Lindsley, represents one of the only instances of an academic institution taking a drug discovery program from the conception phase all the way into clinical development and Phase I trials without investment or partnership with a pharmaceutical or biotech company. Such advancement was specifically important for this program due to the history of pharmaceutical failures and unwanted muscarinic effects seen with past M1 agonists. Passing the program to Acadia will now bring the additional expertise required to advance this program toward being available to treat patients.

Moderna, Inc.

Moderna and Vanderbilt University finalized a license agreement for access to Zika antibodies throughout the lifecycle of Moderna's Zika vaccine, which is currently in Phase I stage of development. These antibodies, created by James Crowe's laboratory in the Vanderbilt Vaccine Center were isolated from human blood samples collected after resolution of a Zika virus infection, and they reveal information about how the human immune system has effectively overcome and can prevent future Zika infections. That information makes these antibodies useful in both the development of an effective vaccine, and in the manufacturing of the vaccine, when the antibodies can be used to verify that each batch of vaccine is performing as desired before entering the supply chain.

Sandia National Laboratories

Researchers at the U.S. Department of Energy's Sandia National Laboratories (SNL) have historically engaged in extensive collaborations with Vanderbilt's Institute for Space and Defense Electronics (ISDE) researchers on a variety of mission-critical programs. Robert Weller and his colleagues at ISDE have developed first-principle modeling tools to predict the behavior of devices under radiative damage. One such powerful tool is nicknamed MRED (Monte Carlo Radiative Energy Deposition); this computer application simulates radiation transport in electronic devices. SNL tested the MRED program and determined that it was programmatically crucial to integrate this program into their project. ISDE's director reported that during a project update, the Vanderbilt collaboration and use of MRED has acquired significant prominence amongst SNL management and researchers.

Inventor Spotlight:

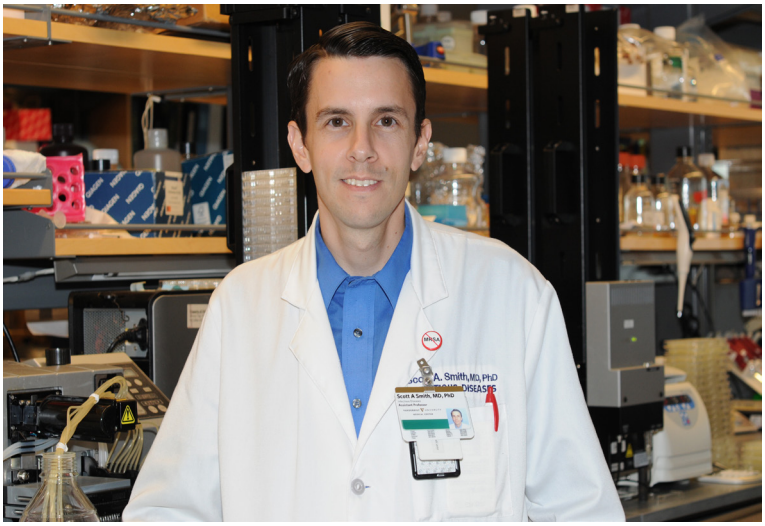
Scott Smith

Scott A. Smith, Assistant Professor of Pathology, Microbiology and Immunology, and his lab at Vanderbilt University Medical Center are on the forefront of allergen research and treatment. But the path to becoming a nationally recognized IgE expert has had a number of twists and turns.

Smith's foray into allergen research is one of good fortune and good timing. After completing both his medical degree and doctorate at the University of Louisville, Smith worked as a part-time post-doc in the lab from which he had obtained his Ph.D. According to Smith, a member of his dissertation committee had become close friends with a local allergist. Smith was introduced to the allergist because the allergist thought Smith could help him test an anti-allergen concoction that he had been developing. It was a spray that one could use on carpets and furniture to destroy allergens, like dog or cat allergen.

> "I agreed to work for the allergist on the side. He had a large space in his private practice which I purchased and equipped with the materials needed to study his anti-allergen spray. Over the course of a year or two I showed that the compounds that made up his spray worked somehow to prevent the allergic reaction in people (using skin testing). We published a paper together and he patented and licensed the product."

