Baylor College of Medicine

# BCM VENTURES

## Commercialization Activities for the College

Annual Report 2023-2024

# TABLE *of* CONTENTS

# LETTER *from the* CHIEF SCIENTIFIC INNOVATION OFFICER

As the Chief Scientific Innovation Officer (CSIO), and on behalf of the Baylor College of Medicine Ventures (BCMV) team, I am excited to present our FY24 annual report on the commercialization mission. This review covers BCMV progress, achievements, and strategic goals as we continue our mission to accelerate the translation of Baylor discoveries into commercial successes that benefit society. Our goal is to catalyze faculty innovation, maximize the public impact of BCM discoveries, and seek fair returns for the college and its inventor-scientists.

Innovation in academic medicine has evolved significantly over the years, and the landscape is rapidly changing, necessitating larger and more complex relationships and collaborations. We are tapping into a broader spectrum of institutional strengths and intellectual assets, across all missions, to stay at the forefront of innovation and commercial translation.

BCMV was designed to serve as a single, trusted interface for commercial relationship management and coordination with faculty and industry partners, streamlining processes for enhanced efficiency and effectiveness. BCMV was created to embed commercialization activities within the college--from intellectual property disclosure to transactional management--and align these functions with the central missions of the institution. This ensures that the pursuit of business objectives would not interfere with academic, clinical, and educational goals. Further, by combining commercialization activities (e.g. executing licenses, launching companies and other transactional outcomes) with the Baylor Licensing Group (BLG—whose function is to evaluate and protect intellectual property), we have centralized intellectual property commercialization operations, ensuring a cohesive approach towards our objectives. Ultimately, the CSIO role was created to oversee the commercialization mission and ensure that these top-level translational resources are connected directly to the faculty, staff and student inventors in the college and are appropriately robust to realize our translational aspirations.

Our ambition is to build a culture of commercialization where new discoveries can seamlessly transition from conception to the marketplace. We are creating an innovation ecosystem that fuels interactions, enhances our institutional profile, increases awareness, and cultivates opportunities, all while attracting skilled and experienced individuals to our cause.

We are executing on a comprehensive plan to realize this vision, focusing on four key areas:

1. **Organization:** We have completed the transition of commercialization activities to an internalized model within the college, hiring key positions, uniting the team, bolstering our technology management skill base, and forming a pool of specialist contractors to support business development. Additionally, we are establishing advisory panels consisting of faculty and board members to inform strategic decisions.

2. **Robust process and infrastructure:** Translating intellectual property into commercial transactions is the core of our mission. Therefore, one of our main objectives has been to create a backbone of operations to streamline technology disclosure intake and the subsequent review and transactional processes so that they are efficient, effective, and transparent. Every disclosure that is submitted to our portal is thoroughly reviewed, and inventors are informed of the outcomes and next steps in a manner that instills trust in the process and the decisions that are recommended.

3. **Education:** To instill a culture of commercialization, we are educating our faculty, students, leaders, and our board in how commercialization works in academic medicine. We introduced a course in Term 4 in the Graduate School of Biological Sciences, “Commercialization of Biomedical Technologies”, which was well attended and well received by faculty and

students alike. We are also in the process of creating content for online education that will be available soon.

4. **Communication:** We are creating platforms to update faculty, leadership, and board members as to the activities in the BCMV office as well as provide updates on technologies and commercial transactions that are moving forward. These will increase trust in the process and add to the ways in which faculty can readily engage with the commercialization mission.

5. **Funding support:** We have built an innovation hub as a physical focal point for commercialization activities at the McGovern Campus (formerly Nabisco), leveraging existing college infrastructure to create new opportunities, and are setting up a philanthropic fund to fuel early-stage development. We aim to build a BCM Venture Fund with which we will be able to further support the growth of de-risked and growing startups as they gain a foothold in the marketplace.

Finally, I am thrilled to highlight some of the excellent progress of a couple of our newest start-up companies, exemplifying our commitment to fostering an entrepreneurial spirit and driving innovation in healthcare:

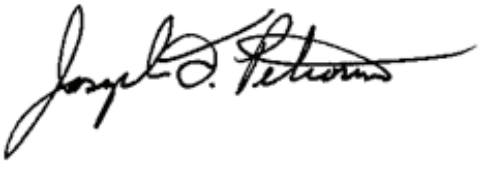
One such standout is March Biosciences, helmed by founding CEO Dr. Sarah Hein. March Bio advances the research of BCM PIs Dr. Maksim Mamonkin and Dr. Malcolm Brenner and is focused on the development of CD-5 CAR T cells (MB-105) to treat certain T-cell cancers. Their CD-5 CAR T cell product candidate has completed a Phase I clinical trial, demonstrating early compelling evidence of clinical efficacy. Launched as a partnership between BCM and the Texas Medical Center, March has been successful in securing multiple streams of funding, including a $13.4M CPRIT product development award in November 2023. With additional recent investment, March plans to initiate a Phase II trial in the near future.

Another rapidly growing start-up is Phiogen Pharmaceuticals, spearheaded by the research of Dr. Anthony Maresso, and led by CEO Amanda Burkhardt. Phiogen is dedicated to developing bacteriophage cocktail products to combat multi-drug resistant bacteria. Since its formation in January 2023, Phiogen has received initial financial support from BCM and has secured the key leadership needed to advance the concept. Their strategy to leverage innovative bacteriophage cocktails to treat discrete, high-impact indications shows tremendous potential and underscores their commitment to maximizing societal impact. They are currently raising funds to begin a phase 1/2 clinical trial for their first indication, chronic urinary tract infections (UTIs).

These ventures exemplify BCMV's dedication to maximizing the impact of Baylor College of Medicine's knowledge by translating cutting-edge research into commercial solutions. Through strategic investments and collaborative partnerships, BCMV continues to drive innovation, propelling the translation of ideas from the laboratory to the marketplace.

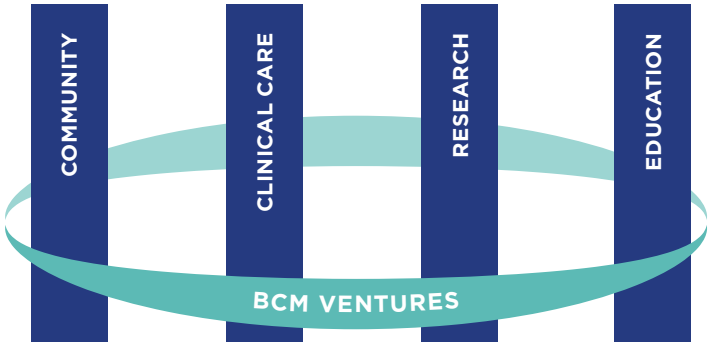
I extend my gratitude to BCM leadership for providing an environment where we can readily translate discoveries from the lab to the commercial marketplace, and to all our stakeholders and partners for their unwavering support and commitment to our shared vision. Together, we will continue to push the boundaries of innovation, making a meaningful difference in the healthcare of people worldwide.

