Annual Report 2016

Office of novation and Industry Alliances



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Moffitt's Office of Innovation and Industry Alliances acknowledges McKenna Kelley for assistance in writing this annual report.

Executive Message

This year was one of change for the Innovation Office. As of May 16, 2016, the Office of Technology Management and Commercialization (OTMC) officially changed its name to the Office of Innovation and Industry Alliances (Innovation Office, for short). The new name better reflects our ongoing initiatives to develop strategic alliances between Moffitt Cancer Center faculty and industry as together we turn discoveries into medical breakthroughs. Additionally, the Innovation Office is moving from its current location at the Moffitt Research Center to its new home on the McKinley campus. This move consolidates office staff into one location.

The successes of new industry alliances have led Research Administration and our office to be the proud recipients of the Spirit of Moffitt award. The Innovation Office has brought in nearly \$35 million in new revenue to Moffitt over the past two years, chiefly from industry alliances and licensing. Two of the most significant deals signed this fiscal year were collaborations with Bristol-Myers Squibb and Incyte Corporation. The Innovation Office also celebrated the 10th anniversary of our Business of Biotech conference, which promotes Moffitt's innovation and technology. Details about the 2016 conference and these and other exciting relationships can be found in this Annual Report.

Innovation Office team members are proud to serve Moffitt faculty as they break new ground in scientific discovery. Whether through patenting, licensing or industry alliances, the Innovation Office supports Moffitt's research mission and each faculty member's academic and research goals. Collaboration is crucial to the success of any effort, and the Innovation Office looks forward to working with Moffitt leadership, faculty and industry to further elevate the fight against cancer.

L. David de la Parte, Esq.



Executive Vice President/ General Counsel Office of General Counsel

James J. Mulé, Ph.D.



Associate Center Director, Translational Science

Jarett Rieger, Esq., M.B.A.



Senior Director, Innovation & Industry Alliances

Science. Synergy. BUSINESS OF BIOTECH: 10 YEARS OF ECONOMIC GROWTH AND IMPACT

Moffitt Cancer Center celebrated the 10th anniversary of the Business of Biotech conference March 18, 2016, with a record number of attendees, all eager to collaborate with the best and brightest in science, industry and investment.

Business of Biotech has grown dramatically since it began 10 years ago, with more than 330 people attending this year. The "Science. Synergy. Success!" themed conference encouraged networking among individuals involved in all aspects of biotechnology.

"Business of Biotech has matured to become a premier life science event in Florida, and it draws national attention to the local biotech cluster," said Jarett Rieger, conference co-chairman and Senior Director, Innovation & Industry Alliances. "This conference gives Moffitt researchers the opportunity to connect with investors and collaborators in their field, ultimately leading to the commercialization of their discoveries.

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Former ABC news correspondent and current member of Moffitt's Board of Advisors Sam Donaldson (right) interviews Arie S. Belldegrun, M.D., founder, president and CEO of Kite Pharma.

Success!

The conference included a Partnering Forum, and Moffitt faculty met with industry representatives to discuss current and potential research collaborations. FORMA Therapeutics, Celgene Corporation and Signal Genetics held joint scientific committee meetings during the conference.

Keynote interviewer, Sam Donaldson, former ABC News correspondent and Moffitt Board of Advisors member, led Arie S. Belldegrun, M.D., founder, President and CEO of Kite Pharma, through a conversation about Dr. Belldegrun's experiences and successes with biotech companies.

The conference included a shark tank event, three educational sessions that focused on smart ways to fundraise, the expanding field of immuno-oncology and the importance of academia-industry partnerships, and a local economic development group meeting.

SAVE THE DATE:

Partnering For The Future

11th Business of Biotech Conference February 24, 2017.

Visit **MoffittIP.com** to register. To find out more, contact Innovation@Moffitt.org or 813-745-6828.



Agreement With Bristol-Myers Squibb Forges Trials For Rare Population Cancers

Moffitt continues to be at the forefront of the expanding field of immuno-oncology through a recent partnership with the biopharmaceutical company Bristol-Myers Squibb.

With immunotherapy agents provided by Bristol-Myers Squibb (BMS), Moffitt faculty will design clinical studies with the aim of creating treatments for rare cancers.

"This partnership with BMS will foster new Moffitt investigator-initiated studies for rare tumors and gives our faculty the opportunity to educate research students about innovative clinical trials," said Daniel Sullivan, M.D., Associate Center Director for Clinical Science at Moffitt.

The collaboration is part of the BMS



Immuno-Oncology Rare Population Malignancy Program. Under this program, BMS is working with a number of research institutions to look specifically at finding treatments for rare population malignancies, or cancers that affect populations at high risk for the disease and are difficult to treat and cure.

