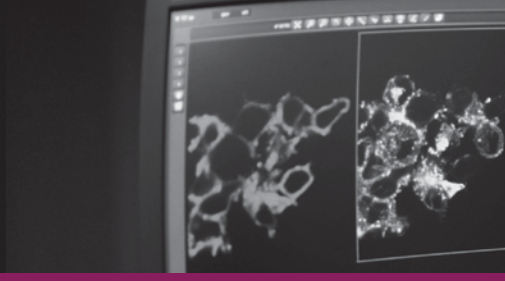
BAYLOR LICENSING GROUP ANNUAL REPORT

2016

Baylor College of Medicine



MESSAGE FROM THE BLG DIRECTOR:
MICHAEL DILLING, PH.D.

I am particularly excited to bring you this year's Baylor Licensing Group Annual Report. The commercialization teams at Baylor College of Medicine have had a great year in FY '16. Commercialization paves the way for the research conducted at Baylor to have its ultimate impact in terms of creating opportunities for the development of new products that benefit patients' lives. Without a healthy, robust level of commercialization, the groundbreaking research conducted at the College will never realize its full potential. This is what we are striving for in our work each and every day at BLG: To support the research mission of the College and to maximize its potential through commercial relationships. It isn't about the money (although if our commercial partners achieve success with a product that originated at Baylor, I want to see the College share in that success); it is about augmenting our research programs. It is about impact. We are hitting an inflection point in terms of Baylor realizing its commercialization potential, and it is exciting to play a role in making it happen.

Among our successes during FY '16, I would draw attention to the considerable increase in industry sponsored research at Baylor. We went from ~$1.86M in industry sponsored research during FY'15 to more than $12.75 million in industry sponsored research expenditures in FY'16. The total contracted amount associated with agreements signed in FY '16 was $25.86 million. Many of these agreements are associated with large-scale multiyear collaborative research relationships between a Baylor laboratory/program and a commercial partner. We are observing a trend toward more multiyear collaborative research relationships. Check out the Featured Commercial Partnerships Section to learn more about some of these specific relationships and the goals associated with them. These industry-sponsored research agreements represented an enormous amount of work for BLG Industry Agreements Manager Kim Weiderhold, Ph.D. During FY'16, Kim shepherded the negotiation and completion of almost 1,500 non-license agreements. When you see her (or email her), thank her.

During FY '16, we entered into a broad, ambitious landmark series of agreements with Cell Medica, Ltd., around the development of cancer immunotherapy products that leverage a proprietary approach for the generation of the modified

natural killer T-cells (NKTs) developed in the laboratory of Baylor principal investigator Dr. Leonid Metelitsa, professor of pediatrics - oncology. Cell Medica is a UK-based company devoted to the development of cell-based therapies against tumors and certain viruses. Cell Medica will be working with Baylor under a unique co-development relationship to develop a series of modified NKT-based products targeted to different tumor antigens. The College will manage the development activities through a first-in-man clinical study, after which the products will be transitioned to Cell Medica for further clinical development and eventual commercialization. This exciting relationship is complex and has required (and will continue to require) a high level of commitment from both sides to produce ultimate success. It took a village to get this done, and it will take continued focus and effort to make it all work. The road won't be easy, but if it results in multiple modified NKT-based products in human clinical trials, it will have been worth it. Read more about this exciting relationship in the report.

Did you know that Baylor College of Medicine is a robust source for the generation of new start-up company ventures? Since Dr. Paul Klotman joined Baylor as president, CEO and executive dean in 2010, there have been more than 25 new startup ventures formed (with more on the way) to leverage and develop technology and intellectual property from the laboratories of Baylor College of Medicine. Some of these companies arise from the efforts of BCM Technologies, Inc., the College's venture development subsidiary. However, many other companies are formed through an alliance between a committed faculty member and an entrepreneur. The article in this report provides a table of these new businesses that are developing a diverse array of new products and services designed to address unmet needs. If you are a faculty member who is thinking about founding or otherwise becoming involved with a startup, there are a number of considerations that you should take into account before taking the plunge. Take a look at the article to learn more. And I would also urge you to get out in the local commercialization community and learn from others at the Texas Medical Center Innovation Institute (TMCx) and other local venues.

Finally, I want to acknowledge the fact that commercialization of the discoveries from Baylor labs is a team sport involving lots of players. I am fortunate to have a team of committed project managers who work each day to craft agreements that benefit the college and open doors for the products of Baylor research to be developed commercially. Their jobs haven't gotten easier – as relationships become more complex and interdependent (and they have), the agreements that are necessary to govern those relationships also have increased in complexity. I want to acknowledge our colleagues within the Baylor Office of Research, the Innovation Development Center and BCM Technologies, Inc. We simply could not do our jobs without the helpful support and guidance provided by the Office of General Counsel. Successful commercialization always involves a partnership and productive engagement with the faculty member. Many of our faculty members commit a great deal of their time and effort to the commercialization process and their involvement is critical to produce success. Producing alignment among all of the players isn't always easy, but it is necessary to make great things happen. I want to thank Adam Kuspa and Shawn Davis for their vision and leadership. It is a privilege to work in a top-tier academic medical environment like Baylor College of Medicine and to support the college's extraordinary research enterprise. Onward and upward!

THE YEAR IN REVIEW
REALIZING OUR POTENTIAL

NEW LICENSE TRANSACTIONS

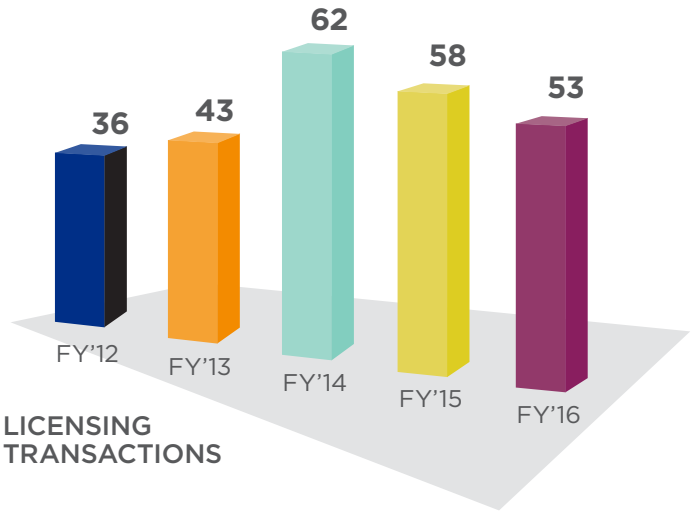
The driving goal at BLG is to translate Baylor's world-class research from the bench into the commercial sector, providing value for patients, inventors and the College. Negotiating license agreements is one of our foundational activities. Licenses can be either exclusive (the technology/IP is licensed to a single company) or non-exclusive (the technology is licensed to multiple companies). Exclusive agreements, which typically involve patented therapeutics or medical devices, are necessary for the commercial partner to justify the time and financial investment to shepherd nascent technologies through regulatory approval into commercial launch. Non-exclusive agreements grant commercial entities the right to use non-patented research tools (such as knockout mouse models or engineered cell lines) for their commercial research. This provides value to companies by saving them the time to internally develop these research tools and provides value to the college in the form of licensing income.

Our approach to the negotiation of license agreements involves a flexible, pragmatic focus on the development of an agreement that reasonably meets the needs of both parties. A key metric of the success of this approach is the number of licensing transactions we negotiate each year. During FY '16, the BLG team executed 53 new licensing transactions, marking the third consecutive year of strong licensing activity (more than 50 agreements per year).

Startup company activity at Baylor was strong in FY'16. We licensed technologies and intellectual property developed here to a diverse group of six new startup companies in FY '16. The technologies under development by these companies include:

- A platform to provide advanced microbiomics and metagenomics analyses for third party clients
- A vaccine development pipeline for the infectious disease Middle East Respiratory Virus (MERS)
- A software program to provide real-time monitoring and integration of patient physiological data with actionable insight for clinicians
- A modified oncolytic virus to treat solid tumors
- A platform of wearable products that create new senses for humans by transducing a non-recognized signal into a recognizable signal. This technology has multiple potential uses, including as a vest with auditory sensors that vibrate to replace the sense of hearing for the hearing impaired

Taking an idea to market requires not only the intellectual and technical contributions of the Baylor inventors,

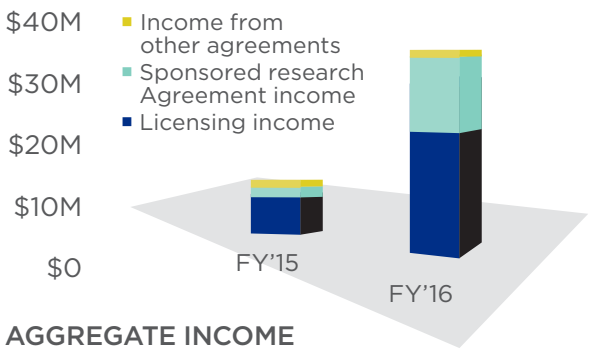


but also significant experience in business management, marketing and capital funding to achieve success. Many of these startup companies have benefited from the expertise and support of groups such as JLABS, TMCx and BCM Technologies (Baylor's wholly-owned venture development subsidiary). Indeed, building and operating a new startup is a full-time team commitment. At BLG, we are proud of our ability to support and connect BCM inventors who are interested in startup company formation through our technology and patent management activities and through the development of balanced license agreement solutions needed to provide the startup company with a solid foundation from which to build its business activities.