Joseph Petrosino, Ph.D.
Chief Scientific Innovation Officer



# MISSION & VISION

**Baylor College of Medicine**
is a health sciences university that creates knowledge and applies science and discoveries to further education, healthcare and community service locally and globally




## BCM VENTURES MISSION

Stimulate the translation of BCM knowledge and discoveries into commercial assets, delivered through organizational relationships, that broaden social impact

## VISION

Build a thriving innovation ecosystem with a culture of commercialization centered around maximizing the impact of BCM knowledge and discoveries

DISCOVERIES · KNOWLEDGE · COMMERCIALIZATION · SOCIAL IMPACT

# BCMV LEADERSHIP

| Joseph Petrosino, Ph.D. | Jennifer McCullough, MBA | Nayla Benyamine, M.P.H. | Michael Dilling, Ph.D. | Brad Kairdolf, Ph.D. |
|---|---|---|---|---|
|  |  |  |  |  |
| Chief Scientific Innovation Officer | Administrator | Senior Manager Business Strategy & Operations | Executive Director Commercialization & Technology Management | Director Commercialization & Technology Management |

bcm.edu/about-us/bcm-ventures/leadership-and-team

# BCMV TEAM

**Dylan Laug, Ph.D**

Therapeutics and Vaccines Portfolio Senior Associate

**Terese Rakow, Ph.D.**

Diagnostics and Tools Portfolio Senior Manager

**Alex Perakis, Ph.D.**

Diagnostics and Tools Portfolio Associate

**Gavin Garvey, Ph.D., MBA**

Medical Device and Digital Health Portfolio Senior Associate

— Commercialization & Technology Management —

**Gauri Bhave, Ph.D.**

Medical Device and Digital Health Portfolio Senior Associate

**Sarah Molina, Ph.D., MBA**

TCH Based Investigators Principal

**Mercy Chen, Ph.D.**

Senior Associate, Commercialization Compliance Management

**Marc Vazquez, MHA/ MBA, PMP**

Associate, Business Strategy & Operations Management

— Commercialization & Technology Management —

**Brenda Kissack, MBA**

Senior Financial Analyst

**Jessica Mendez, MBA**

Lead Accounting Coordinator

**Wendy Contreras, MBA**

Lead Accounting Coordinator

**Janice Ward**

Senior Coordinator, Executive Support/ Office Manager

# COMMERCIALIZATION PROCESS

## High-level overview of the process focused on faculty and industry engagement

### SUBMISSION PORTAL

- Discoveries, inventions, technologies, and other intellectual assets are disclosed (https://orit.research.bcm.edu/BaylorLG/)
- Team facilitates invention disclosures and partners with faculty to identify and explore other assets with commercial and impact potential

### EVALUATION

- BCMV searches for prior art, determines patentability and assesses potential to generate commercially valid claim
- High impact candidates trigger further strategic assessment

### PROTECTION

- Disclosures with commercial potential have intellectual property protected through a variety of measures such as patent protection, trade secrets, copyrights, trademark and data security

### VENTURE PLANNING

- BCMV works with the creator and internal advisory committees (e.g. ITVC) to determine optimal commercialization vehicle for the technology (e.g. licensing to industry or forming a new venture)

### MARKETING

- BCMV analyzes market to identify potential partners and markets broadly to find the best fit for the technology
- BCMV may generate marketing collateral, list the technology on the website and showcase at key conferences and events

### DEAL MAKING

- BCMV forges relationships with a range of stakeholders including entrepreneurs, investors and corporate companies
- BCMV team structures deals and negotiates agreements (licenses, commercial collaborations etc.)

### FINANCIAL MANAGEMENT

- BCMV Finance team manages distribution of commercialization revenue (e.g. license income distributions, annual maintenance fees, royalty payments, etc.) and oversees terms, invoicing and management of other financial activities specified in each agreement

# COMMERCIALIZATION PROCESS

High-level overview of the process focused on faculty and industry engagement

## How the BCMV team fits into the process and helps build commercial paths

**The Commercialization Process at BCM**

1 **Submission Portal:** Inventors use an Online submission portal to disclose their invention

2 **Evaluation:** The invention is reviewed for its technical feasibility, market potential, and commercial viability. The prior art landscape is analyzed to identify existing solutions and potential patentability. A development roadmap is created, outlining the necessary steps to advance the technology. Acknowledgment & Project Manager Interview: After the technology or invention is disclosed, the technology manager will get in touch with you to learn more about it. They'll arrange a one-on-one meeting to understand the research that led to the invention, how far along the development is, if you've already shared it publicly and your future plans for its development. They'll also want to know what you hope to achieve with a potential business relationship: Do you want funding for further research? Do you want to license the invention to an existing company or are you interested in starting your own company?

**What to Expect**

- You'll receive an acknowledgment of your disclosure within 48 hours after submitting.
- You'll meet with your IP project manager within 3 weeks to discuss your disclosure.
- If your disclosure has enough information, you'll receive an Invention Disclosure Analysis (IDA) with a recommendation for commercialization within 90 days. If not, your IP project manager will let you know when to expect it.

**Assessment:** Once your IP project manager gathers more information, they'll conduct a thorough assessment of your invention. They'll examine scientific and patent literature related to your invention, look at the commercial market it addresses, and identify potential partners for commercialization. They might work with a BCMV Fellow intern to help gather information. The results of the assessment will be shared with you, along with a recommendation on how to proceed with commercialization. You'll have a chance to provide feedback.

**Components of the Invention Disclosure Analysis (IDA):**

- Description of the technology and how it addresses unmet needs. How is it different from other existing technologies?
- Examination of prior art to see if your invention can be patented or how it stands out from existing solutions.
- Description of the market size and trends, as well as potential commercial partners.
- Comparison with competing technologies already on the market.
- Identification of any obstacles that might affect commercialization, like agreements with third parties that involve intellectual property rights.
- Commercialization recommendation with the rationale behind it. This could include creating a marketing brief, filing a patent application or checking progress in a few months.

Each technology is unique, so recommendations will be tailored to your invention with an opportunity for your input

3 **Protection:** Depending on the type of idea or invention you share with us, we'll work together to figure out the best way to protect it. If your invention is something like a medicine or a medical device that could be used in treating people, we might consider applying for a patent. The decision to apply for a patent depends on whether it's possible to get broad enough protection for your invention, so it's worth investing money and effort into it. The main question we'll ask ourselves is whether having a patent will make



your invention more valuable and attract investors or if it's necessary to successfully bringing your invention to the market. Our ultimate goal is to help you achieve commercial success for your invention. The focus is not just on getting a patent for the sake of it, but rather on making sure your invention thrives in the business world.

4 **Venture Planning:** The venture planning process is all about finding the best way to turn your invention into a successful business. In most cases, the best option is to partner with an existing company that already works on similar research and product development. This partnership is called a "license" where the company gets permission to use your invention commercially.

Sometimes, you, as the inventor, might already know companies that are interested in your research area, and they would be the easiest ones to approach for licensing your invention. Some inventors are interested in creating their own startup companies. Startups are new companies that aim to have an edge in their market by offering a unique product or service. If your invention can lead to multiple related products, then starting a new company might be a good option. But if your invention is mainly focused on just one product, it might be better to license it to an existing company that already operates in that market. This way, your invention can reach more people and be more successful.

5 **Marketing:** After the Roundtable discussions, if we decide that it's a good idea to start promoting our technology or intellectual property (IP) to potential partners, the BCMV IP project manager will work with the PI (Principal Investigator) to create a marketing plan. The first step is to create a summary of the technology that doesn't reveal any confidential details. This summary will highlight the important features and benefits of the technology to generate interest among potential partners. We will directly share this marketing summary with companies that we believe would be good candidates to license the technology. Additionally, we might use a website called In-Part, which connects companies looking for new technologies with academic innovators like us.