Cancers in this category frequently spread to other sites in the body and are resistant to conventional treatment or recur early in the course of traditional treatment. Through their partnership with BMS, Moffitt faculty hope to break new ground in immunotherapy and provide all patients with the best course of care.

"This partnership with Bristol-Myers Squibb will foster new Moffitt investigator-initiated studies for rare tumors and gives our faculty the opportunity to educate research students about innovative clinical trials."

Incyte and Moffitt Establish Multi-Year Oncology Research Alliance

Collaboration focuses on basic and translational research involving novel therapeutic approaches for hematologic malignancies.



Incyte Corporation, a world leader in the development and discovery of novel therapeutic compounds in oncology, and Moffitt Cancer Center have entered into a three-year research collaboration. In this exciting new alliance, Incyte will support innovative research by Moffitt's basic and physician scientists through access of Incyte's proprietary drug compounds. Research projects are focused on hematological malignancies, with a specific interest in the

areas of myeloproliferative neoplasms, mantle cell lymphoma, diffuse large B-cell lymphoma and chronic myelomonocytic leukemia.

"Having access to Incyte's diverse pipeline of targeted cancer therapies represents a unique and exciting opportunity for Moffitt researchers to expand our efforts to advance medical research in oncology and improve medical care for patients with cancer," said Jarett Rieger, Senior Director,

Innovation & Industry Alliances. "A huge strength of Moffitt is our ability to form interdisciplinary research teams, and this exciting research alliance, involving numerous faculty members, is a testament to our team science culture."

Designed to stimulate research and innovation, the alliance will provide significant funding to numerous Moffitt research studies. Research from this study will be submitted for publication and may lead to further grant funding for cancer research.

"Incyte and Moffitt are both committed to improving the lives of patients with cancer through the discovery and development of novel medicines. This research alliance will enable new and important research into multiple blood cancers in a manner that both leverages and extends our current drug discovery efforts," said Reid Huber, Ph.D., "This research alliance will enable new and important research into multiple blood cancers in a manner that both leverages and extends our current drug discovery efforts."

Incyte's Chief Scientific Officer. "We are pleased to expand our growing network of academic collaborations and join forces with the world class investigators from Moffitt to advance the landscape of cancer treatment."

Research Analysis Software Is Licensed To University of North Carolina

A new agreement with the University of North Carolina Health Care System involving BMT research and clinical data software is the first of its kind at Moffitt.

Moffitt has agreed to license its Blood and Marrow Transplant (BMT) Department Research Analysis Information Network (BRAIN) software, developed by the Moffitt Research IT Department for the

BMT Department, to the University of North Carolina Health Care System.

"This deal is the first of its kind at Moffitt, where we are both licensing and providing maintenance and support for software developed by our IT Department," said Haskell Adler, Ph.D., M.B.A., Senior Licensing Manager at Moffitt.

During the course of a patient's treatment, Moffitt's BMT Department gathers an enormous amount of data for clinical and research purposes. The



information collected in the electronic medical records systems facilitates patient care, treatment and billing documentation. The BRAIN application is the central repository for all BMT research and clinical-related data. Using the system, Moffitt's BMT Department reports on outcomes, provides analytics and fulfills governmental and organizational reporting requirements. Data entry is automated. The system manages and tracks all the forms due for each BMT patient, and it creates a color-coded calendar of patient appointments for the month organized by visit type.

"This deal is the first of its kind at Moffitt, where we are both licensing and providing maintenance and support for software developed by our IT Department." "Moffitt's unique BRAIN application was developed in collaboration with the physicians, clinical staff, abstractors and IT specialists specifically to meet the needs of Moffitt's BMT Department," said Ed Chwieseni, Director, Research IT Systems at Moffitt. "Licensing this technology to other institutions is positioning Moffitt as a leader in this exciting field of technology. Multiple benefits to licensing the product to other institutions include cost sharing of future BRAIN technology development."

Aptose and Moffitt TEAM UP To Develop Novel Therapies

Moffitt faculty members are licensing groundbreaking discoveries at a record pace, with the expert support of the Innovation Office. One such example is the recent agreement with Aptose Biosciences.

Aptose Biosciences has the exclusive rights to develop a specific class of epigenetic therapeutics created at Moffitt. These molecules are dual inhibitors that bind two proteins, bromodomaincontaining protein 4 (BRD4) and Janus kinase 2 (JAK2), and are designed to treat both hematological and solid tumor cancers.

"We've built an oncology drug development organization with valuable ties to leading clinical centers and thought leaders," said William G. Rice, Ph.D., Chairman, President and CEO of Aptose Biosciences, "and we are exceptionally pleased to partner with Moffitt on advancing new epigenetic inhibitors, specifically bromodomain inhibitors that simultaneously inhibit specific kinases in key regulatory pathways."