REVENUE TO BCM

2016 was a landmark year for BLG with regard to the value that its activities delivered to the College. BLG activities generate revenue for the College in the form of license agreements, industry-sponsored research agreements and other fee-for-service agreements. We experienced significant growth in terms of industry sponsored research revenue to the College. During FY '16, research agreements executed with industry sponsors brought in an unprecedented $12.7 million in research support (the total contracted amount over all years associated with these agreements was $25.8 million), compared to $1.8 million of income from this type of agreement in FY '15. These industry sponsored research agreements support multidisciplinary research and encourage collaborative projects

between academia and industry. We have observed an increasing trend toward large-scale multi-year collaborative research agreements, which we believe reflects increasing industry recognition of the outstanding research programs at the College. Additionally, the FY '16 licensing income from other sources tripled from $5.9 million in FY '15 to $19.4 million in FY '16. License agreement revenue is distributed according to the College's Patent Policy. As has always been the case, much of the license agreement revenue is driven by a handful of key agreements and will fluctuate from year-to-year. Our goal is to drive the completion of agreements that are positioned to add value to the College – if we are successful with doing that, then we'll generate opportunities for the College to derive income from them.



AGGREGATE INCOME FY '15 & FY '16

THE CONFLICT POSED BY NO CONFLICTS LANGUAGE IN RESEARCH AGREEMENTS

As we negotiate and execute an increasing number of industry-sponsored research agreements, our industry partners are more frequently requesting No Conflicts provisions. A typical No Conflicts statement might read as follows:

> *No Conflicts. Both parties will cooperate with each other in obtaining rights from any third party that may be necessary to commercialize any invention. Institution will ensure that the laboratory PI (and each research personnel involved in performing the project research) are bound by and shall have agreed (i) to comply with the terms of this Agreement, (ii) to assign all their rights and interest in any invention made by them to Institution and (iii) not to enter into agreements with third parties which would impair their ability to perform this Agreement, excluding any government authority. Institution represents and warrants, after conducting reasonable due diligence, on behalf of itself and each research personnel (including the laboratory PI) that it/he/she is not a party to any other agreement or arrangements that would conflict with its/his/her obligations hereunder.*

Provisions like this pose a number of issues for the College:

- No Conflicts provisions that reach beyond agreements drawn to the principal investigator's laboratory to encompass any agreement that Baylor may enter into on a College-wide basis require an additional level of administrative oversight and diligence that we are not staffed/resourced to handle. We will strive to limit Baylor's obligations under such a clause to research funding agreements linked to the PI's laboratory operations for a specified time period. To go beyond that level of diligence in an institution as large and complex as Baylor presents an oversight challenge that we aren't prepared to meet.
- A commercial research sponsor should care most about verifying that Baylor has not entered into any agreements with a commercial third party encompassing activity in a particular PI's laboratory that would pose an obvious conflict with the proposed research project that the industry sponsor wishes to fund. This is not an unreasonable concern. An examination of the funding sources used to support a PI's research program can be done (with the active counsel and participation of the PI); and the PI must understand that entering into a commercial partnership to fund research may lead to restrictions on the PI's ability to obtain funds from other sponsors (particularly commercial) to support a certain research program. BLG will discuss such restrictions with the PI, and we may ask the PI to sign a statement that they understand their obligations and risks under a sponsored research agreement. We want to be sure that all parties have their eyes open when they enter into a sponsored research relationship.
- No Conflicts provisions expose the institution to risk: Even if we engage in good-faith efforts to identify conflicting agreements but still miss a third party agreement that has obligations that could pose some degree of conflict with the current agreement, we could expose the College to liability. For this reason, we will always work to limit the scope of our diligence obligations under a No Conflicts provision.
- Some commercial sponsors will take a hard line with regard to negotiating a No Conflicts provision, which may pose a barrier to completing a research agreement. There may be situations in which the College has to walk away. We are striving for balance in these matters—it is reasonable for a commercial research sponsor to be concerned about verifying that a PI does not have agreements with other research sponsors that pose an obvious conflict with the proposed research project, but it is not reasonable to insist that the College verify that any agreement that it has signed around any PI's research program across the entire institution does not pose any conflict. We want to get the job done, while protecting the interests of the College in the process.

NEW DISCLOSURE SUBMISSIONS

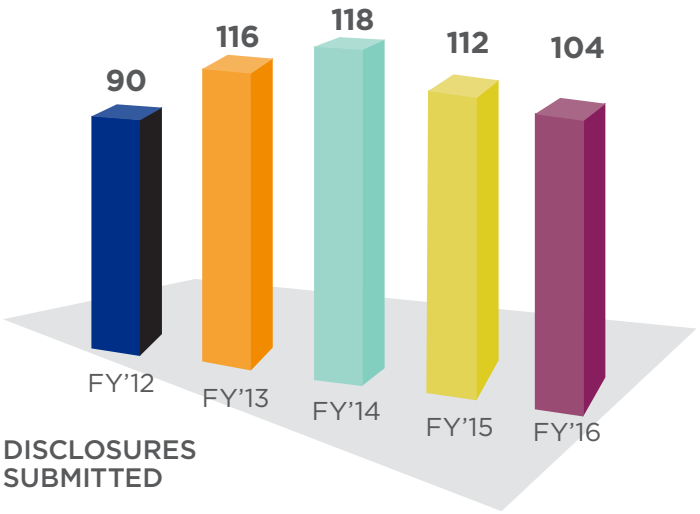
Invention disclosures are the first step to bring Baylor's research discoveries at the bench to serving patients in the clinic. We encourage all researchers to submit a disclosure on a potential new technology prior to publication or other public disclosure of the technology. We received 104 new disclosure submissions in FY '16, representing the fourth year in a row with more than 100 disclosures. This consistently high level of disclosures indicates the sustained strength of research at Baylor College of Medicine. Disclosures were submitted from 26 different departments, with the Department of Pediatrics (30 disclosures), the Center for Cell and Gene Therapy (16 disclosures), the Department of Surgery (11 disclosures) and the Department of Molecular and Cellular Biology (10 disclosures) leading in disclosure submissions. As Baylor continues to build infrastructure around drug discovery and translational medicine, we believe there is potential for growth in disclosure submissions.

Submitting a disclosure is a simple, straightforward process using our online disclosure submission application: https://ota.vpdr.bcm.tmc.edu/disclosuredefault.asp

When you initiate the submission process, gather the following information:

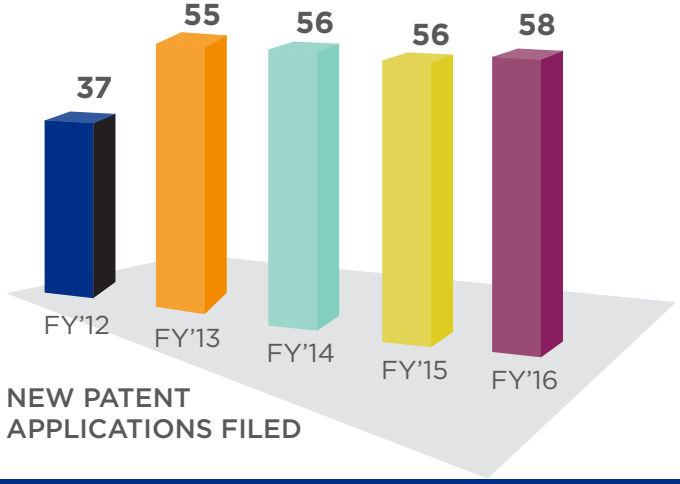
- **The names of the developers of the technology**, along with their respective percentage contributions to it. The developers need to mutually agree on their contribution percentages.
- **The names of funding sources** used to support the development of the technology, along with accompanying grant numbers. The grant numbers are absolutely essential for our purposes because we have reporting obligations to the federal government and other providers of funding for research.
- **A description of the technology**—you can attach documents to your submission or you can write a description of the technology you're disclosing.

Once you've submitted the required information, the application will ask for your electronic signature (as well as those of other Baylor contributors) to complete the process. Once all electronic signatures have been submitted, the disclosure is complete and will be uploaded into our database.



DISCLOSURES SUBMITTED

Patenting activity climbed to 58 total new patent applications in FY '16, representing the fourth consecutive year of more than 50 patent applications per year. We are pleased that this sustained activity reflects the emphasis at Baylor on developing technologies with clear translatability to the clinic. The decision to patent a technology is contextually driven by whether the patent is necessary to attract a commercial license. Our goal is to negotiate commercial licenses rather than submit patents per se, as the college and inventors gain nothing by patenting a technology without matching the technology to an interested commercial partner for licensing. The decision whether to pursue patenting often is a calculated gamble based on our experience in the types of technologies that have commercial potential.



NEW PATENT APPLICATIONS FILED

BAYLOR COLLEGE OF MEDICINE RANKED NO. 67 IN REUTERS LIST OF THE WORLD'S 100 MOST INNOVATIVE UNIVERSITIES FOR 2016

For the second year in a row, Baylor College of Medicine was ranked in a list of the world's 100 most innovative universities. Reuters compiles this list by examining factors such as high-profile commercial partnerships, new patent filings and impactful scientific publications. For 2016, Reuters took note of the fact that BCM had entered into its partnership with Cell Medica Ltd., to develop novel immunotherapeutic approaches to cancer treatment that are based on a proprietary natural killer T-cell platform technology, and they noted our license to NeoSensory, Inc., a startup company devoted to the development of products based on a wearable "vest" technology that converts sound waves into tactile sensations that the wearer can perceive to replace a lost sense of hearing. Reuters notes that the ability to get on this list and remain on it requires a consistent level of impactful commercial activity, and that is exactly what we are striving to accomplish.

NEW MEMBERS OF THE BLG TEAM!