In-Part is different from other technology marketing websites because they actively promote the technologies they have on their platform. They match uploaded technologies with industry partners in their network, increasing the chances of finding a suitable match. In-Part also regularly posts technology challenges and campaigns initiated by industry partners who need innovative solutions to their problems. They keep track of each technology uploaded on their website, so the technology manager can inform the faculty innovator about which companies have shown interest and any feedback provided by those companies.

6 **Deal Making:** When two parties want to work together and create a contract that benefits them both, they start the deal making process. It usually starts with a simple document called a "term sheet" that outlines the important business aspects of their future relationship. This term sheet acts as the basic structure for the deal's business terms.

7 **Financial Management**

- Monitoring deals to ensure compliance terms – financial and diligence
- Distribution of license revenue to faculty, BCM and other stakeholders
- Financial activities & support are ongoing, based on agreement structure

In the realm of financial management within deal making, vigilance is key. Regular monitoring ensures that both parties uphold their financial commitments and diligence obligations outlined in the initial agreement. As revenue streams in, a transparent process for distributing license revenue to faculty, BCM, and other stakeholders maintains trust and fosters ongoing collaboration. Financial activities and support, guided by the agreement's structure, must persist throughout the deal's lifespan, adapting as necessary to evolving circumstances or opportunities.

# IMPROVING ENGAGEMENT *with* BCMV

## Drive Faculty Disclosure Submissions


**Faculty can now submit invention disclosures on any device, anytime, anywhere!**

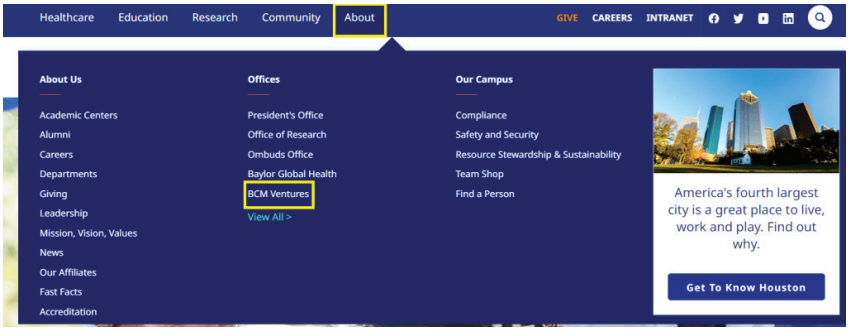
Three pieces of information needed for submission:

- List of contributors to the IP and contribution percentages
- List of funding sources (including grant numbers)
- Brief description of the proposed IP

### NEW INITIATIVES TO IDENTIFY AND REVIEW NEW IP

- Work with BCM Communications/Public Affairs to review publicized information related to any new technologies and assess for any IP potential
- Work with Research IT to enhance the BCM IP Database to improve workflow for submitted disclosures
- Improve speed, quantity and quality of faculty feedback

## Improve visibility & Access to BCMV Website from BCM Homepage




Linking to BCMV on the BCM website has been streamlined.
Visit us at bcm.edu/about-us/bcm-ventures.

### INITIATIVES

We are in the process of creating a robust and dynamic website with enhanced features to improve communication and marketing with internal and external partners.

# INTERNAL TARGET VALIDATION COMMITTEE USHERS REVIEW PROCESS *for* PROMISING DRUG TARGETS

The Internal Target Validation Committee (ITVC) was formed to provide a mechanism to review and strengthen BCM drug target/development opportunities before they are presented to commercial partners. Faculty and opinion leaders with diverse drug and therapeutic development experience were recruited to serve on the ITVC, ensuring it represents significant collective expertise to improve our therapeutic submissions. This evaluation process serves to identify strengths and weaknesses with therapeutic opportunities and helps PIs who are developing therapeutics to think about the most appropriate experiments needed to strengthen their submissions.

Additionally, the ITVC helps increase faculty members' awareness of potential collaborative opportunities that may enhance a PI's therapeutic research program. While many elite academic biomedical research institutions have partnership agreements with Deerfield, BCM is the only one to implement a mechanism like the ITVC (Deerfield has since requested its partnering institutions to have a review process such as this as part of their submission pipelines). The BCM Ventures team wishes to thank our ITVC committee members for their time and service to increase the odds of success associated with therapeutics projects from BCM laboratories.

BCM faculty who wish to submit a therapeutic program for ITVC review can do so here: https://orit.research.bcm.edu/BCMCommercializationApplication

# INTERNAL TARGET VALIDATION COMMITTEE (ITVC)

The ITVC assists in curating drug development projects with commercial potential

## Salma Kaochar, Ph.D.

**ITVC CHAIR**
Assistant Professor,
Medicine – Hematology
& Oncology

## Damian Young, Ph.D.

**ITVC Co-Chair/Blue Square Scientific Business Dev. Director**
Associate Director, Center for Drug Discovery, Associate Professor, Pharmacology & Chemical Biology and Pathology & Immunology

## Malcolm Brenner, M.D., Ph.D.

Professor, Center for Cell & Gene Therapy, Molecular & Human Genetics, Pediatrics, Medicine, Translational Biology & Molecular Medicine

## David Nelson, Ph.D.

Professor, Molecular & Human Genetics

## Trey Westbrook, Ph.D.

Professor, Molecular & Human Genetics, Biochemistry & Molecular Biology, Director, THINC

## Tim Palzkill, Ph.D.

Chair and Professor, Pharmacology & Chemical Biology

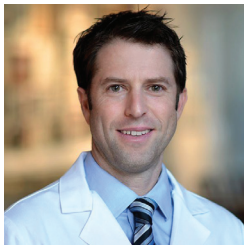
## Suzanne Fuqua, Ph.D.

Professor, Breast Center

## William Decker, Ph.D.

Associate Professor, Pathology & Immunology

## Benjamin Musher, M.D.



Medical Director, Medical Oncology, Dan L Duncan Cancer Center, Associate Professor, Medicine-Hematology & Oncology

## S. Gail Eckhardt, M.D.

Associate Director, Translational Research, Dan L Duncan Cancer Center, Associate Dean, Experimental Therapeutics

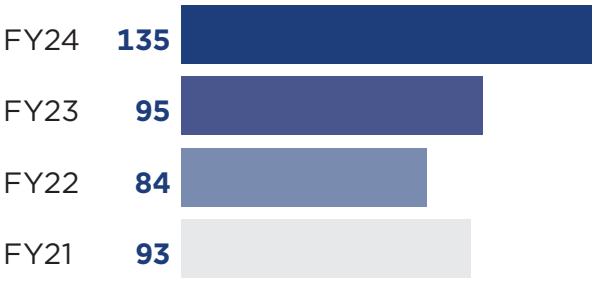
# FY24 PERFORMANCE DASHBOARD

We use key performance indicators to track our progress at improving the culture of commercialization of the College and translating meaningful technologies to the marketplace. The initiatives we have implemented over the past two years are designed to raise awareness and trust in the commercialization program. The 42% increase in disclosures reflects the success of those efforts. We are now working to see that these discoveries are effectively protected and translated to the marketplace. This should result in an increase in the number of patents, licenses and transactions in the years to come.