After that early work with allergens, Smith went on to residency and a fellowship at VUMC. Smith continued his research as an infectious diseases fellow working under James Crowe in the Vanderbilt Vaccine Center. While there, he started his breakthrough research on dengue virus and chikungunya virus using monoclonal antibodies. "I developed a method to make human hybridomas efficiently from the circulating blood cells of research subjects following an infection with dengue virus" said Smith.



Smith then accepted a faculty position at VUMC and started his own lab working on dengue virus antibodies to assist with vaccine design. During this time, the allergist friend with whom he had previously worked reached out to continue their research. "He wanted me to determine the mechanism of action of his anti-allergen spray (which was a Nature's Miracle™ product)" explained Smith. "It was a very simple experiment that I needed to perform. All I had to do was purchase some human IgE monoclonal antibodies and test their binding to cat allergen, before and after exposure to his spray. This would show that the mechanism of action was alteration of the structure of the allergen, such that the IgE would no longer bind and cause an allergic reaction."

Smith believed that if the anti-allergen spray was changing the allergen protein's structure (denaturing it), the IgE antibody that would normally bind and cause the allergic reaction, would not bind. It was during the course of this research that Smith came to a stunning realization that no one had ever successfully manufactured a single IgE monoclonal antibody. After reviewing the literature for almost a year, Smith decided to commit to studying IgEs, leaving infectious diseases research.

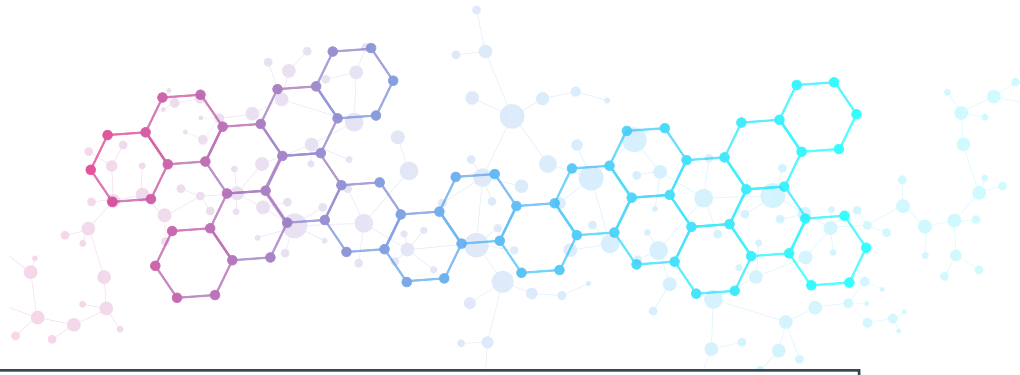
It took nearly 2 years to develop the method that would create the very first human IgE monoclonal antibody, named 1C14 – targeting the most common allergen protein on earth: dust mites.

Smith's lab has now made over 500 human IgE mAbs including antibodies that target just about every important allergen protein. The impact of this work is immense to say the least. According to Smith, having these tools will provide insights that will enable for the design and development of improved allergy diagnostics, vaccines, and immunotherapies.

Smith's research into antibody therapies and diagnostics are more far reaching than many realize. In developed countries allergic diseases collectively affect nearly 20% of the population, and in developing countries 2 billion people worldwide are infected with parasitic worms; these two diseases seem very much unrelated; however, both involve the human IgE antibody response. As industrialized countries eliminate parasitic worms the incidence of allergic diseases, particularly those to foods, has steadily risen – resulting in an "allergy epidemic."

Studying human IgE at the molecular level as monoclonal antibodies will allow for the most basic and critical interactions to be assessed between the human IgE antibody and the allergen proteins, such as those of peanut, and will provide new insights into the often pathological but potentially protective aspect of the human adaptive immune system.