We are very proud to announce two new members to the BLG team: Meagan Pitcher, Ph.D., joined us as a licensing associate, and Kelly Porter, J.D., has joined us as an industry contracts associate. Our goal is to provide top-notch service to the Baylor research community, and we need great people to make achievement of this goal possible. Meagan Pitcher and Kelly Porter both fill important roles on the BLG team. In her new role as a licensing associate, Meagan will strengthen our licensing team by adding much needed bandwidth to the group. Kelly Porter is working with Kim Weiderhold, Ph.D. (industry agreements manager.) to support our extensive activities in non-license agreements, which include MTAs, DTAs/DUAs, Sponsored Research Agreements (SRAs), Research Collaboration Agreements, and Service Agreements. Kim (with help from other BLG team members) was managing an extraordinary but unsustainable workload, and Kelly's addition will allow BLG to provide better service to the College research community and will allow Kim to focus on more strategic aspects of her role. It takes a team to make it all happen, and I'm looking forward to Meagan and Kelly doing great things in BLG!

Meagan R. Pitcher, Ph.D., joined the Baylor Licensing Group in 2016. She is responsible for evaluating and marketing inventions and negotiating licensing agreements. Prior to joining Baylor, Meagan held positions at the University of Texas Health Science Center at Houston as a research program manager with the Center for Clinical and Translational Sciences and as a postdoctoral research fellow with the Translational Psychiatry Program. Meagan earned her Ph.D. in Translational Biology and Molecular Medicine from Baylor College of Medicine, where she conducted research in animal models of Rett Syndrome. Prior to beginning her Ph.D. program, Meagan worked at Lexicon Pharmaceuticals as a researcher in ophthalmology and neurology. She earned a B.S. in genetics from Texas A&M University.

Kelly Porter, J.D., joined BLG in October 2016, becoming an industry contracts associate. She began her career as an intellectual property intern at the LSU Agricultural Center and advanced to a contract specialist position in its office of sponsored programs. Her work involved reviewing and negotiating federal, state and non-profit contracts, grants and research agreements. Seven years of combined work history in the field of sponsored research has prepared her well for this new role. Kelly is an alumna of Southern University Law Center and Louisiana State University, where she studied political science.

MEET THE BCM TECHNOLOGIES (BCMT) STAFF

Robert Christner, Ph.D., has more than 20 years of experience in the life sciences tools industry and has held positions in research and development, sales, manufacturing and operations. He was part of the leadership team of Assays Designs, Inc. that brokered the sale of that company to Enzo Life Sciences, Inc. where he stayed on as site manager and head of global manufacturing and operations. He has worked in companies at all stages of development, from startup through small and mid-size private and large public organizations. He also is a certified Lean Six Sigma Black Belt and plans to leverage his broad experience to assist Baylor College of Medicine with its commercialization efforts. As a BCMT entrepreneur -in-residence he works closely with faculty, the Baylor Licensing Group and the Office of Research, where he is director of business development, particularly focusing on company creation opportunities in life science tools, drug development services and global health. Contact Robert at Robert.Christner@bcm.edu.

Brian Patrick, M.B.A., is a healthcare innovation entrepreneur. He brings significant, hands-on founder and executive experience to BCMT. Working closely with the Baylor Licensing Group, Baylor and the BCM Office of Research, his mission is to actualize Baylor College of Medicine's vision to improve health through science and innovation. Having started two medical device companies (spun out of UT Austin), Brian has extensive experience connecting the academic and business sectors to commercialize life sciences research. At BCMT, Brian supports the formation and growth of new companies. He focuses on early-stage development of medical innovations with disruptive, commercial potential and fostering relationships between inventors, investors, and strategic partners. To learn more, contact Brian at bpatrick@bcmtechnologies.

FY ’16 FEATURED COMMERCIAL PARTNERSHIPS

CELL MEDICA LICENSING AND CO-DEVELOPMENT AGREEMENTS TO SUPPORT THE DEVELOPMENT OF NATURAL KILLER T-CELL-BASED CANCER IMMUNOTHERAPY PRODUCTS

One of the key highlights of Baylor College of Medicine’s commercialization efforts during FY ’16 revolved around the signing of agreements with Cell Medica, Ltd., to support the development of cellular immunotherapy products for the treatment of a variety of cancers. The collaboration is set up to leverage the considerable strengths of both parties in a way that is designed to accelerate the clinical translation of products based on chimeric antigen receptor (CAR)-modified natural killer T cells (NKTs) developed in the laboratory of Baylor principal investigator Leonid Metelitsa of the Department of Pediatrics – Oncology. The license/option component of the Cell Medica transaction conferred an exclusive license to Baylor’s proprietary modified natural killer T-cell platform technology, five product candidates arising out of this platform and options for future technologies developed at the College. The innovative co-development agreement sets up a unique structure and partnership that couples Baylor’s expertise in the development of immunotherapeutic approaches to cancer treatment with Cell Medica’s expertise in cell therapy manufacturing and commercialization.

“The joint program with Cell Medica provides an opportunity to accelerate the clinical translation of my research in a way that would not have occurred without their support,” Metelitsa stated. “We are both strongly committed to developing novel immunotherapies that will impact patients’ lives.”

The modified natural killer T-cell offers a unique platform that can be used to design immunotherapeutic products to attack solid tumors, which have been notoriously difficult to treat using cell-based immunotherapeutic approaches. The modifications developed in the Metelitsa laboratory augment the survival and persistence of NKT cells in the tumor microenvironment, which poses hostile challenges to immune effector cells.

Negotiating and executing the agreements that govern our relationship with Cell Medica represented an all-hands-on-deck effort involving BLG, the BCM Innovation Development Center (IDC), the Baylor Research Business

Development team, the Office of General Counsel, key faculty/leadership in the Department of Pediatrics and the Center for Cell and Gene Therapy and administrative personnel at Baylor and our partner Texas Children's Hospital. The license/option and co-development agreements between Baylor and Cell Medica are complex because they are designed to provide a strong foundation for a multi-faceted relationship that both parties view as being long term. Andrew Wooten (formerly with the Baylor Innovation Development Center) and BLG Director Michael Dilling led the agreement negotiations on behalf of Baylor College of Medicine. Adam Kuspa, Shawn Davis, Susan Blaney, John Averill and others have provided (and continue to provide) research and operational leadership. The agreements required extensive involvement by the Office of General Counsel throughout the negotiation process, notably from Patrick Turley, Bob Corrigan and outside Counsel Guy Birkenmeier (Baker McKenzie, LLP). Support from the Center for Cell and Gene Therapy via Helen Heslop, Malcolm Brenner and Cliona Rooney has been instrumental, as has support from Texas Children's Hospital from Mark Kline and Dan DiPrisco, among others.

On the Cell Medica side of the equation, this collaborative relationship would not have come to fruition without the vision and leadership of CEO Gregg Sando and Ross Durland, senior vice president of Development. Their efforts were supported by Barbara Kosacz and Marjorie Wagman (Cooley, LLP), legal counsel to Cell Medica. There are many others on both sides who have made and continue to make important contributions to the success of this partnership. A team effort makes it happen.

Since the signing of the foundational agreements, work has begun on a number of product development projects in the laboratories of Leonid Metelitsa and Center for Cell and Gene Therapy faculty member Andras Heczey. Both Cell Medica and Baylor have hired additional personnel and purchased equipment to support the effort. A Joint Steering Committee composed of Cell Medica and Baylor representatives has been meeting to guide and orchestrate the activities of both sides and to review and assess progress. From the BLG perspective, it has been particularly gratifying to see this relationship launch into the important work that the agreements are meant to facilitate. I look forward to reporting on the successes of the Baylor-Cell Medica relationship in the years to come.

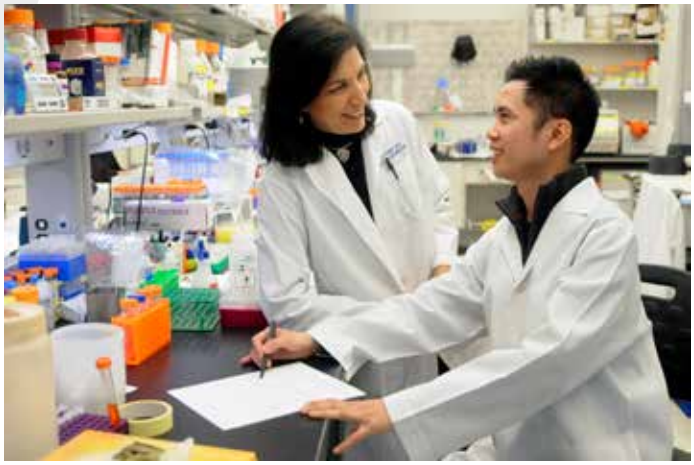
You can read more about the BCM-Cell Medica partnership at the following links:

https://tinyurl.com/cell-medica-1
Baylor, Cell Medica announce groundbreaking collaboration to create cellular immunotherapy products for cancer treatment

https://tinyurl.com/cell-medica-2
Cell Medica and Baylor College of Medicine announce exclusive licensing agreement and co-development partnership to create next generation cellular immunotherapy products for the treatment of cancer

UCB AND BAYLOR COLLEGE OF MEDICINE LAUNCH ALLIANCE TO DISCOVER TRANSFORMATIONAL THERAPIES FOR NEURODEGENERATIVE DISORDERS

UCB, a global biopharmaceutical company based in Brussels, Belgium, has aligned forces with Baylor Professor Huda Zoghbi in a collaborative research effort geared toward the discovery of new therapeutics to treat neurodegenerative diseases. In an effort to accelerate the pace of drug discovery and development, UCB has been formulating alliances with academic partners to leverage efforts to identify novel therapeutic targets for intervention. The Zoghbi laboratory brings to the collaboration extensive capabilities in functional genetics using organisms that model human neurodegenerative disorders. The expertise of the Zoghbi laboratory will facilitate the discovery and characterization of novel targets for therapeutic intervention that will be leveraged by UCB's drug development capabilities to develop new medicines and improve clinical outcomes for patients. Dr. Zoghbi stated, "This collaboration with UCB presents a fantastic opportunity to leverage the powerful model systems and tools developed over years of research in my laboratory to accelerate the pace of drug development for patients suffering for neurodegenerative disorders in a way that will directly address their profound unmet medical needs."