## Disclosures: Up 42% from last year

## Patents:

### DISCLOSURES SUBMITTED

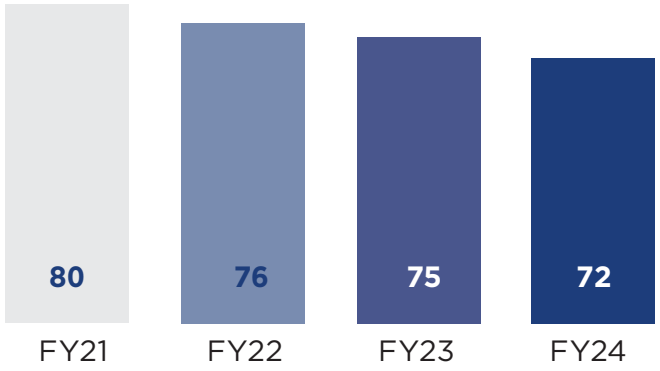



| TOP AREAS | FY23 | FY24 |
|---|---|---|
| Therapy | 50 | **44** |
| Medical Device | 15 | **39** |
| Research Tools | 8 | **27** |
| Diagnostics | 9 | **10** |
| Software | 13 | **15** |

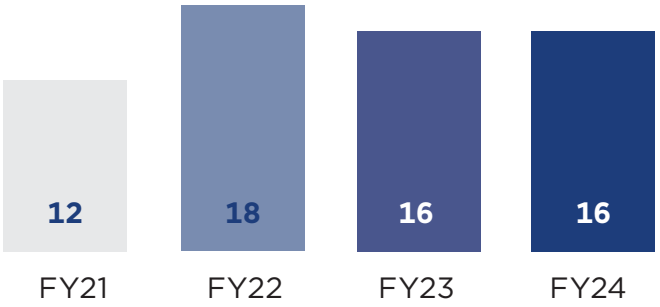
### LEADING AREAS IN FY24 DISCLOSURE SUBMISSIONS

| | |
|---|---|
| **39** | Medical Devices (29 adult, 5 pediatrics, 3 women's health) |
| **15** | Software (11 clinical applications, 3 research) |
| **27** | Research Tools (mouse models, genomic tools, cell lines) |
| **10** | Diagnostics (oncology biomarkers, single cell 'omics) |