"We've built an oncology drug development organization with valuable ties to leading clinical centers and thought leaders."

"We view the advancement of epigenetic multi-inhibitors as a highly promising strategy in the treatment of cancer," said the principal investigators Ernst Schonbrunn, Ph.D., and Nicholas Lawrence, Ph.D., members of Moffitt's Drug Discovery Program. "Targeting broad-

acting epigenetic regulators of transcription like bromodomain proteins is needed to suppress the induction of gene expression that results when cancer cells respond to kinase inhibitors."

"We are excited to work with an organization as scientifically driven to develop novel therapeutics as Aptose," said Haskell Adler, Ph.D., M.B.A., Senior Licensing Manager at Moffitt.



Commercialization Strategy Committee

Haskell Adler, Ph.D., M.B.A. | Scott Antonia, M.D., Ph.D. | L. David de la Parte, Esq. Eric Haura, M.D. | Nicholas Lawrence, Ph.D. | Howard McLeod, Pharm.D. James J. Mulé, Ph.D. | Jarett Rieger, Esq., M.B.A. | Saïd Sebti, Ph.D.

Under the direction of Co-Chairs **James J. Mulé, Ph.D.**, Associate Center Director, Translational Science, and **Jarett Rieger, Esq., M.B.A.**, Senior Director, Innovation & Industry Alliances, the Commercialization Strategy Committee is leading the way in bringing Moffitt scientific research from "bench to bedside." The Committee helps guide Innovation Office efforts to license discoveries and gives input on the best strategies for the commercialization of Moffitt technologies.

"Being part of this committee has opened my eyes and educated me on strategies for working with industry partners, protecting intellectual property and ultimately commercializing Moffitt property. We've generated our own intellectual property, and the Innovation Office has been involved in filing patents to protect that IP and finding industry partners. It's crucial to commercializing discoveries."

Eric Haura, M.D., Co-Leader, Chemical Biology & Molecular Medicine Program; Director, Lung Cancer Center of Excellence

"To ensure that the scientific research we do is translational and will extend to the clinic requires a large investment, and we must involve industry partnerships. For the most part, our work is not funded through federal grants, so we have to partner with biotech companies and biotech startups. The Innovation Office is critical in this respect."

Nicholas Lawrence, Ph.D., Senior Member, Department of Drug Discovery

"Working with the Innovation Office helps sharpen the science. We think about the science that's been done and whether it has hit or missed the mark on actually helping patients. It causes me to think more about my own work. How does science make it past the great journals and actually help patients in that next step? When we have a better idea of where the data is going, we can create better data. Publication is not the end of the process."

Howard L. McLeod, Pharm.D., Medical Director, DeBartolo Family Personalized Medicine Institute

"With the current licenses, we need to know which ones are failing, which ones are doing all right, which ones have opportunity, which ones to push hard on, and when to give up and take the license back. We need to hold startups accountable and challenge the CEOs on how they're fundraising. The IP has been protected and the patents have been issued. Then, we want to see how faculty can provide commercialization leads for the Innovation Office."

James J. Mulé, Ph.D., Associate Center Director, Translational Science

"My role is to contribute law expertise and serve as a conduit to leadership, helping to make sure the Innovation Office connects to Moffitt's larger plan so that it can be effective and contribute in a way that matches the talent in the Innovation Office. The Innovation Office helps us get to our destination institutionally. I help inform others of what that destination is and how the Innovation Office's talents get us there."

L. David de la Parte, Esq., Executive Vice President, General Counsel, Office of General Counsel



THE HIGHLIGHTS

Acetylon Pharmaceuticals

Research with Acetylon pertains to the effect of selective HDAC6 inhibition on T-cell programming either as single treatment or in combination with various kinase inhibitors in preclinical models of chronic lymphocytic leukemia (CLL). The findings show that this inhibition combo may provide a successful immunotherapeutic strategy for treating CLL.

Biotheranostics

Moffitt researchers are teaming up with Biotheranostics to further validate the company's Breast Cancer Index (BCI) technology. Research will examine whether BCI can accurately predict the benefit of chemotherapy for early-stage female breast cancer patients who are estrogenreceptor positive. Results from these studies may lead to the improvement of BCI as an adjuvant-chemotherapy treatment decision support tool.

Bristol-Myers Squibb

As part of Bristol-Myers Squibb's Immuno-Oncology Rare Population Malignancy program, Moffitt and Bristol-Myers Squibb will conduct clinical investigations of immuno-oncology therapeutics as potential treatment options for patients with high-risk, "poor prognostic cancers", defined as rare population

malignancies. A number of the clinical trials will be performed by young investigators to enhance their development as clinical research scientists.