You can read more about the BCM-UCB neurodegenerative disease collaboration here: http://www.ucb.com/stories-media/press-releases/article/UCB-and-Baylor-College-of-Medicine-launch-strategic-alliance-in-neurodegeneration

MEDICAL INFORMATICS CORPORATION LICENSES BCM TECHNOLOGY FOR PREDICTING ACUTE DETERIORATION IN PATIENTS AFTER STAGE 1 PALLIATION

In October 2015, Baylor executed an exclusive license agreement with Medical Informatics Corp., a software development company based in Houston that provides clinical decision support technology for healthcare professionals. Medical Informatics offers clinical decision support solutions that link real-time clinical observations, such as physiological data with health knowledge to improve patient outcomes. Medical Informatics also provides alarm management solutions, which transmits the real-time physiological data streams from a bedside monitor to a nurse's notification device.

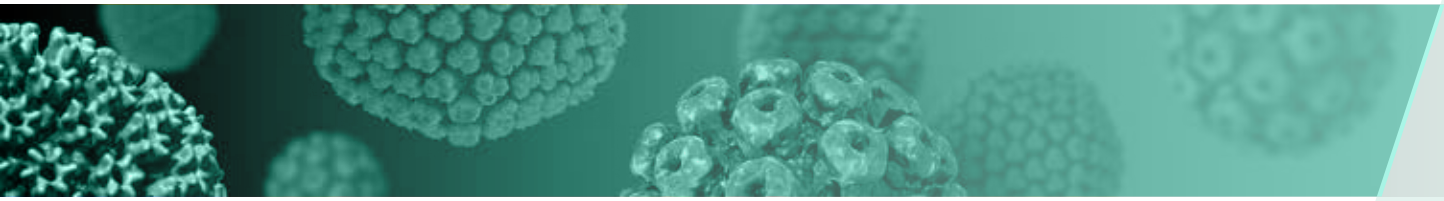
The exclusive license agreement will enable the commercial development of a novel computer algorithm providing a clinical metric to physicians to predict the onset of sudden deterioration within patients who have undergone Stage 1 Palliation surgery. Patients who have undergone stage 1 palliation surgery for hypoplastic left heart syndrome and related lesions are at risk of life threatening deterioration resulting in shock, cardiac arrest, & hypoxemia.

By identifying precursors of these sudden deteriorations, Medical Informatics is working to provide an opportunity for early, life-saving intervention.

This metric is derived from standard physiological data being generated by patient motioning equipment, and as such, can be calculated continuously and in real-time.

Under the agreement, Medical Informatics obtained the right to commercialize a technology that was developed by Dr. Craig Rusin, Dr. Kenneth Brady, Dr. Dan Penny, and Dr. Eric Vu in the Department of Pediatrics. Dr. Rusin is also a founder of Medical Informatics Corp and his previous work focused on developing the Sickbay™ system which is utilized by Medical Informatics to collect high frequency physiological data and provide predictive outcomes based on unique algorithms.

Learn more about Medical Informatics Corp. at the company website: http://medicalinformaticscorp.com/



VIRACYTE, LLC., FORMED TO RESTORE THE VIRUS-FIGHTING CAPABILITY OF A PATIENT'S IMMUNE SYSTEM THROUGH INNOVATIVE T-CELL THERAPIES

ViraCyte, LLC., was formed by Baylor founding faculty members Juan F. Vera and Ann M. Leen (both with the Center for Cell and Gene Therapy) in partnership with John R. Wilson (Wilson Wolf Manufacturing) to attack the problem of viral infection after hematopoietic stem cell transplant (HSCT). Vera serves as the company's chief product development officer, and Leen serves as chief scientific officer. The company's mission is to safely and effectively treat viral infections that attack people with weakened immune systems. Patients receiving HSCT are profoundly immunosuppressed, and this state of immunosuppression leaves them vulnerable to a number of viral infections that often prove to be life-threatening for these patients, but would generally not threaten a person with a normal, healthy immune system. ViraCyte addresses this problem by supplying the immunosuppressed patient with millions of T-cells that have been manipulated to specifically attack viruses that pose threats to HSCT patients.

The T-cell products in development by the company represent years of research devoted to developing more effective methods for manipulating and expanding virus-specific cytotoxic T-lymphocytes (CTLs). ViraCyte's product development pipeline includes Viralym-A (CTLs against adenovirus), Viralym-B (CTLs against BK virus), Viralym C (CTLs against cytomegalovirus) and Viralym M (CTLs specific to five different viruses). Importantly, this approach works in the clinic—patients treated with Viralym-C showed a decrease in viral load in seven out of seven patients treated to date, with no significant negative side effects. Additionally, clinical studies with the company's Viralym-M multivirus-specific CTL product showed that the administration of third-party derived (donor cells from a "non-self" donor that are HLA-matched to the recipient) CTLs were effective against CMT, EBV, AdV, BKV and HHV6 infections, with persistence of the transferred cells for up to 12 weeks. The ability to use third-party derived HLA-matched cells as the source of virus-specific CTLs will mean that this beneficial therapeutic strategy can be applied to more patients in need.

ViraCyte recently appointed Dr. Brett Giroir, M.D., as president and chief executive officer. Giroir brings more than 25 years of healthcare and research and development leadership experience to the company's efforts. Giroir previously served as the chief executive officer of the Texas A&M Health Science Center and has held leadership positions at the University of Texas Southwestern Medical Center, and he was the first physician director of the Defense Advanced Research Projects Agency's Defense Sciences Office. The ViraCyte team also benefits from the considerable regulatory affairs expertise of Bambi Grilley (director, regulatory affairs), and from the expertise of Scientific Advisory Board members Helen E. Heslop, Malcolm K. Brenner and Cliona Rooney. John Wilson (managing director) stated,

"ViraCyte represents such an exciting opportunity because the company is able to leverage the very best scientific and clinical expertise devoted to the development of virus-specific CTLs. This company is uniquely positioned to make a dramatic impact on the lives of patients who will receive its therapeutic products."

Finally, ViraCyte was selected to be a resident company at the new JLABS@TMC facility, which is a 34,000 square foot life sciences incubator supported by Johnson & Johnson Innovation, LLC. The company will be able to leverage access to offices, state of the art equipment and operational and business services as it grows its operations.

Find out more about ViraCyte at the company's website: http://www.viracyte.com/

NEOSENSORY EXECUTES EXCLUSIVE LICENSE AGREEMENT WITH BAYLOR TO DEVELOP THE VERSATILE EXTRA-SENSORY TRANSDUCER (VEST) TECHNOLOGY FOR HEARING AID AND HUMAN PERCEPTION EXPANSION

There are at least 2 million functionally deaf individuals in the United States, and an estimated 53 million worldwide. One conventional tool available for deaf individuals is the cochlear implant. However, this is not a viable hearing solution for a large fraction of deaf individuals who want to use hearing technology, primarily due to its high costs, requirement of invasive surgery, and limited benefits in early-onset deaf adults who receive the cochlear implant after the age of 12.

Dr. David Eagleman, a former Baylor faculty member, and Dr. Scott Novich, a Rice University Ph.D. graduate mentored by Dr. Eagleman, developed a wearable sound-to-touch sensory substitution system, VEST, designed to allow deaf and hard of hearing people to pick up on sound information from their environment and perceive it as patterns of vibration on their skin.

The VEST is comprised of a vest undergarment that is embedded with an array of vibratory actuators, microphones, and other embedded electronics—it can process sound and convert the information to a tactile representation in low-latency real-time.

Leveraging recent advances in computation power in mobile devices and modern battery technologies, the VEST is designed to be low cost, non-invasive, and comfortable to wear.

The prototype development of VEST was in part supported by Baylor's John B. Carter Jr. Technology Catalyst Fund, a dedicated source of funds to aid in the advancement and commercialization of inventions developed at Baylor. Dr. Eagleman demonstrated the VEST technology and prototype in a TED talk in Vancouver, Canada. Since then, this technology has garnered a wide range of media coverage, including CNN, National Geographic, PBS, the Washington Post, and more.

This invention is jointly owned by Baylor and Rice, and patent applications have been filed in the United States and foreign countries. The United States patent application has recently been allowed by the United States Patent and Trademark Office. Baylor and Rice decided to collaboratively commercialize the VEST technology and entered into an interinstitutional agreement designating Baylor to take the lead on commercialization efforts. In November 2015, Baylor executed an exclusive license agreement with NeoSensory, a startup company co-founded by Dr. Eagleman and Dr. Novich, to enable commercial development of the VEST technology for those with hearing loss and other potential applications to expand human perception. NeoSensory already raised more than $4.2 million from investors to support its operation, and it has hired a team of engineers, designers, and clinical coordinators to advance product development.

BCM TECHNOLOGIES PORTFOLIO START-UP COMPANY ACTIVITY

BCM Technologies is Baylor's wholly-owned for-profit venture development subsidiary. They've been developing and launching a number of new startup companies, including the following:

DIVERSIGEN FORMED TO UNLEASH THE POWER OF THE MICROBIOME

Diversigen is a BCM Technologies, Inc., portfolio company that was formed to leverage Baylor College of Medicine's leadership position in human microbiome research catalyzed by the Alkek Center for Metagenomics and Microbiome Research (CMMR). Joe Petrosino, Ph.D., associate professor of molecular virology and microbiology at Baylor and CMMR director, serves as chief science officer for the company. Diversigen's efforts are led by CEO Caroline Popper. Diversigen offers an array of metagenomics services to its clients, along with consulting and analytical services. The company has successfully executed numerous projects for third-party clients. Because of the expertise of its team, Diversigen is uniquely positioned to benefit from exploding interest in understanding how the microbiome contributes to human health, agriculture, and the environment. Additionally, this information can be used to develop novel interventional strategies for clients.