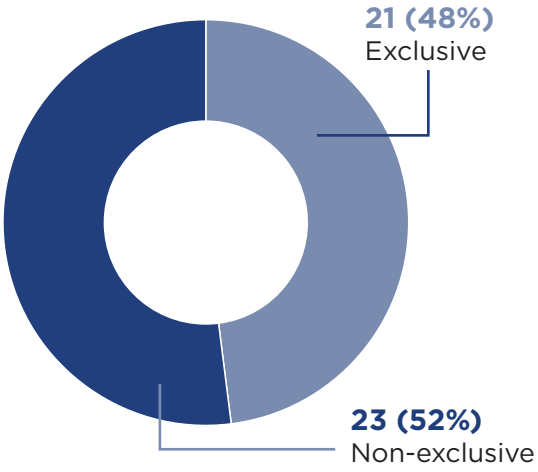
### PATENTS FILED




### PATENTS ISSUED



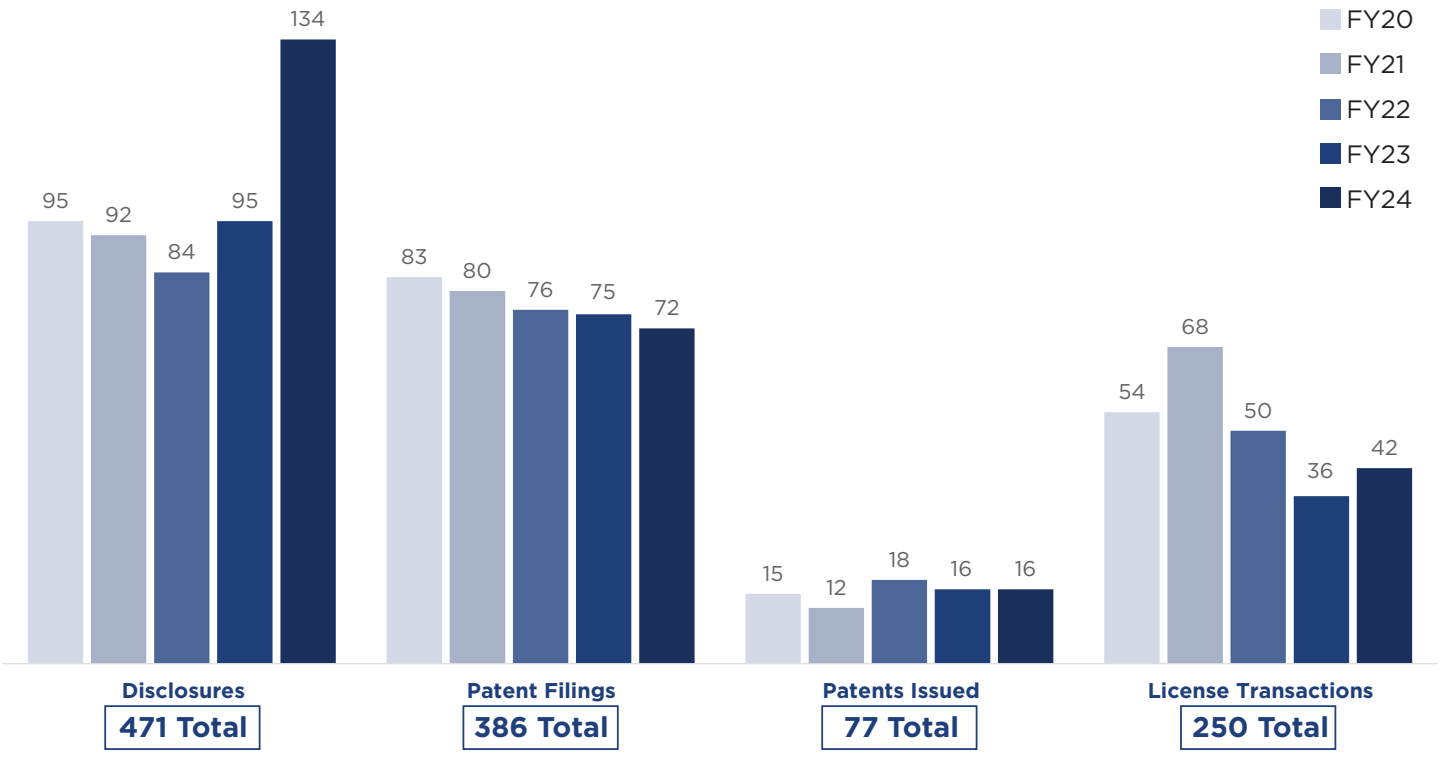
# Licenses




**42** FY24 Licenses (exclusive & non-exclusive)

**5** FY24 Inter-institutional Agreements

## FY20–24 IP MANAGEMENT & LICENSING PERFORMANCE



## New Start Up Licenses

| Company | Product | BCM PI + Founders | License Date | Status |
|---|---|---|---|---|
| Phiogen, Inc. | Bacteriophage cocktails to treat multi-drug resistant bacterial infections. | Anthony Maresso & Austen Terwilliger (Molecular Virology & Microbiology) | 07.07. 2023 | • BCM financial support<br>• CEO Amanda Burkardt hired<br>• COO Mayukh Das hired<br>• Research & development ongoing<br>• Preparing for fundraising |
| Pioneer Genomics, Inc. | Genomics services based on single cell sequencing & 'Omics technologies | Chenghang "Chuck" Zong (Molecular & Human Genetics) | 07.26. 2023 | • Company planning launch and fundraising activities |
| DELiver Therapeutics, Inc. | Small molecule therapeutic targeting Bcr-Abl oncogene. | Damian Young (Molecular Biochemistry & Pharmacology) | 08.01. 2023 | • Company founded by and financed by former BCM faculty member Kevin Slawin Leads Rapha<br>• Capital investment group<br>• Preclinical development of drug candidate |
| Tikva Allocell, Pte., Ltd. | Cell therapy products against solid tumors using a virus-specific T cell (VST) platform developed at BCM | Cliona Rooney, Malcolm Brenner, and Helen Heslop (Center for Cell & Gene Therapy) | 12.12. 2023 | • Company led by former Tessa CMO Ivan Horak<br>• Company attempting to raise capital; market conditions difficult |
| Xploration Health | Delivery of medical services using Smart Pod modular units. | Sharmila Anandasabapathy (Baylor Global Initiatives) | 04.03. 2024 | • BCM financial support<br>• CEO Ross Gordon building pod manufacturing & potential customer relationships |
| Aspira Medical (formerly GeoClin Diagnostics) | Wearable device & software for early detection of gastric aspiration pneumonia risk. | Todd Rosengart and Jared Mortus (DeBakey Department of Surgery) | 05.03. 2024 | • CEO Zaffer Syed (TMC EIR) developing fundraising plan<br>• Human testing of technology begins soon |

**FY 2024 Start-Up Licenses reflect the diversity of the technology mix our BCM innovators produce.** We had three new therapeutics start-ups: One developing cell therapy products, another developing **therapeutic bacteriophage**, and a new **small molecule-focused** company. There is also a **genomics services** company, and a very promising **wearable device-based** approach for preventing gastic aspiration pneumonia.

# FY24 HIGH IMPACT ACHIEVEMENTS

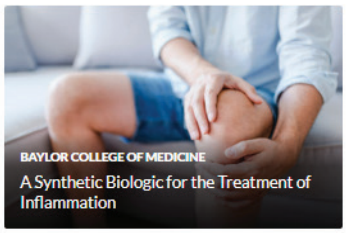
| COLLABORATOR/ LICENSEE | KEY ACTIVITIES | PARTNERSHIP FOCUS | FINANCIAL OUTCOME |
|---|---|---|---|
| March Biosciences<br>PIs: Max Mamonkin, Malcolm Brenner<br><br>CEO: Sarah Hein (former BCM trainee) | Phase II clinical development of CD5 CAR T cell therapy against T cell lymphoma to begin. Series A capital raise with leading VC firms complete. Recipient of CPRIT & Cancer Focus Fund awards. | Development of CAR T cell therapies against T cell lymphomas. | BCM has equity stake in March; and will receive milestones and royalties associated with product development. |
| Phiogen, Inc.<br>PI: Anthony Maresso<br><br>CEO: Amanda Burkardt | Phiogen currently raising capital, and continuing research & development in the Maresso lab. | Clinical development of proprietary bacteriophage cocktails for the treatment of drug-resistant urinary tract infections. | BCM has an equity stake in Phiogen and has provided capital to support Phiogen founding activities and operations. |
| CoRegen, Inc.<br>PIs: O'Malley, Lonard, others.<br><br>CEO: Steve Gorlin | CoRegen successfully raised capital & is continuing to raise additional funds. Company is supporting continued R&D at BCM. | Clinical development of genetic approach to suppress SRC-3 expression in T-regulatory cells for cancer immunotherapy. | BCM has equity stake in CoRegen; and will receive milestones and royalties associated with product development. |
| Marlinspike Therapeutics, Inc.<br>PIs: Trey Westbrook, Kristen Karlin, Calla Olson | Venture-funded (Apple Tree Partners) conducting research and development of small molecule inhibitors of RNA helicases; key targets in oncology. | Continued preclinical development and characterization of new RNA helicase inhibitors. | Marlinspike supporting R&D activities at BCM. BCM has equity in company & royalties and milestones associated with product development. |
| Biological E<br>PIs: Peter Hotez, Maria Elena Bottazzi<br><br>CEO: Mahima Datla | Bio-E obtained EUA regulatory approval for COVID-19 vaccine in India (Corbevax). Vaccine has been administered to >100M pts. | Clinical development and distribution of COVID-19 vaccine formulation developed at BCM/TCH; ideal for developing countries. | Transaction done for humanitarian goals to disseminate stable, immunogenic COVID-19 vaccine to developing nations. |
| Aspira Medical<br>PI: Todd Rosengart<br><br>CEO: Zaffer Syed | Preclinical development of wearable device for early detection of gastric aspiration pneumonia risk in the ICU setting. Company is raising capital. | Development & approval of wearable device approach gastric aspiration detection device & software. Development of other clinical applications of technology. | BCM has equity stake in Aspira; College is supporting company through an investment via a convertible note. |
| Deerfield/Blue Square Technologies<br>PI: Damian Young – BCM/Deerfield liaison. | Investment group focused on supporting development of novel therapeutics from academic sources. BCM has pitched multiple targets/ drug development candidate programs to Deerfield. | Development of novel therapeutic approaches with a focus on targets that have a genetic link to a human disease state. | Financial commitment to support projects from BCM into clinical development and potentially beyond. |

# CONNECTING BAYLOR TECHNOLOGIES *to* INDUSTRY PARTNERS

## Marketing Available Technologies via IN-PART

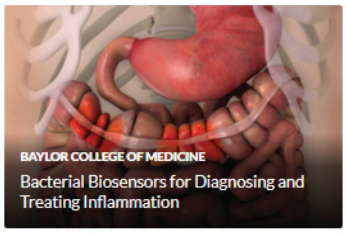
**BCMV has expanded marketing efforts through the IN-PART portal.**
bcm.edu/about-us/bcm-ventures/available-technologies

Creatively marketing our growing portfolio of technologies and platforms is an ongoing challenge and opportunity. BCMV is bringing on new business development personnel and implementing new marketing tools to introduce our technologies to a broader group of potential partners. One such marketing platform is the IN-PART portal. BCMV uses IN-PART, an online marketplace to streamline technology transfer between research institutions and industry, fostering efficient, scalable connections. The platform has facilitated over thousands of introductions between academic innovators across the globe and a network of industry R&D professionals, ensuring relevant, actionable partnerships. IN-PART complements BCMV's direct marketing by connecting groundbreaking research to industry contacts, supporting global technology transfer to positively impact society.