Currently, Smith and his lab are working on a new strategy of allergy immunotherapy; by turning the pathogenic IgE antibody into a therapeutic IgG antibody in hopes to block severe allergic reactions to things like foods, most notably the severe peanut allergy that affects millions.



Indoor Biotechnologies

Indoor Biotechnologies has recently signed a license agreement with Vanderbilt University for technology that enables the production of human IgE monoclonal antibodies to various allergens that are inhaled into the body, present in food and other types of allergens. Under this agreement, Indoor Biotechnologies has worldwide, exclusive rights to commercialize the IgE monoclonal antibody technology for research and diagnostic use. Previously, it was not feasible to obtain purified IgE antibodies for research on allergic diseases. A remarkable breakthrough by scientists at VUMC harnessed the power of monoclonal antibody technology to produce unique, human IgE antibodies that can be manufactured in unlimited amounts and that are available in perpetuity. Indoor Biotechnologies is the leading provider of allergen-specific monoclonal antibodies.

STARTUP SPOTLIGHT

Meru Biotechnologies

Meru Biotech is a Richmond,Virginia-based company that is developing analytical instrumentation, reagents and services based on Darryl Bornhop's "Backscattering Interferometry" technology. The technology, called "Free Solution Analysis" (FSA), improves the drug discovery process by providing more accurate and sensitive measurements and data on drug target interactions. FSA combines the strengths of existing label-free approaches in a straightforward platform powered by advancements in compensated interferometry. It uses a single laser to measure experimental and reference samples in the same microfluidic channel simultaneously. In addition to life sciences, the company's Free Solution Analysis methodology is being applied to much broader fields including agriculture, environmental science, forensics and DoD testing. The company is pursuing a Federal STTR grant to support this R&D effort and has raised seed stage private investment.

IDBiologics

IDBiologics was founded in 2017 to develop human monoclonal antibodies for the prevention, treatment, and cure a variety of infectious diseases. The company's first assets are from the laboratory of James Crowe, MD, director of the Vanderbilt Vaccine Center. The company is developing human monoclonal antibodies to be broad and potent therapeutic molecules. Recently, the company partnered with the Vanderbilt University Medical Center to develop novel monoclonal antibody medicines that could treat COVID-19 or prevent infection from the SARS-CoV-2 virus. The overall goal of the alliance is to develop safe and effective monoclonal antibodies through FDA approval useful as treatments for people suffering from COVID-19 or for protecting people exposed to the SARS-CoV-19 but not yet showing symptoms of disease, and for preventing infection in susceptible individuals in the community.

SkyNano LLC

SkyNano is developing manufacturing techniques to economically manufacture carbon nanotubes. Traditional manufacturing techniques used to create advanced carbon additives require high vacuum and high pressure gas flow systems, which are both expensive and suffer from a lack of scalability - this accounts for the high price of advanced carbon structures. The company is developing a low cost manufacturing technique to create these carbon additives by using inexpensive materials, electricity and carbon dioxide as direct inputs. The technique is based on a process developed by Dr. Cary Pint's laboratory at Vanderbilt University. The company's technique makes use of high-value secondary material produced from greenhouse gases and relies on electrochemistry, rather than environmentally unfriendly catalysis. The result is a highly efficient process that converts atmospheric carbon dioxide into useful functional nanomaterials.

WHERE ARE THEY NOW

AI Biomed

AI Biomed was spun off from ANASYS INSTRUMENTS, Inc. who in 2012 licensed a photonics technique for discerning between parathyroid and thyroid tissue developed in Dr. Anita Mahavdeven-Jansen's laboratory in the Vanderbilt Biophotonics Center at Vanderbilt. The Vanderbilt Biophotonics Center and AIBiomed have continued their collaboration over this time with support by STTR and SBIR grants. The company successfully developed a hand-held product design that was subsequently approved by the FDA as a Class II device in 2018 (known commercially as "PTEye"). AI Biomed began development of an improved device that incorporates laser speckle imaging into the technology portfolio. While this technology development and integration was in progress, Medtronic's ENT division expressed interest in acquiring AI Biomed. In March 2020, AI Biomed was acquired by Medtronic and Vanderbilt continues to work with Medtronic in bringing this beneficial technology to the surgery suite.