Diversigen has executed an exclusive license agreement with Baylor and has executed a master services agreement with the college. The company also announced a strategic partnership with Baylor Genetics, a global leader in clinical genetic testing. The partnership will allow each company to provide access to the services of the other to offer a stronger value proposition to customers.

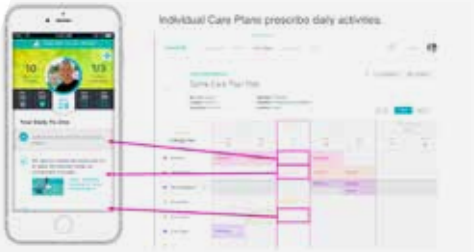
Diversigen is currently seeking third-party investment to facilitate growth and expansion of its capabilities.

You can read more about Diversigen at:
http://diversigen.com/diversigen-announces-strategic-partnership-with-baylor-miraca/

SYNCED CARE LAUNCHED TO IMPROVE SURGICAL OUTCOMES AND REDUCE READMISSIONS

Synced Care is a BCM Technologies, Inc., portfolio company that was formed to address unmet needs with pre- and post-operative care in surgical patients. The goal of the company, founded by David Berger, M.D., Baylor professor of surgery and senior vice president/chief operating officer at Baylor St. Luke's Medical Center, is to develop new mobile applications that will deliver information to patients and their caregivers to better engage patients in pre- and post-surgery activities that will lead to better outcomes. These applications will offer two-way communication between the patient and medical team to facilitate more timely and effective exchange of information that the patient can use to his or her benefit. Implementation of Synced Care's tools will reduce costs for healthcare providers through fewer cancelled surgeries and reduced readmissions following surgical procedures. With the increased emphasis on linking reimbursement to improved quality of care and better outcomes, Synced Care's innovative solutions are well positioned to address needs for better patient engagement and to deliver value to providers.

SyncedCARE: The Patient Experience



You can learn more about Synced Care here:
http://syncedcare.com/

ASTRO HEALTH TECHNOLOGIES FORMED TO ADDRESS HEALTHCARE CHALLENGES IN THE DEVELOPING WORLD

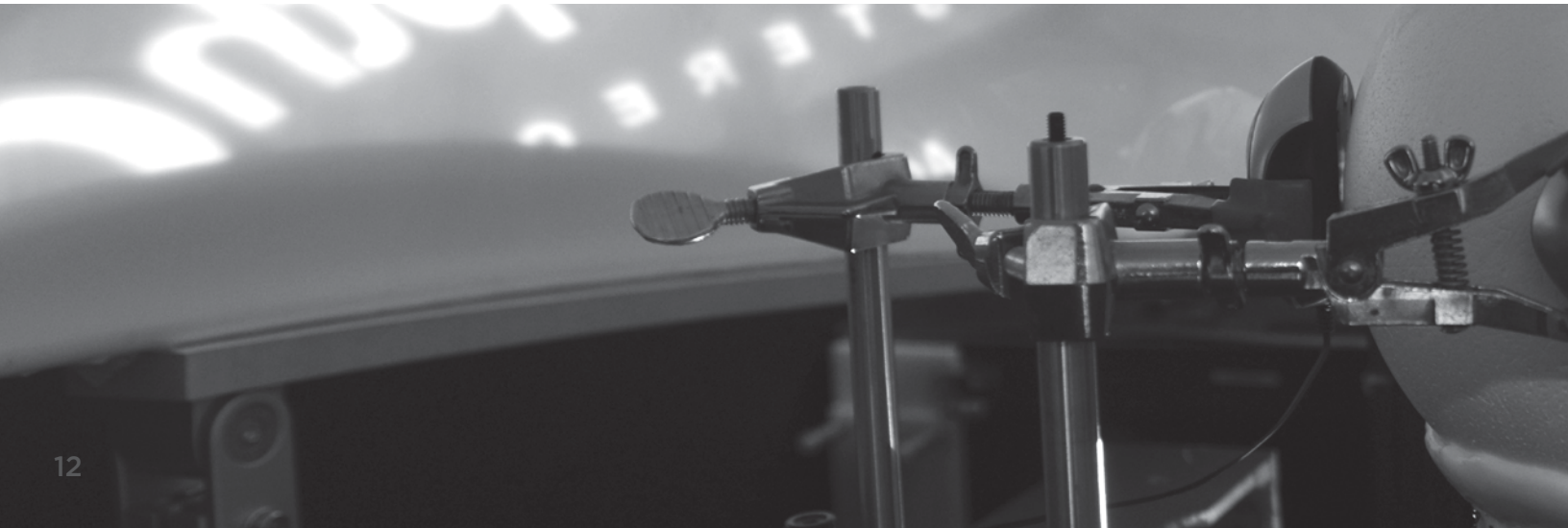
Astro Health Technologies, Inc. (AHT) is a BCMT portfolio company founded by Sharmila Anandasabapathy, M.D., professor of medicine and director of Baylor Global Initiatives (BGI) at Baylor College of Medicine. The company seeks to commercialize SmartPod technology developed with awards from the USAID Ebola Grand Challenge and the Paul Allen Foundation and licensed from Baylor. SmartPod technology is a system that integrates low cost, robust, rapidly deployable and redeployable medical capacity with connectivity, applications and on-site or remote medical training and/or services. The system can be deployed by land, sea or air to remote areas, set up in under an hour and be used in routine screening, triage, diagnostic or treatment settings. The company is in discussions to field test existing prototype units, and additional prototypes are under manufacture.

STARTUP COMPANIES AT BAYLOR DURING THE KLOTMAN ERA: A DIVERSE ARRAY OF NEW BUSINESSES DEVELOPING A VARIETY OF SOLUTIONS TO MEET PATIENT NEEDS AND THE NEEDS OF THE MARKETPLACE.

Did you know Baylor College of Medicine is a hotbed for the formation of new entrepreneurial startup ventures? When Paul Klotman joined Baylor College of Medicine as president and CEO in 2010, one of his priorities revolved around enhancing the college's commercialization outcomes. The cornerstone of this effort is the Baylor Genetics joint venture partnership with Miraca Holdings that was completed in 2015. This transaction leveraged Baylor's extraordinary expertise in genetic diagnostics developed over decades of groundbreaking work at the College. What made this transaction so unique is that it was not simply a "hand-off" of the College's assets in this space to a corporate partner. Rather, the joint venture structure provides the college with an ongoing ownership interest and helps to ensure the continued competitiveness of Baylor Genetics because it will provide the venture with access to new technologies developed at Baylor. The joint venture structure truly is a big win for both parties.

While the Baylor Genetics story is well-known across the Baylor community, what may be less well-known is the fact that more than 20 new startup ventures have been formed since 2010 based on technologies developed at the College. Some of these companies have operations located in Houston, while others are operating in distant locations around the globe, including Germany, Costa Rica and Singapore, but they all share a common thread in that they're based on technology developed at Baylor. These new businesses reflect the strength and diversity of research programs across the college and include companies devoted to developing:

- Human microbiome-based products and services.
- Small molecule drug candidates against SREBP, an important target in oncology, metabolic disorders and obesity.
- Software solutions to:
  - Assess traumatic brain injury and its impacts on cognitive function.
  - Streamline pre- and post-operative care and reduce readmissions.
  - Facilitate the transfer of patient medical data between healthcare practitioners to reduce error rates and enhance efficiency.
- Therapeutic approaches to treat maple syrup urine disease (MSUD) and other rare genetic disorders.
- Immunotherapeutic approaches to cancer treatment using oncolytic viruses or manipulated T cells.
- Wearable sensory replacement/augmentation devices.



We are in the midst of a wave of interest and activity around startup company formation at Baylor, and we think this is due to a number of factors, including the continued efforts of BCM Technologies, along with support for new ventures provided by the Texas Medical Center Innovation Institute (TMCx) and Johnson & Johnson's J-Labs@TMC incubator. We've never had a presence in Houston from a major pharmaceutical company devoted to supporting innovative startups like we now enjoy. The TMC's commitment to and support of commercialization across the entire medical center is important because it provides an opportunity to grow and achieve a sustainable "critical mass" of startup commercialization activity that isn't possible for the TMC member institutions to achieve acting individually. The fact that the collective research prowess of the TMC institutions is extraordinary but has not yet led to the level of commercial success observed in other regions of the country is well-known, but we believe that this is poised to change dramatically for the better over the next 5 to 10 years. The process takes time – it took 50 years for Boston/Cambridge to become the biotech hotbed that it is today. A sustained commitment from the TMC, its member institutions and other organizations, like Fannin Innovation Studio, to build the commercialization infrastructure and community will get us there in the long run.

Although we're pleased to see the recent surge in startup interest at Baylor College of Medicine, the College has had a long history of supporting commercialization. BCM Technologies was founded in 1983 and was a pioneer in supporting and launching startups in the Texas Medical Center. A number of companies with roots at Baylor have gone on to achieve successful IPOs, most notably Lexicon Pharmaceuticals, which began in the mid-1990s as a company devoted to leveraging the ability to knock out genes in the mouse genome to find new drug targets for its pharmaceutical company partners. The company then changed business models, opting to become a drug development company in its own right and leverage its high-value targets internally versus providing them to partners. Lexicon currently has small molecules in clinical development directed to the treatment of carcinoid syndrome and type 1 and type 2 diabetes.