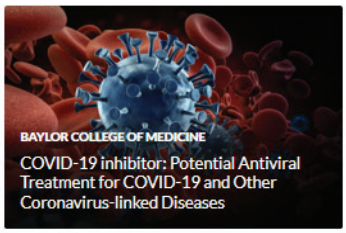


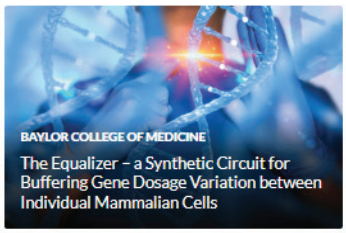


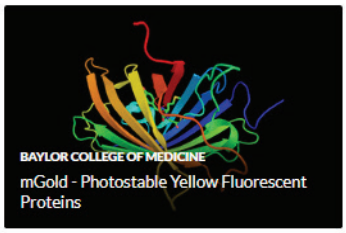


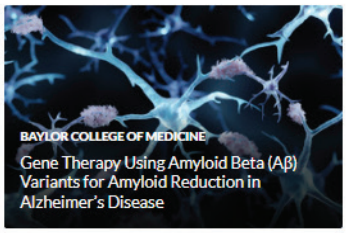


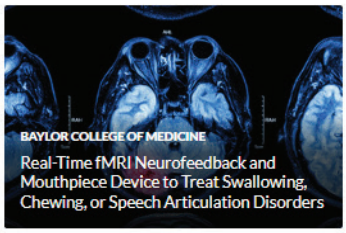


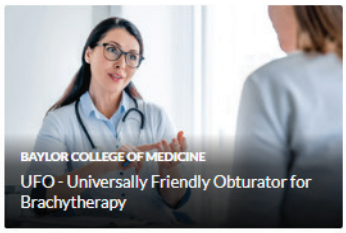



# COMMERCIALIZATION OFFICERS

## Strengthening engagement between BCMV and Faculty

Departmental commercialization officers (DCOs) serve as a liaison between BCMV and faculty. They are responsible for working closely with researchers and faculty members within their specific department. They facilitate the process of identifying promising technologies, assessing their commercial potential, and connecting them with BCMV. These officers bridge the gap between academia and industry, ensuring that groundbreaking discoveries and inventions have the opportunity to make a meaningful impact on society and the economy.

- DCOs serve as additional conduit of information between BCMV and the faculty
- Implemented fall 2023
- Each department is represented by one DCO
- DCOs attend a quarterly BCMV meeting to
  - Receive updates
  - Receive educational material/information
  - Receive slides/material to share at departmental faculty meetings
  - Bring departmental concerns forward

# BUILDING COMMERCIALIZATION EDUCATION *at* BCM

## Introducing the Commercialization of Biomedical Technologies Course

We are thrilled to announce an exceptional opportunity for professional growth and advancement within our community. In FY'24 we launched the eagerly anticipated "Commercialization of Biomedical Technologies" course. The response to the course was very strong, with 59 total attendees: 23 GBSS students who were taking the course for credit, and 36 students, post-docs and employees who audited the course.

Spearheaded by the esteemed Dr. Michael Dilling, a prominent figure in Commercialization and Technology Management at BCM Ventures, this course is poised to educate participants on the intersection between academia and commercialization. Dr. Dilling was joined by an array of distinguished guest lecturers, including business and venture leaders from BCM, the Texas Medical Center (TMC) and beyond.

The course focused on providing students with exposure to a variety of commercialization topics, taught by seasoned professionals with connections to BCM. Guest presenters included five women: three CEOs, one venture capitalist, and one patent agent. Our guest lecturers were:

- Melissa Sistrunk, Ph.D. and Andy Guo, Ph.D., J.D. (Norton Rose Fulbright) – both are former BCM trainees and Guo was a former BCM Ventures team member.
- Amanda Burkardt, M.S., MBA – CEO of BCM start-up company Phiogen.
- Sarah Hein, Ph.D. and Max Mamonkin, Ph.D. Hein is the CEO and Mamonkin is the scientific founder of March Biosciences, a BCM start-up. Hein is a former BCM trainee.
- Mitra Miri, Ph.D. (Osage University Partners), BCM is an associate partner with OUP.
- Jeff Larson, Ph.D. (Tvardi Therapeutics). Tvardi licensed Stat3 small molecule inhibitors developed at BCM and are now in clinical development.
- Meagan Pitcher, Ph.D. (CEO, Bairitone Health). Meagan is a BCM trainee and former BCM Ventures team member.

From understanding market dynamics to navigating regulatory landscapes, participants gained invaluable insights essential for success in the competitive biomedical industry. They also learned about potential career options and pathways that are open to them. Topics covered included:

- Intellectual Property Protection Strategies
- Intellectual Property Licensing
- Start Up Entrepreneurship, Part 1
- Start Up Entrepreneurship, Part 2
- Obtaining Venture Capital Funding
- Development of Therapeutics
- Development of Medical Devices & Software

We hope to see you at the next iteration of this course and others that will follow in the near future!

# BCMV PROOF-*of*-CONCEPT FUNDING

- **The Reppert Family Gift and Kristen and Christopher D. Wallis:** Empowered BCM Ventures to create a commercial pilot fund dedicated to proof-of-concept (POC) studies, with an emphasis on technologies that have strong commercial potential.
- **First Cohort Selection:** Five projects have been selected to receive pilot awards.
- **Funding Allocation:** Each project will receive $50,000 for POC studies to reduce commercialization risks and enhance market attractiveness.

**Drs. Alexander Ropper and Alex Flores**

CT Radiomics predict new or progression of compression fracture in tumor infiltrated thoracolumbar vertebrae

**Drs. Michael Belfort and Cara Buskmiller**

General Purpose Fetoscope

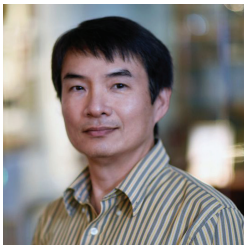
**Drs. Ben Frankfort and Zheng Jiang**

Glial Activity Profiling (GAP) via Electroretinogram

**Dr. Robert Britton**

A synthetic biologic for the treatment of inflammation

**Dr. Laising Yen**



RNA nano-structures for synthetic biology applications

# FIVE MINUTES WITH FACULTY INNOVATORS

## Launching a New Startup: The Phiogen Story with Founder Anthony Maresso, Ph.D. Why he thinks naturally evolved bacteriophage offer the solution to the growing public health crisis of multidrug resistant bacteria and why Phiogen will lead the way.

**Q:** The problem of multidrug resistant bacteria is growing as a public health threat. Can you explain the magnitude of the problem, and what might happen if new solutions to address it aren't developed?

**A:** In the year 2050, it is predicted more people will die for multidrug resistant bacteria then cancer. More people will die from MDR then cardiovascular disease. The current projections are 10 million deaths/year. If that holds, every year, 3x more people will die than did from Covid in a single year during the pandemic. In other words, we will be in a continuous pandemic. The total cost of this to the year 2050 is expected to be 100 trillion dollars, or 5x the entire GDP of the United States. What will happen if new solutions are not found is rather then these numbers being some hand-waving fancy (of which they are not, even now), they will be real. In other worlds, real totals, real deaths, real dollars.

**Q:** Why are bacteriophages so well-suited to address the problem of multidrug resistance?

**A:** Because they have had 3 billion years to perfect their craft. Imagine the most creative and intelligent engineer with nearly unlimited manufacturing capability to be given 3 billion years to make something work... what would this person create? They would make enough diverse infecting particles that exceeds all the stars in number in the known universe (1031 to be exact). This is the level of diversity I speak of. The engineer here is evolution, the product a phage. With 3 billion years, phage have evolved so many remarkable ways to infect their host, and under drastically different conditions, there are many more ways than we can ever possibly discover. The boundless amount of such adaptive power has not even remotely been uncovered. The answer to all our MDR problems literally lies right at our feet. We just have to find creative ways to discover and unleash this genetic power.