Alliances

FORMA Expansion

Following the success of the original collaboration, FORMA and Moffitt have expanded their existing research collaboration focused on epigenetics and histone deacetylase molecules (HDACs). An interdisciplinary team of Moffitt scientists will collaborate with FORMA's drug delivery team on three new and innovative projects, exploring the effect of HDAC inhibition on non-small cell lung cancer, myelodysplastic syndromes and melanoma.

Incyte

Using the biological expertise of Moffitt faculty members, Moffitt and Incyte Corporation will examine the effects of Incyte's proprietary compounds on lymphoma, myeloproliferative neoplasms, and chronic myelomonocytic leukemia. These studies are the first of their kind for Moffitt.

lgnyta

Moffitt and Ignyta have entered into a research collaboration relating to RXDX-106, Ignyta's small molecule, pseudo-irreversible inhibitor of TYRO3, AXL, Mer (TAM) and cMET that is in late-stage preclinical development. The collaboration will explore and develop novel protein-based diagnostic assays that can assess RXDX-106 inhibitory activity in relevant solid tumors and associated tumor microenvironments.

Signal Genetics

Moffitt has entered into an agreement with Signal Genetics to complete validation studies to test the clinical utility of Signal's MyPRS® (myeloma prognostic risk signature) test. The studies will examine the use of the test in multiple myeloma and its precursor conditions, monoclonal gammopathy of unknown significance and smoldering multiple myeloma. Moffitt researchers believe the collaboration has the potential to further validate a "first in class" clinical decisionmaking tool based on the genetics of these precursor conditions.

Patent Review Committee

Alan F. List, M.D.

President and CEO Senior Member, Department of Malignant Hematology and Chemical Biology and Molecular Medicine Program

Thomas A. Sellers, Ph.D.

Center Director, Moffitt Cancer Center Director, Moffitt Research Institute Executive Vice President

James J. Mulé, Ph.D. Associate Center Director, Translational Science

Srikumar P. Chellappan, Ph.D.

Senior Member and Chair, Tumor Biology Department

Robert J. Gillies, Ph.D.

Senior Member and Martin Silbiger Chair, Cancer Imaging and Metabolism Department Director, Center of Excellence in Cancer Imaging and Technology Vice Chair, Radiology

Eric Haura, M.D.

Co-Leader, Chemical Biology & Molecular Medicine Program Director, Lung Cancer Center of Excellence Senior Member, Department of Thoracic Oncology

Jae K. Lee, Ph.D.

Chair and Senior Member, Department of Biostatistics and Bioinformatics

Howard McLeod, Pharm.D.

Medical Director, DeBartolo Family Personalized Medicine Institute Senior Member, Department of Cancer Epidemiology

Saïd Sebti, Ph.D.

Senior Member and Manuel & Adeline Garcia Endowed Professor and Chair, Drug Discovery Department Co-Leader, Chemical Biology & Molecular Medicine Program

The Patent Review Committee is a team of professionals who are instrumental in guiding a promising discovery along its patenting and commercialization journey. After a provisional patent application has been filed for a new discovery, the Innovation Office conducts a thorough exploration to determine novelty in view of prior patents as well as commercial potential. Then the Patent Review Committee reviews the information and must deem the new technology to be both patentable and marketable before the Innovation Office takes the next step in committing to the expensive and long process involved with filing international and foreign patent applications.

9 U.S. Patents Issued in 2016

PATENT TITLE	INVENTORS
Aurora Kinase Inhibitors and Methods of Making and Using Thereof	Nicholas Lawrence Ernst Schonbrunn Saïd Sebti Harshani Lawrence Mathew Martin
Biomarkers for Predicting Response to Immunosuppressive Therapy	Pearlie Burnette
Creating Bioengineered Lymph Nodes	James Mulé
Gene Signature for the Prediction of NF-kappaB Activity	Amer Beg Dung-Tsa Chen Steven Alan Enkemann
Inhibition of Shp2/PTPN11 Protein Tyrosine Phosphatase by NSC-87877, NSC-117199, and their analogs	Saïd Sebti Jerry (Jie) Wu Nicholas Lawrence
Malignancy-Risk Signature from Histologically Normal Breast Tissue	Timothy Yeatman Dung-Tsa Chen
Marinopyrrole Derivatives as Anti-Cancer Agents	Rongshi Li Saïd Sebti Ƴan Liu
Method for Assessing Breast Density	Thomas Sellers John Heine
Pyridylthiazole-Based Ureas as Inhibitors of Rho Associated Protein Kinase (ROCK) and Methods of Use	Saïd Sebti Nicholas Lawrence Roberta Pireddu

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