START UP COMPANIES AT BAYLOR COLLEGE OF MEDICINE DURING DR. KLOTMAN'S TERM AS BCM PRESIDENT

COMPANY NAME	BCM PI/DEPT	PRODUCT/SERVICE COMPANY IS DEVELOPING	AGREEMENT WITH BCM	NOTES
Joint Ventures, BCMT Portfolio Companies + Internally Incubated Podcos				
Baylor Genetics http://bmgl.com	Multiple PIs; Department of Molecular & Human Genetics led by Brendan Lee, M.D., Ph.D.	"Ready with Answers" Delivering the world's highest quality genetics and genomics services by bridging academic and operational excellence and leading the medical community to advance patient health.	Joint Venture between BCM and Miraca Holdings (40:60) Transaction Closed February 2015; involved multiple agreements needed to form joint venture.	Landmark series of commercialization agreements that led to the formation of joint venture between BCM and Miraca Holdings. BCM remains actively involved with the development of new technologies to support the joint venture. Transaction won 2015 Healthcare Deal of the Year in the *Houston Business Journal*.
Diversigen, Inc. http://diversigen.com	Joe Petrosino, Ph.D. Department of Molecular Virology & Microbiology; Alkek Center for Metagenomics & Microbiome Research (CMMR)	BCM Technologies portfolio company devoted to products and services related to microbiomics and metagenomics for third party clients.	Exclusive license agreement executed 08/27/2015.	BCMT start-up company engaging CMMR to perform services on behalf of third party biotech and pharmaceutical company clients. World class BoD facilitating pharma relationships.
FGH Biotech, Inc. http://fghbiotech.com (Internally-incubated BCM PodCo)	Salih Wakil, Ph.D., Department of Biochemistry & Molecular Biology, and Motorari Uesegi, Ph.D. (now with Univ. of Kyoto)	Small molecule drug development company developing a series of SREBP inhibitors for the treatment of metabolic disorders and cancer.	Exclusive license agreement executed 03/23/2010.	FGH has been using non-dilutive NIH STTR funding to advance their candidate compounds. FGH successfully won a phase II STTR award.
Twister Biotechnology, Inc. http://twisterbiotech.com (Internally-incubated BCM PodCo)	Lynn Zechiedrich, Ph.D. Department of Molecular Virology & Microbiology	Services and reagents involving the custom production of DNA minivectors to meet customer specifications.	Exclusive license agreement executed 12/15/2011.	As a "graduate" of the Podco program, Twister has produced products and delivered to first adopter customers.
Astro Health Technologies	Sharmila Anandasabapathy, M.D.	Development of a portable medical treatment facility based on a modified shipping container – the "Epidemic Smart Pod." Pods are pre-stocked with all needed equipment, can be easily transported to remote locations, and can function off-the-grid.	Agreements pending.	Grant funding has been awarded to further support the development of pod medical treatment facility. Focus on extension of Smart Pod concept to develop portable clinical laboratories, prenatal and postnatal care facilities.

COMPANY NAME	BCM PI/DEPT	PRODUCT/SERVICE COMPANY IS DEVELOPING	AGREEMENT WITH BCM	NOTES
Synced Care http://syncedcare.com (BCMT portfolio company)	David Berger, M.D. Department of Surgery	Develop of consumer software to streamline pre and post- operative care and reduce readmissions.	Agreements pending.	Start-up company seed funded by BCMT, has attracted in-kind investment from software developer and currently establishing Board with national opinion leaders.
DeepBio, Inc. (BCMT portfolio company + internally incubated podco)	Michael Mancini, Ph.D., and Fabio Stossi, Ph.D., Both from the Department of Molecular & Cellular Biology , and others to be named.	Customized high-throughput microscopy-based screening services for third party clients.	Agreements pending.	Business model in development; operations commencing.
mAbVista, Inc. (BCMT portfolio company +internally incubated podco)	Dean Edwards, Ph.D., and Michael Mancini, Ph.D. Both from the Department of Molecular & Cellular Biology.	Services for third party customers to develop monoclonal antibodies that are pre-qualified for imaged-based applications per customer specifications.	Exclusive license agreement executed 04/18/2012.	Success achieved with delivery of high-value antibodies to customers.
Coregon, Inc. (BCMT portfolio company + internally incubated podco)	Bert O'Malley, M.D., David Lonard, Ph.D., both from the Department of Molecular & Cellular Biology. Jin Wang, Ph.D., Department of Pharmacology.	Novel small molecule inhibitors of Steroid Receptor CoActivator-3 (SRC-3) for a variety of oncology clinical indications.	Agreements pending.	Company seeking third party investment. Candidate compounds undergoing proof-of-concept experiments in animal models.
Glipper Oncology Research, Inc. http://www.tpcr.org	Tim Thompson, Ph.D. (MD Anderson Cancer Center) Formerly BCM Scott Dept. of Urology	Development of diagnostic and therapeutic approaches based on the GLIPR1 protein to treat prostate cancer.	Exclusive license agreement executed 08/20/2014.	Supported by Tony's Prostate Cancer Research Foundation. Successor to Progression Therapeutics, a BCMT start-up company. Progression/BCMT is separately pursuing commercialization of prostate cancer diagnostic assets.
BrainCheck, LLC http://braincheck.com	David Eagleman, Ph.D. (Stanford Univ.) Formerly BCM Department of Neuroscience	Development of software applications for assessment of cognitive function as it relates to determination of traumatic brain injury. Other software applications in development.	Exclusive license agreement executed 01/13/2014.	A Texas Medical Center Innovation Institute (TMCx+) portfolio company.

COMPANY NAME	BCM PI/DEPT	PRODUCT/SERVICE COMPANY IS DEVELOPING	AGREEMENT WITH BCM	NOTES
Start-Ups developing BCM IP, but not BCMT Portfolio Companies or Podcos				
Acer Therapeutics, LLC http://www.acertx.com	Brendan Lee, M.D., Ph.D., Department of Molecular & Human Genetics	Development of therapeutic approaches for maple-syrup urine disease (MSUD) and other ultra-orphan diseases.	Exclusive license agreement executed 04/04/2014.	Company supporting clinical development of NaPBA (phenylbutyrate) to treat MSUD.
BIoCentric Development, LLC	Steve Pflugfelder, M.D. Department of Ophthalmology	Climate-controlled goggle device (ClimaTears) for the diagnosis of dry-eye syndrome and other similar disorders.	Exclusive license agreement executed 12/08/2014.	Attempting to secure funding to do additional clinical testing of device.
BioSeed XOI Fund, Inc.	Changyi "Johnny" Chen, M.D., Ph.D. Department of Surgery	Development of novel xanthine oxidase inhibitors for treatment of gout and other disorders.	Exclusive license executed 06/13/2014; later terminated.	Company fundraising efforts unsuccessful. BCM attempting to find new commercial partner for these compounds.
Brighton Biotech, Inc. http://brightonbiotech.com	Peter Hotez, M.D. Department of Pediatrics; Dean, National School of Tropical Medicine	Development of a MERS vaccine.	Exclusive license agreement executed 08/24/2015.	Brighton is currently raising funds to support the development of its pipeline of products.
ConsultLink, Inc. http://www.mdconsultlink.com	Alexander Pastuszak, M.D., Ph.D. Department of Urology	Development of software applications to facilitate the transfer of patient medical data/information between healthcare practitioners to enhance physician efficiency and reduce errors.	Exclusive license agreement executed 05/29/2015.	Working with BCM to implement use/ testing of the company's software to facilitate transition of a patient's care from one medical professional to another.
Diakonos Research, Ltd. http://diakonoslabs.com	William Decker, Ph.D. Department of Pathology & Immunology	Development of immunotherapeutic approaches for cancer treatment revolving around manipulation of antigen-presenting cells.	Exclusive license agreement executed 06/17/2015.	Raising investment funding; attempting to secure grant funding to develop its product portfolio.
Genequine Biotherapeutics http://www.genequine.com/en/	Brendan Lee, M.D., Ph.D., Department of Molecular & Human Genetics	Development of gene therapy-based approaches for the treatment of osteoarthritis in humans, and for veterinary applications in horses & dogs.	Exclusive license agreement executed 01/13/2014.	Company started operations in October 2012 with seed investments by High-Tech Grunderfonds and Innovationsstarter Fonds Hamburg.
Icell Kealex Therapeutics, LLC http://www.icellkealex.com/	Xiao-tong Song, Ph.D. Formerly with the Center for Cell & Gene Therapy.	Development of oncolytic virus therapeutic products for solid tumor treatment.	Exclusive license agreement executed 02/22/2016.	J-Labs at TMC portfolio company.

COMPANY NAME	BCM PI/DEPT	PRODUCT/SERVICE COMPANY IS DEVELOPING	AGREEMENT WITH BCM	NOTES
Medical Informatics Corporation medicalinformaticscorp.com	Craig Rusin, Ph.D. Department of Pediatrics	Development of software tools to provide real-time monitoring of patient physiological data and to provide actionable clinical intelligence to medical professionals.	Exclusive license agreement executed 10/26/2015.	A TMCx+ company. Company expanding operations; gained FDA 510(k) clearance as a Class II medical device.
NeoSensory, Inc. http://neosensory.com	David Eagleman, Ph.D. Stanford University Formerly BCM Department of Neuroscience	Development of wearable products to expand perception and create new senses for humans. Developed Versatile Extra-Sensory Transducer technology that employs tactile sensors that respond to auditory stimuli to replace/enhance the sense of hearing.	Exclusive license agreement executed 11/24/2015.	A TMCx+ company. NeoSensory successfully raised more than $4.2 million from investors to support its operation, and it has hired a team of engineers, designers, and clinical coordinators to advance product development.
Shenzhen Tian De Medical Investments, Ltd.	Laising Yen, Ph.D. Department of Pathology & Immunology	Development of diagnostics associated with recurrent chimeric RNAs that are enriched in cancers.	Exclusive license executed 05/06/2014.	
Speratum CR, SA http://www.speratum.co/#home	Christian Marin-Mueller, Ph.D. (now full-time with company) and Qizhi "Cathy" Yao, M.D., Ph.D., Department of Surgery	Development of miRNA 198 based therapeutic approach to the treatment of pancreatic cancer and other malignancies.	Exclusive license agreement executed 04/30/2015.	Speratum has raised approximately $1 million in a Series A round of financing. Speratum was named the "Most Innovative Startup" by the Costa Rican government and received the distinction of being named the "Project of National and Public Interest".
Tessa Therapeutics http://www.tessatherapeutics.com/	Carlos Ramos, M.D., and Malcolm Brenner, M.D., Ph.D., Center for Cell & Gene Therapy	Development of immunotherapeutic approaches for cancer treatment. Virus-specific CTLs for the treatment of HPV-and Epstein-Barr virus-associated malignancies.	Exclusive license agreement executed 01/29/2015.	Focus on Asian markets. Singapore-based company. Currently supporting clinical development of HPV CTL product licensed from BCM.
Vax-Immune LLC http://www.vaximmune.com/	Leonard Weisman, M.D. Department of Pediatrics	Development of vaccine and diagnostic approaches for ureaplasma infection.	Exclusive license agreement executed 11/17/2013.	Company attempting to raise capital and/or secure grant funding.
ViraCyte LLC http://jlabs.jnjinnovation.com/partners/viracyte	Ann Leen, Ph.D.,, Juan Vera, Ph.D., and Cliona Rooney, Ph.D. All with Dept. Pediatrics/Center for Cell & Gene Therapy	Company is in clinical development with antiviral CTL products to combat virus reactivation events in post-HSC transplant patients.	Exclusive option agreement executed 11/5/2015.	J-Labs at TMC portfolio company.