**Q:** What is the strategy behind the development of a bacteriophage cocktail? Why are bacteriophage cocktails so much more effective than a single bacteriophage?

**A:** The answer is pressure. Simply put, by populating an environment with many phage that each kill the bacterium by different mechanisms, the pressure placed on the bacterium to successfully adapt is too high. As a result, resistance to the phage (here now a therapeutic) becomes difficult if not impossible. Although it may seem that the genetic plasticity of bacterial genomes will allow for change to overcome this, they simply cannot without a significant trade-off. We exploit that trade-off because now the bacteria are so weak they are harmless. With one phage, the pressure is lower and the bacteria can make some changes to get around the phage and still be quite fit for battle.

**Q:** You've been involved with the clinical use of bacteriophage that have been selected/evolved to attack bacterial pathogens. What have the outcomes been? How have patient's lives been improved through treatment with engineered bacteriophage preps?

**A:** The outcomes have exceeded expectations. The objective of the technology and program is to design personalized cocktails tailored to kill a person's specific infecting strain of bacterium. When this occurs, patients are literally getting a custom medicine, as precise as one can be. No antibiotic can ever achieve this level of resolution. We have cleared biofilms off implanted devices, taken patients off the no-transplant list because they have a chronic infection, completely eliminated bacteria in cases when all tested antibiotics could not, improved symptoms for most types of bacterial infections, and generally not only improved quality of life but also saved lives. We have had some cases with "no observable effect." In these, we think we know what went wrong. If this technology is mastered, and especially if it can be mastered in the presence of antibiotic co-treatment, the expectation is that we can halt the MDR crisis.

**Q:** What do you see as the full potential for engineered bacteriophages to impact human health?

**A:** The low hanging fruit is they can be used to clear bacterial infections, reduce symptoms, improve quality of life, and save lives. This is clear. What they can also do that is not being as spoken about is they can be used to remove certain bacteria from your microbiome (so called "bad" bacteria) and allow it to be replaced with a good bacteria, or probiotic. Imagine you have a colitis-causing bacterium. Simply get treated with the phage that edits it from your intestine and then take your probiotic to maintain intestinal health and balance. Phage will one day be added to the surface of devices like catheters and pacemakers to prevent bacteria from growing on these surfaces. Phage will be added to food products like poultry and beef to prevent bacterial accumulation and growth. Phage can be added to unpure drinking water, can be used to control bacterial spread in agriculture, and help drive antibiotic use down (so-called antibiotic sparing, which itself can restore antibiotic efficacy by lowering resistance). My most imaginative use of phage is to "contaminate" hospitals, nursing homes, or even households with high risk family members with these "unseen" bacterial killers which work in the background as we live our lives.

**Q:** Why is Phiogen well-positioned to be a leader in the development of therapeutic bacteriophage?

**A:** Because the people that founded it have the luxury of both understanding the problem (bacteria) and the cure (phage) at the same time. By knowing how bacteria live, think, breath so to speak, you learn their vulnerabilities. They are not infallible. What is fallible is the archaic way we approach the problem, as if nothing has changed in the past 80 years. Bacteria adapt, so too must the drugs that kill them. Phiogen will generate the world's first and only formulation of natural and directed evolution viruses that attack every element of the bacterial arsenal that undermines conventional antibiotics. A three, four even five-pronged approach, each uniquely built against one bacterial vulnerability, will be too much to overcome. More than this, Phiogen will leverage phage genomes, which harbor more genetic capability then the rest of life combined (it's not even close), to identify new genes and enzymes that also solve the problems of other diseases, including cancer, mutation, and ageing. These genes will have direct medical and biotechnology uses. They just need to be discovered.

# Pioneering COVID-19 Vaccine Technology and Global Health Access with Dr. Maria Elena Botazzi

**Maria Elena Botazzi, Ph.D., Discussion with the Developer of a COVID-19 Vaccine Technology**: Dr. Bottazzi (senior associate dean of the National School of Tropical Medicine, professor of pediatrics and molecular virology and microbiology at Baylor and co-director of the Texas Children's Hospital Center for Vaccine Development) discusses vaccines, COVID-19, and why she thinks recombinant protein vaccine technologies are key to providing global access to highly effective vaccines.

**Q:** Vaccine access continues to present a challenge for responding to emerging and endemic disease, particularly in the developing world. Can you discuss why this is an important issue and the difficulties in addressing the disparities to global access?

**A:** Vaccine access is central to achieve global health. Therefore, to chart a successful pathway for the future and tackle emerging or endemic diseases in the low- and middle-income countries (LMICs), there is a constant need for sustainable and efficient development, testing, financing and deployment of vaccines and therapeutics. Our academic- and children's hospital-based Center for Vaccine Development has a 20-year track record leading and advancing a vaccine development model that has changed the paradigm to achieve vaccine access. Our model relies on open science, global cooperation, transparency, solidarity and the rapid dissemination of accurate information and best practices. As scientists it is important that we not only do the science in the laboratory, but that we also learn how to advocate for global justice and enable public health and public acceptance and ensure that the vaccine sciences lead to sound policies.

**Q:** For COVID-19, the cost, scalability, ultra-cold storage requirements of the novel mRNA vaccine technologies, as well as vaccine hesitancy, prevented many countries to access vaccines and individuals to receive vaccinations

especially those populations in the high-risk groups. What were the disadvantages of the mRNA vaccines and how do the recombinant protein subunit vaccines solve these problems, particularly for LMICs?

**A:** Recombinant protein subunit vaccines, in general, are based on an older and more widely used vaccine technology compared to the mRNA-based or viral vector vaccines. Protein vaccines have several distinct features that make them suitable for use in resource-poor settings: they are safe, effective, inexpensive, can be produced locally at high quantities and they are easy to store and deliver. For COVID-19 the recombinant protein subunit vaccines, were shown to be as effective as the mRNA vaccines and with more durable immunological protection. Therefore, the development of protein vaccines showed the world that they can serve as a blueprint for equitable and global vaccine access. For example, the COVID-19 vaccine technology developed by our vaccine center at Baylor and Texas Children's was transferred to two manufacturers, one in India an done in Indonesia. They were able to scale the production process and produce more than 100 million doses per month. Their vaccines, Corbevax and Indovac, respectively eventually were authorized and upon government purchases, the vaccine was delivered in more than 100 million arms. Furthermore, in the case of COVID-19, protein vaccines were developed in the absence

of substantial public or private funding as they were produced primarily by local manufacturers within LMICs delivering large quantities for minimal costs. In summary, this occurred because protein-based vaccines are a mature technology, which has been used for decades with an existing trained workforce, infrastructure and clearer supply-chains. Furthermore, due to their wide use in pediatric populations against many diseases including Hepatitis B, it was shown that this technology could help end vaccine hesitancy in some parts of the world.

**Q:** One often touted advantage of the mRNA vaccines is that they can be quickly adapted for a rapidly evolving virus. What has the Baylor vaccine done to counter the perception that other vaccine technologies as slower?

**A:** To counter the perception that other vaccine technologies are slower or not suitable in response to an emergency, all our scientists engaged in communicating the science to the general public and other stakeholders. Especially, Dr Hotez was instrumental to raise awareness of this fact during the many media engagements. Furthermore, and importantly, we worked with the vaccine producers to establish a timeline from transfer to scale up and delivery. Initially, from technology receipt to authorization, Corbevax and Indovac took approximately 18 months. However, now that we recently transferred the technology for the COVID-19 XBB variant is projected to take half of the time. What this shows is that it is imperative to diversify technology to adapt to regional or local needs.