nPhase

Since beginning operations in 2016 with the development of its REDCap Cloud technology, nPhase has developed and implemented a number of additional and improved products that enable patients, life science companies, contract research organizations, government agencies, integrated healthcare systems and foundations to collect, manage, analyze and share health data for research and clinical care purposes. The company has raised several million dollars to support its growth, and employs nearly forty people. Fourth generation improvements to the REDCap Cloud Part 11 compliant EDC solution include:

- Development of the REDCap Cloud Unified Life Science Platform which collects, integrates and analyzes clinical research data. This product has nearly 200 clients worldwide.
- Launch of their Patient Engagement Portal for mobile apps, eConsent, ePRO and eCOA.
- Launch of their integration "platform as a service" to enable eSource aggregation of all clinical data.
- Support for more than 20 COVID-19 related research projects for screening, testing, contact tracing and clinical research.

Path Ex

PATH EX is a medical device company focused on the diagnosis and treatment of sepsis. The company is based in Houston, TX, and is a resident company at Johnson & Johnson Innovation Laboratories (JLABs) at the Texas Medical Center accelerator (TMCx). Since 2017, the company has raised over $1M in dilutive funding through early stage and institutional investors and has raised over $1M in non-dilutive funding through the National Science Foundation. PATH EX was selected as one of the 20 companies from around the world to be accepted into the TMCx accelerator program. The PATH EX CycloPE medical device was awarded Breakthrough Device Designation with the FDA as a potential means to treat a patient population for which no current alternative exists. Additionally, PATH EX won the Johnson & Johnson Quickfire Challenge award for breakthrough technology. The company is completing large animal studies and will be performing pilot studies with partner institutions within the Texas Medical Center.

As mentioned in the introductory letter to this issue of DIF, with the declaration of the COVID-19 pandemic CTTC revamped its processes to ensure that key transactional documents related to coronavirus research were prioritized – the most common of such documents being Material Transfer Agreements that enable coronavirus research to advance. Most COVID-related MTAs are processed within a few hours from request, whether for incoming materials or outgoing materials.

Vanderbilt's home-grown system MTAShare has played an important role in the rapid processing of MTA, and has allowed us to keep pace with demand. CTTC implemented MTAShare six years ago, and last year agreed to partner with an external software company to make the system broadly available to the academic and non-profit research community. CTTC and its partner have been working for nearly a year to recreate MTAShare from the ground up, so that it is adaptable and usable in the workflow of many institutions (not just ours.)This revised system is in beta-testing and is scheduled for launch in the fall of 2020. Broad adoption of MTAShare by other institutions will make the system more automated and efficient for all users.

Those that have heavily used the existing MTAShare system (including CTTC) will need to adjust a bit to the new system, which has a somewhat different look and feel, but very similar functionality as the original MTAShare. But the new system has features that go beyond the current system that improve usability, scalability, and transparency.

Vanderbilt awarded inaugural Golden Stopwatch

Addgene, the largest repository of plasmids in the U.S. and a party to more than a million MTAs with academic research institutions, created the Golden Stopwatch Award in 2019 to recognize academic organizations dedicated to accelerating the pace of research by processing agreements rapidly. Vanderbilt was among a handful of academic institutions named an awardee of the 2019 Golden Stopwatch Award for outstanding MTA turnaround times. Eligibility requirements include completing MTA requests in less than two days on average.

ANCORA INNOVATION

THE EVOLUTION OF A DEEP COLLABORATION

In March of 2018, Vanderbilt entered into a collaboration with Deerfield Management called Ancora Innovation, designed to develop and bring new pharmaceuticals to the market by leverage Vanderbilt's innovative life science research and Deerfield's expertise in accelerating state-of-the art drug development. How has a major collaboration such as this evolved, and how has it benefited Vanderbilt and its researchers?