STARTUP COMPANY FORMATION AT BAYLOR COLLEGE OF MEDICINE: ROLES OF COMMERCIALIZATION TEAMS – WHO DOES WHAT?

BCM Technologies, Inc.: BCMT is Baylor College of Medicine's wholly-owned for-profit start-up venture development subsidiary. Led by Caroline Popper, M.D., BCMT has a growing list of active companies in its portfolio. BCMT forms and operates companies, recruits management and seeks investment partners for its portfolio companies. BCMT's capabilities have expanded through the additions of Rob Christner and Brian Patrick. Rob's activities are focused on developing company opportunities in the research tools/research services sector, while Brian's efforts will be devoted to developing company opportunities in the medical device arena.

Baylor Licensing Group: Whether a startup company is formed through BCM Technologies or through a faculty member working with outside entrepreneurs, BLG's role is to manage and protect College-owned intellectual property rights and to negotiate the terms of the license agreement conferring rights to the startup company to develop products and services using intellectual property assets owned by the College. Led by Michael Dilling, Ph.D., BLG seeks agreements in a pragmatic, principle-based way to balance the needs of the startup company with the College's desire to reasonably share in the company's success. Because startup companies vary widely in their product offerings and business models, there is no one-size-fits-all approach to startup company license agreements. Each agreement will be product of a unique negotiation.

BCM Innovation Development Center: The IDC seeks to leverage internal and external funding resources to advance and develop assets toward a commercial value inflection point (a key "yes/no" proof-of-concept experiment) or clinical entry. Many intellectual property assets may show commercial promise but may lack needed data to support the case for forming and operating a startup company. The IDC works with Baylor principal investigators to seek commercialization grant funding (NIH STTR, CPRIT and others) to advance assets in a non-dilutive capital efficient way. If the work pans out and commercial proof-of-concept is achieved, then the asset may be partnered with a company or may form the basis for formation of a new company, which will involve BLG and/or BCMT, as appropriate.

The Faculty Start Up Company Founder

For faculty who are thinking about forming or becoming involved with a startup company, there are a number of considerations that bear thought and planning prior to taking the plunge:

- The potential for the company to generate a sustainable competitive advantage in its target market. This requires an unflinching assessment of the startup's product offering versus other players in the market. An understanding of the customers that comprise the target market also is essential. Business considerations should always drive the decision to form a startup. A startup company should not be viewed as a source of research funding for an academic laboratory.
- The availability of experienced entrepreneurial talent to lead the company. Investors buy management teams; they do not buy technologies. Success can sometimes be achieved with a technology that has some "warts" in the hands of a capable management team, but it can be very difficult to achieve (even with the best technology) in the hands of an inexperienced management team. Fortunately in Houston, there are programs at TMCx, Rice University and Fannin Innovation Studio devoted to the development of local entrepreneurial talent. Over time, the pool of experienced talent in Houston will deepen and grow. It's happening already.
- A clear vision toward a revenue-generating product or toward achievement of product development milestones that can lead to an exit and the steps (and dollars) that it will take to reach the goal. An in-depth understanding of how the company's product addresses unmet customer needs is essential. We've seen startup companies struggle because they fail to pursue their product development efforts with focus and discipline or because the company is started too soon prior to the completion of key proof-of-concept experiments.
- An understanding of the appropriate role of the faculty founder in the company: The founding faculty member's role in a startup company typically revolves around supplying scientific and technical expertise to support the company's efforts. The role may take the form of a position with fiduciary responsibility to the company such as chief scientific officer or it may take the form of an advisory role, such as scientific advisory board chair or member. It is important for a founding faculty member to understand the difference between an advisor and a position with fiduciary responsibility to the company. If you have a fiduciary role, your obligations should be defined in writing (typically in company bylaws) and you should understand them (and have your own attorney review them). It is possible that you may engage in a consulting relationship with the startup company, but be mindful of the potential for conflict of interest or conflict of commitment if your academic laboratory is engaged to perform research on behalf of the company. Understand your conflict of interest reporting obligations to the college. It takes a diverse set of skills and a well-rounded team to build a successful company, and while the technical expertise supplied by the founding faculty member may be essential for the company's success, there are other skill sets (formulation of company strategy and vision, financial management, project management, regulatory affairs/approval expertise, market expertise) needed for success. Building a successful company is a full-contact team sport.

Because startup companies often are formed around a researcher's most prized discovery/invention developed over the course of years of research, it is only natural for the faculty founder to wish to remain involved with the startup company's efforts to develop the invention into a product. Problems can ensue when the desire for a "voice at the table" becomes a desire to be "in control" of all aspects of product development or company operations. Investors often will avoid investing in companies that are controlled by the founding faculty member.

- The founding faculty member should not be in a position of negotiating against the College on the startup company's behalf in any contract with the College, whether the contract is a license agreement or a research agreement. The company should designate another management professional on the startup team to manage negotiations with the College. BLG will not negotiate the terms of a license agreement with a startup when the company's interests are represented by the founding faculty member who also is a College employee.
- The role of a faculty founder in a startup can be an incredibly rewarding experience, but it will almost always require an extensive, long-term commitment from the founder. I've never had a faculty founder who was involved with a startup company state that it was less challenging or consumed less time than they thought it would at the outset. It will be a roller coaster ride, and there will be plenty of highs and lows. On the positive side, being involved in a startup and seeing a discovery from your laboratory get developed into a product or a service that will benefit patients can be exhilarating because it means that the impact of your discovery and your research program is being maximized. It will be a great learning experience.

COMMERCIALIZATION TOPICS IN FOCUS:
PATENTING AND CONSULTING AGREEMENTS

We frequently receive questions from the Baylor research community on patent strategy and industry consulting agreements, and we're always glad to discuss these topics with faculty. Additionally, we provide answers to some of the more frequently asked questions on the following pages. We hope these explanations are useful and informative.

PATENTING FAQS

Q: How does BLG decide whether to file a patent application?

A: The decision of filing a patent is always linked to the necessity of having a patent application in order to attract a commercial licensee. The end goal is execution of a license with a commercial partner who will develop the licensed intellectual property into a product or service, and filing a patent application is an important tool to secure a licensee for some types of inventions. The goal is not to possess a patent, in and of itself. The college will, as a matter of practice, abandon patents or patent applications that are not commercially licensed or lack prospects of a commercial licensee. Inventions that we file patent applications on are most often therapeutic compositions and methods and medical devices. The period of exclusivity that a patent affords the patent holder is necessary to make it economically viable for a biotech, pharmaceutical or medical device company to make the investment necessary to develop a product from university-owned intellectual property and to guide it through the costly regulatory approval process. If a company has no prospect of capturing a period of exclusivity after securing regulatory approval, they will not make the investment to develop the product. Once we've determined that the invention is the type of invention that we would consider patenting, we then turn our attention to an examination of factors that impact patentability. In order for an invention to be patentable, it must be: (i) novel, meaning that it has not been described in a prior art reference anywhere in the world, (ii) non-obvious to a skilled practitioner in the art, and (iii) it must have a specific, substantial and credible utility. During our assessment process, we examine the prior art related to an invention to determine the degree to which the invention may be novel and/or non-obvious. Overcoming the obviousness hurdle often is a challenge because the patent examiner will cite combinations of prior art references and assert that when considered together, the prior art might lead a skilled practitioner in the field to develop the same invention. In addition to our internal prior art search, we will enlist the help of outside patent counsel to assess patentability of an invention when warranted.

Q: What is a patent claim? What does that mean?

A: The claims are the heart of the patent—they define in precise technical terms the scope of the attributes of the invention that are protected by the patent. The claims that we prosecute are typically directed to some sort of composition of matter or to a method of use. For example, a composition of matter claim might be directed to the chemical structure of a compound or a novel genetic construct designed to express a novel sequence or a specific medical device. A method of use claim would typically be directed to cover the use of a substance or thing to treat a medical condition in a human. For example, a methods claim might involve the use of a manipulated T cell comprising a chimeric antigen receptor sequence to GD2 for the treatment of a subject with a GD2-positive malignancy in need of such treatment. Patent claim structures can be quite intricate and complex, particularly in the biotech arena, because of the complexity of many of the therapeutic approaches that we undertake and the need to describe our invention in ways that are not covered by other prior art in the field.

Q: What is the period of exclusivity associated with a patent application?

A: The period of exclusivity associated with a patent (the term) is 20 years from the date of filing of the earliest non-provisional application.