**Q:** You've had years of experience in the development of vaccines for Neglected Tropical Diseases and have even conducted early academic clinical trials. How has your experience with the COVID-19 vaccine differed from the translational clinical activities related to these other vaccines?

**A:** The major difference between our experience developing vaccines for neglected diseases and COVID-19 was the sense of urgency. Negelcted diseases are chronic and affect the billions of poor people all the time but clearly there is not a sense of urgency to develop a vaccine that relies on government purchasing or financial systems. In contrast, for COVID-19 even the poorest of the countries felt the sens of urgency to develop and support vaccine development, especially when the vaccines developed by the big multinationals were not in sight, due to vaccine nationalism, cost or lack of inventory. We however, have now shown that a partnership between an academic health center vaccine center and developers in LMICs can break the paradigm of vaccine development, hence we are optimistic that there will be new opportunities to advance neglected disease vaccines at a faster pace than before.

**Q:** To date, close to 100 million doses of vaccines based on your technology have been administered primarily to children and adolescents in India and in Indonesia. What has been the key to such a rapid clinical development and deployment of the technology?

**A:** For more than two decades, the Baylor and Texas Children's Vaccine Center has built the vaccine research & development programs inclusive of a strong understanding of the regulatory sciences and anchoring our work within a total quality management system. This was the key formula to our success, which allowed us not only to shae our knowhow with the manufacturers but also provide them with documentation, reagents, assays and the cellbanks immediately suitable for entering the critical path of scale-up manufacturing, toxicology testing and clinical devleopment. In addition is worth noting that we had for years cultivated a relationship with the LMICs network of vaccine producers, which allowed us easy access to their leadership and scientists. Lastly, and very importantly, since our arrival to Baylor and Texas Children's we also established a close relationship with the licensing, commercialization, legal teams and many other supporting offices within the college and hospital. Including these groups very early and throughout the research & development processes was crucial and allowed them to support all our needs and expeditiously and successfully establish the framework for our collaborations around the world. We were all ready to respond y sciences.

# NATIONAL ACADEMY OF INVENTORS

The National Academy of Inventors (NAI) was founded in 2009 by Paul Sanberg to recognize academic innovators who are inventors on at least one issued U.S. patent. The organization inducted its first class of Fellows in 2012 to honor inventors in the government and non-profit research institute sectors who have developed patented inventions that have positively impacted quality of life and have generated positive societal impact. Fellows are nominated by their peers and nominees must be a named inventor on patent(s) issued by the USPTO, and they must have a track record of activity in the development of intellectual property that has (or will) lead to societal benefit. Baylor College of Medicine is proud to have seven faculty members among the ranks of NAI Fellows. Importantly, four of the seven BCM NAI Fellows are women, reflecting BCM's focus on supporting female scientists and innovators.

In each case, our NAI Fellows aren't just inventors on issued patents, but they are also associated with commercial partnerships (with both start-up companies and existing companies) that focus on advancing their innovative discoveries toward clinical entry and eventual commercial success. Not every innovative approach will make it through the regulatory approval process to become a marketed product. Most will fail at some point in the product development life cycle. But, it is a testament to the innovative, entrepreneurial spirit of our faculty that all of our NAI Fellows have been associated with commercial partners (in some cases, numerous companies). Additionally, some of our NAI Fellows are inventors on far more issued U.S. patents than the sample listed here, but the examples cited here represent patents that were also licensed to companies to support the development of new products. The patents developed by our NAI Fellows are focused on a diverse array of technologies, including small molecule therapeutics, gene therapies, vaccines, immunotherapies, and medical imaging agents. The BCM Ventures team salutes our NAI Fellows, and we look forward to supporting the nominations of future BCM faculty to join the growing ranks of NAI Fellows.

## BCM RANKED #35

- Baylor College of Medicine has been ranked as one of the top 60 (#35) non-profit research institutes and government agencies granted U.S. utility patents.
- Very few medical centers ahead of BCM and most of the top ranked organizations represent government agencies.
- This new ranking was created by the NAI to highlight the role non-profit research institutions and government agencies play in advancing innovation around the world and driving the global economy.


## LEGACY OF NAI FELLOWS & SENIOR MEMBERS AT BCM

**2020**
ANANTH V. ANNAPRAGADA, Ph.D.

**2019**
QIZHI CATHY YAO, M.D., Ph.D.

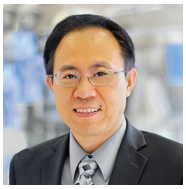
**2018**
MARY ESTES, Ph.D.

**2018**
HUDA ZOGHBI, M.D.

**2018**
BERT O'MALLEY, M.D.

**2017**
E. LYNN ZECHIEDRICH, Ph.D.

**2016**
MARTIN MATZUK, M.D., Ph.D.



**INAUGURAL CLASS**
CHANGYI JOHNNY CHEN, M.D., Ph.D.

# GOALS *for* FY25

**Enhance infrastructure to improve the commercialization process.**

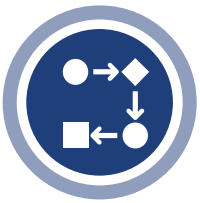
- Optimize processes by leveraging experts to market viable technologies to industry and potential partners.
- Enhance operations to better manage industry network and relationships.

**Drive engagement of faculty and all pertinent stakeholders in the commercialization process**

- Drive faculty engagement by assigning Department Commercialization Officers, setting up additional faculty-led technology review panels, and implementing a College-wide Commercialization Symposium.
- Develop ongoing education on commercialization activities and policies with the BCM Board of Trustees (BoT) Commercialization subcommittee.
- Implement curriculum on commercialization across all constituents at the College by establishing more commercialization courses (Graduate School of Biomedical Sciences) and producing educational video content accessible college-wide.

**Build endowment to support venture philanthropy and support proof-of-concept funding**

- Create a leadership approved and board vetted process for the venture philanthropy fund and Proof-of-concept fund.



**Build a strategic business development mission within BCMV**

- Engage business development officer to drive marketing of commercially viable BCM IP.
- Recruit critical mass of supportive personnel to move commercially viable technologies.

Baylor College of Medicine
VENTURES

Baylor College of Medicine

# Save the Date

# Commercialization Symposium

**When**: Tuesday, February 18th, 2025
**Location**: Baylor College of Medicine
Cullen Auditorium/Rayzor Lounge

Cheer on an investor pitch competition, gain insights from founders, discover local ventures, explore emerging technologies, seize opportunities for student presentations.

**Keynote Speaker:**
Nancy Chang, Ph.D.
President, The Tang Family Foundation
Adjunct Professor, Baylor of College of Medicine

Baylor College of Medicine Ventures is the commercialization engine for all technologies and intellectual property emerging from the college. We foster a culture of commercialization by engaging university innovators, entrepreneurs and industry to fully develop ideas and identify market opportunities or collaborative ventures for the benefit of society.

**More information about BCM Ventures:** https://www.bcm.edu/about-us/bcm-ventures


Baylor College of Medicine

ONE BAYLOR PLAZA
HOUSTON, TEXAS 77030
BCM.EDU

# BCM VENTURES ANNUAL REPORT

LEARN MORE
bcmventures@bcm.edu • bcm.edu/about-us/bcm-ventures

GC110263