To date, two drug development projects have been accepted into the program and several other programs are in review. (We plan to have an exciting announcement soon!) As the collaboration to identify promising projects has developed over time, changes in how we collaborate have been enacted. We have evolved from seeking out new project via RFP to a more 'curated' process, where projects can be considered at any time, and are vetting at VU in advanced of submission to ensure they are ripe for Ancora review. The criteria for selecting projects has crystallized and is highly dependent on a clear pathway to a commercial product (including having validated animal models and clear pathway through clinical development scoped out in advance of launch).

The bar for accepting projects into the Ancora collaboration is understandably high. And we appreciate it can be frustrating for a proposal to be turned down by Ancora. We have, however, observed numerous advantages through the collaboration, beyond the obvious direct funding of projects. Working through the curated process has exposed Vanderbilt researchers to the Deerfield Discovery and Development (3DC) unit, a group of industry research and development experts whose sole goal is to help investigators optimize the advancement of their Ancora programs and in similar collaborations with others in the Deerfield academic collaboration network. 3DC did not exist at the time Ancora was formed and represents a substantial investment in Deerfield in maximizing benefits to their university partners. Researchers that engage with 3DC, both during the proposal vetting stage and the program development stage become smarter and more knowledgeable about the many aspects that must be addressed to develop a novel therapeutic. This collaboration is making our drug discovery researchers better.

Further the Ancora collaboration has opened the door to other opportunities. Deerfield has invested capital in one of Vanderbilt's startup companies and is serving on its board of directors (and Deerfield is reviewing another investment opportunity with Vanderbilt); Deerfield has provided Vanderbilt with multiple leads to explore collaborations with other companies to explore projects that were not accepted into Ancora; and Deerfield even connected the Medical Center to one of its collaborators to launch a COVID-related human clinical trial.

Would Vanderbilt like for more projects to be funded through the Ancora collaboration – absolutely. Would Vanderbilt like for the process of reviewing proposals to be a lighter lift for the researchers – we are working on that. But the review process and related criteria has evolved, as has the way in which feedback is provided to the researchers on their proposals. And the faculty interactions with Ancora have been beneficial and a learning experience. And the other business interactions have proven quite beneficial to Vanderbilt, even if not completely anticipated at the start of the collaboration.

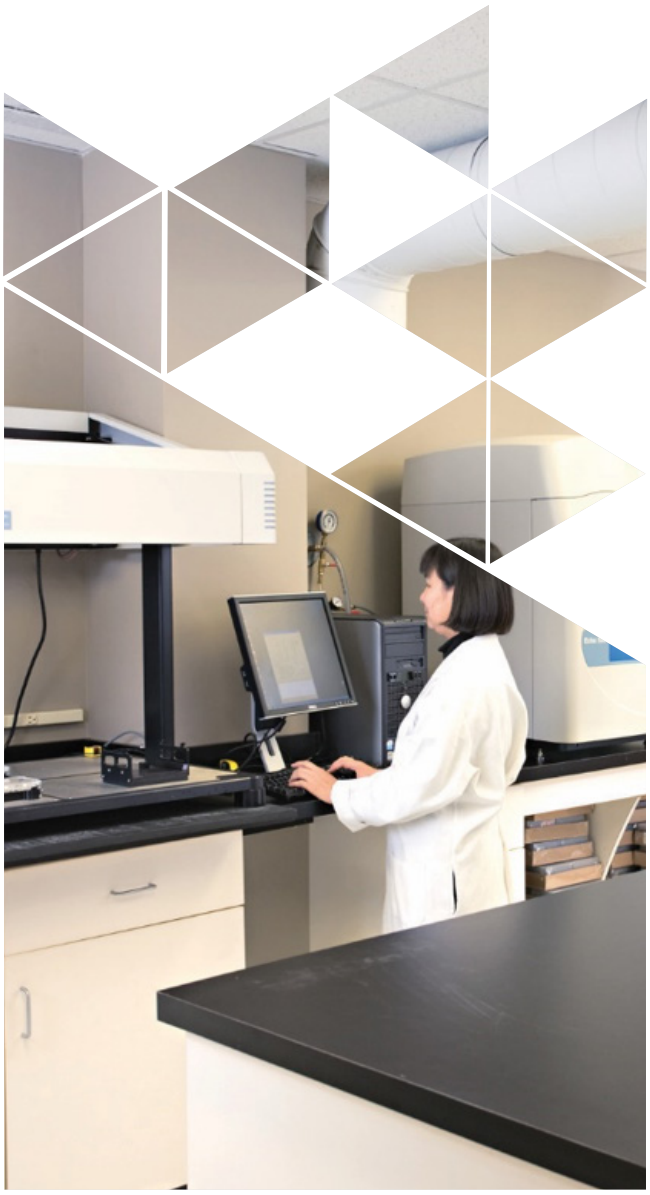
Every time we facilitate faculty interactions with industry, it is a win for the faculty and for the University. We are activity working on expanding the Ancora collaboration, and on exploring similar collaborations with other companies in the pharma space and in other industries. These types of relationships are complex to form, but are well worth the effort.