Q: What is the difference between a provisional patent application and a non-provisional patent application?

A: A provisional patent application is not examined by a patent examiner, whereas non-provisional applications are subject to examination. The provisional application is useful for establishing a priority date for an invention – to the degree that the invention and its attributes can be fully described in the provisional application. Our decision to file a provisional patent application is frequently driven by a pending public disclosure, such that we make a decision to move forward and file an application, even though we may not yet have the supporting data in hand that we would ideally like to have in order to pursue an optimal patent claim structure. Once a provisional patent application is filed and a priority date established, we must make the decision to convert the application to a non-provisional application within 12 months. We can (and almost always do) incorporate additional supporting data into the converted non-provisional application.

Q: Who is an inventor on a patent application, and who makes that determination?

A: Inventorship on a patent application is a legal determination, and it is linked to contributing to the conception of the invention. A person is an inventor on a patent application if they have contributed to the conception of at least one claim on the application. BLG does not make the determination of inventorship. Because inventorship is a legal determination, this matter is handled by outside legal counsel when the patent application is prepared and filed. Unlike scientific manuscripts published in a journal, there is no significance associated with the order in which inventors are listed on a patent application. There is no such thing as a "senior inventor" versus a "junior inventor." One is either an inventor, or one is not.

Q: What is enablement, and why is it important?

A: In order to be granted a patent, the patent applicant must demonstrate that they possess and can practice the claimed invention and that the patent application describes the invention in sufficient detail to allow a skilled artisan in the field of study to practice the invention without the need for undue experimentation. This is the concept of enablement, and the reason that it is so important to us as an academic medical center is linked to the fact that we are often trying to pursue patent claims that are relevant to the treatment of a disease or condition in a human. In order to get such a claim to issue, we must present data from a relevant animal model system that demonstrates that the invention does what it is claimed to do. Lack of enablement is an issue that we are frequently confronted with during the patent prosecution because the supporting data that we have is not sufficient to support the scope of the patent claims that we want to obtain. In academia, our patenting practices often are dictated by a pending public disclosure in an abstract or publication. We frequently file patent applications to beat a pending disclosure deadline, yet the data that we have on hand are not sufficient to fully support the patent claims that we'd eventually like to see become granted. If may be possible to supply supporting data in a later document called a declaration.

Q: How long does it take to get a patent to issue? What happens during that process?

A: We always tell faculty to be prepared for a lengthy process. From the time that we file a non-provisional application, it may be a couple of years until we receive the first Office Action from the patent examiner. The first Office Action will almost always be a Restriction Requirement, under which the patent examiner will segregate the claims into separate groups that constitute separate, searchable inventions. The applicant must then choose which group of claims to continue to prosecute (the other claim groups can be prosecuted in other divisional applications). The second Office Action will almost always result in rejection of the claims we are attempting to prosecute—this is a normal part of the process. The examiner may reject the claims based on lack of novelty, obviousness, lack of enablement or a combination of those reasons. We will then work with our outside patent counsel (and with you, as the inventor) to respond to the Office Action. Our response will state the reasons why we as the applicant contend that the examiner's objections to our claims should be overcome and our patent should be granted. This process essentially constitutes a negotiation with the patent examiner on the scope of our claims, which will typically be altered during the examination process through proposed amendments to the claims. Some patent applications can take 5 years or more to issue, depending on a variety of factors including the complexity of the case or the existence of prior art closely related to the invention. Patent pendency is difficult to predict.

Q: How much does patenting cost, and who pays for it?

A: The college pays for patent prosecution costs through the use of outside patent counsel. The cost of filing a patent application is directly proportional to the complexity of the case. Filing a provisional patent application can range from a few thousand dollars for a hastily developed application filed to beat a pending public disclosure to $10,000 to $15,000 for a more comprehensive application. To prosecute a patent through the examination process and to issuance in the United States alone can cost $35,000 to $50,000 or more. If the decision is made to continue prosecution into foreign countries (which is infrequent unless we have a licensee on board paying patent costs), a conservative foreign portfolio consisting of Europe (UK, France, Germany, Italy), Australia, Canada, Japan, (and more frequently China and/or India) will easily cost $150,000 or more in fees and annuities. Prosecuting a patent to issuance is not an inexpensive proposition. The College's resources to support patent prosecution activities are limited, so we always try make informed patent prosecution decisions.

If we are successful in licensing the invention to a commercial partner, the commercial partner will pick up continued patent prosecution costs from the date of the license agreement forward. We also negotiate for reimbursement of the College's past patent costs. There is no cost to the faculty inventor (other than a commitment of time to participate in the process), and yet the faculty inventor stands to receive 40 percent of any net revenue the College receives from a license of the College-owned intellectual property under the terms of the Baylor Patent Policy. This is a very favorable arrangement for the faculty inventor, and one that no inventor employed by a biotech or medical device company would ever receive.

Q: I just developed a really interesting new software app. Should we patent it?

A: In the vast majority of cases, no, we would not elect to file a patent application with claims directed to a software application. While the patenting process takes years to result in an issued patent, the software development life cycle is much more rapid. By the time that a patent might actually issue, the software will have gone through significant evolution and iterations, such that the patent will in all likelihood no longer be relevant because the software has significantly changed.

INDUSTRY CONSULTING AGREEMENT FAQS

Because Baylor College of Medicine faculty are thought and opinion leaders in their fields of research, companies often will seek to engage them in consulting relationships. The following questions frequently arise as faculty members consider becoming engaged as a consultant or an advisory board member to a for-profit company:

Q: Where can I find information on College policy regarding consulting relationships, and what are my obligations?

A: Faculty consulting relationships fall under the purview of the Baylor Corporate Compliance and Audit Services team. The College allows faculty to consult for for-profit companies with the understanding that there should be consistency between the faculty member's consulting relationship and the College's mission of applying science and discoveries to further education, healthcare and community service locally and globally. The Compliance and Audit Services website has a link entitled: Addendum for consulting relationships, advisory boards and speaking engagements. You can find it here: https://intranet.bcm.edu/?fuseaction=home.showpage&tmp=/compliance-audit/pdfs/Addendum_to_Consulting_Agreement_11_25_2014. This link contains an addendum that must be attached to any consulting agreement signed by a faculty member and a for-profit company. Faculty who enter into consulting relationships should read and understand their obligations to the College under the Disclosure of Outside Interest policy, and should keep their disclosures current.

Q: What are the potential conflicts associated with my consulting relationship, and how do I manage them?

A: There are two potential key sources of conflict associated with faculty consulting relationships:

- Conflict of commitment: Faculty can engage in consulting activities but only to the point that the time commitment associated with consulting activities does not exceed 20 percent of their total effort. Most faculty consulting relationships (service on a scientific advisory board, for example) will typically consume less time than this, with spurts of activity associated with company board meetings, etc.
- Conflict with a faculty member's academic research program: This type of conflict is one that can prove to be challenging to manage. When a company reaches out to a Baylor faculty member to enter into a consulting relationship, they are doing so because the faculty member possesses expertise in a particular focal area of research that is of interest to the company. In many cases, the company's research interests may strongly align with the faculty member's research interests. It is very important for the faculty member to understand and appreciate how their consulting activities can be kept separate and distinct from their academic research activities, and there should be clear differences between the two – they should not intermingle. Faculty members have obligations to the College and to the third-party sources of research funding (federal grants and/or awards from non-profit foundations, etc.) that are used to support their research programs. Faculty should exercise care not to enter into any consulting relationship that could potentially run afoul of college policy or place support of their academic research program in jeopardy.

Q: What does the Addendum for Consulting Relationships say in plain English, and why is it important that it be attached to my consulting agreement?

A: The purpose of the Addendum is to clarify the fact that, as a Baylor faculty member with a primary employment relationship with the College, you are subject to College policies, including the Disclosure of Outside Interest policy. Additionally, the addendum clarifies the following:

- As a consultant, you will not disclose to the company any confidential information that is the property of the College. This includes data and information associated with your research program that has not been publicly disclosed.
- As a consultant, you will provide scientific and medical expertise related to the company's existing products and services and that the services that you provide will not conflict with the scope of your research program at Baylor.
- You will not engage in marketing the company's products or services.
- You will not engage in the practice of medicine during your role as a consultant.
- You will not allow the company to use your image or any logo or image owned by the College in any way that conveys an endorsement of the company's products or services.
- The company shall gain no rights to any intellectual property that is owned by the College through the consulting relationship with you. This point is particularly important, because your consulting agreement will stipulate that the company will own any intellectual property that you develop that arises out of your role as a consultant for the company. Some consulting agreements will go so far as to state that if you inadvertently convey any rights to intellectual property that is owned by the College, the company will be automatically granted a non-exclusive license to that intellectual property. Provisions like this will not fly; as a consultant, you cannot convey rights to intellectual property that you do not own. As a consultant, it is very important that your consulting activities do not intermingle or intertwine with your academic research program.

Q: Will the College help me negotiate my consulting agreement?

A: Faculty members should retain their own legal counsel to assist them with negotiation of their consulting agreement. The company will be represented by legal counsel during the agreement negotiation process, so it is important for the faculty member to be represented by legal counsel as well to keep the playing field level. Because the College is not a signatory to your consulting agreement, the College will not represent you in your negotiation with the company. Your legal counsel should have experience working with faculty in an academic research institution, and they should be experienced in the negotiation of contracts. College personnel, including members of the Baylor Licensing Group, may provide you with advice about your consulting agreement, but this is not legal advice and is not a substitute for the advice that you will receive from your own attorney. College personnel are representatives of the College and are not responsible for representing a faculty member's personal interests in a contract negotiation.

Baylor College of Medicine

One Baylor Plaza
Houston, Texas 77030
bcm.edu

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713.798.6821
blg@bcm.edu
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