PARTNERSHIP SPOTLIGHT

CET and the Life Sciences Center

Cumberland Emerging Technologies, Inc (CET), headquartered on the 9th floor of 2525 West End, was established as a joint initiative between Vanderbilt University, Cumberland Pharmaceuticals, Inc, and Launch Tennessee (formerly the Tennessee Technology Development Corporation). It represents a unique partnership among regional academia, industry and government. CET identifies commercially viable biomedical technologies conceived at academic research centers and advances them toward the marketplace. Vanderbilt and CET have entered into more than a dozen development collaborations over the past decade, and CET has established collaborations with a half dozen other universities and research hospitals over that time.

Identifying a dearth of non-academic wet-lab research space in the region, CET established the Life Sciences Center (LSC) in Nashville. The LSC was established to foster the development of the local biomedical industry. One of the best-kept secrets in the region, the LSC provides flexible laboratories, office space, shared spaces to tenant companies, and has undergone expansion three times since inception. The facilities are conveniently located at 10th and Broadway in the Gulch, less than 2 miles from campus – making it ideal for faculty entrepreneurs and others working off campus to commercialize technology. Currently three LSC tenants are Vanderbilt-faculty run, and a half dozen other former Vanderbilt-affiliated tenants have graduated to larger facilities.



Contact CTTC for more information on the CET Life Sciences Center or visit their website at:

http://www.cet-fund.com/life-sciences-center/

INNOVATING IN TIMES OF CRISES

Small Molecule Treatment of COVID-19

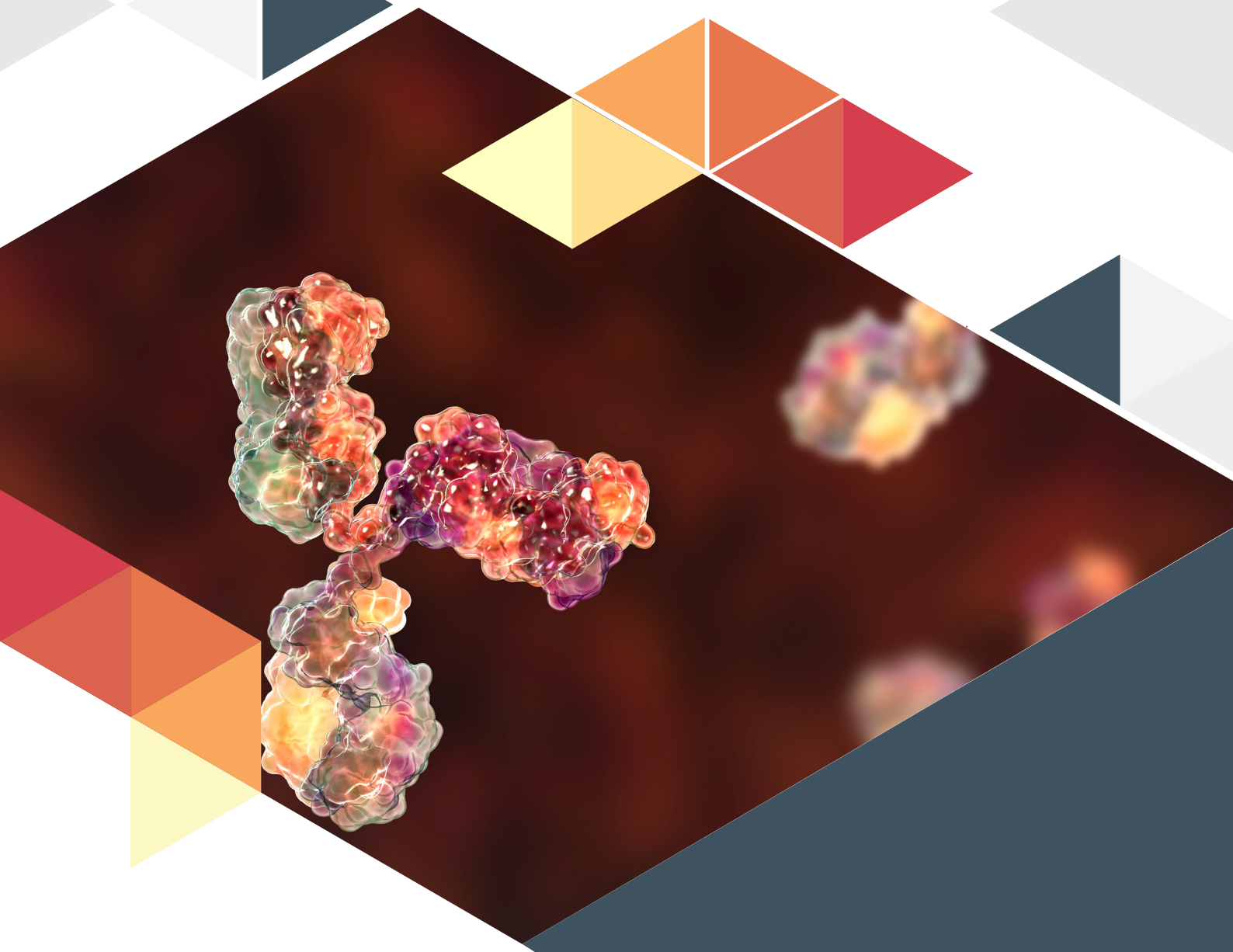
The Fesik Lab, run by Stephen Fesik, Ph.D., has rapidly delved into the discovery and testing of selective small molecule inhibitors of SARS CoV-2 proteases for treatment of COVID-19. Activity of two CoV-2 encoded cysteine proteases, PLpro and 3CL Pro, are required for processing the polyproteins that are translated from the viral RNA. Inhibitors of either of these proteases will block maturation and viral replication, making them both good targets for antiviral drug design. The Fesik lab's unique approach to drug discovery is enabled by an NMR-based screen using a proprietary fragment library followed by structure-based design to generate drug-like compounds.

Virtual COVID Screening Tool

In response to the COVID-19 pandemic, researchers at Vanderbilt University have come together to develop a free, web-based, COVID-19 "virtual-self screening" tool, designed for patients, providers, and health departments to be an interactive healthcare-based hub for promptly identifying, mapping, treating, and reducing the public health risk and impact of COVID-19. Developed by Tom Scherr, T.S. Harvey and colleagues, the goal of the screening tool is to facilitate a safe re-opening of businesses during the ongoing pandemic. The tool can be accessed at the following website: virtualcovidscreen.com

Commodore Open-Source Ventilator

Engineers and physicians teamed up at the height of the ventilator shortage to design, manufacture and test a low-cost, easy-to-build ventilator option for emergency usage in times of crisis, using everyday materials that are readily available almost everywhere. Led by Vanderbilt engineers Kevin Galloway, Robert Webster, Richard Schroeder, and others, the system uses readily available materials, utilizes a windshield wiper motor donated from Nissan, and can be scaled up in short order. The Vanderbilt team has built a hundred ventilators and are seeking emergency use authorization from the FDA just in case they are needed.



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