ANNUAL REPORT | 2017

Office of Innovation and Industry Alliances

MOFFITT CANCER CENTER

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Executive Message

Since 2014, the Innovation Office has brought Moffitt Cancer Center $50 million in global revenue chiefly from traditional technology transfer deals along with industry alliances. A few significant transactions are highlighted below and more fully described in this Annual Report.

We entered into a manufacturing agreement with Iovance Biotherapeutics (formerly known as Lion Biotechnologies), an industry alliance partner that has been instrumental in advancing tumor infiltrating lymphocyte (TIL) therapy. Moffitt's Cell Therapies Core is one of only five cancer center facilities in the nation that can generate a patient's own TIL cells for clinical use. Availability of this resource was instrumental in expanding the Iovance Biotherapeutics relationship into cell manufacturing. As part of Moffitt's first manufacturing agreement, the cells will be used in Iovance's clinical trials conducted at Moffitt Cancer Center and other sites.

L-R: Jarett Rieger, Esq., M.B.A., James J. Mulé, Ph.D., L. David de la Parte, Esq.

M2Gen®, a for-profit subsidiary of Moffitt Cancer Center since 2006, signed a substantial deal that will support M2Gen's commercialization initiatives. The agreements involve three patent licenses (trial matching, healthcare information network and decision support tools), a trademark license, trademark and domain assignments and a database content license.

The Moffitt Cancer Control Journal, established in 1994, assigned its trademark, copyright and domain name to SAGE Publishing, the world's largest independent, family-owned publisher. Moffitt is able to more efficiently focus on core competencies through the partnership with SAGE Publishing. SAGE has the enthusiasm and the resources to maintain the quality reputation of this peer-reviewed journal and to increase circulation.

Moving forward, the Innovation Office will continue to strengthen our relationships with industry through new and innovative partnerships as well as expand our faculty outreach to engage Moffitt's newest basic science and clinical faculty.

Jarett Rieger, Esq., M.B.A.
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Innovation & Industry Alliances

James J. Mulé, Ph.D.
Associate Center Director,
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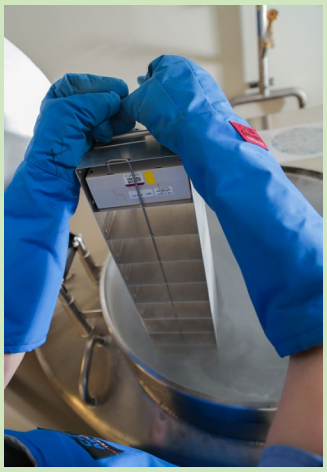
L. David de la Parte, Esq.
Executive Vice President/
General Counsel
Office of General Counsel

Firing on All Cylinders

WITH IOVANCE BIOTHERAPEUTICS

"Moffitt Cancer Center and Iovance Biotherapeutics have established a fruitful academic-industry alliance that has had an immediate clinical impact."

MOFFITT AND IOVANCE BIOTHERAPEUTICS (FORMERLY KNOWN AS LION BIOTECHNOLOGIES), a clinical stage biotechnology company focused on development and commercialization of novel cancer immunotherapies, are expanding their multi-year relationship involving the development of tumor infiltrating lymphocyte (TIL) therapy for cancer. The original partnership included two joint research projects and an expanded phase 1 clinical trial. As both parties worked together on the projects and the trial, Iovance became familiar with Moffitt's talented physician-scientists, organizational capabilities and resources, in particular Moffitt's Cell Therapies Core facility. This expanded relationship includes Moffitt's first manufacturing agreement.



"Moffitt Cancer Center and Iovance Biotherapeutics have established a fruitful academic-industry alliance that has had an immediate clinical impact. Due to this partnership, patients afflicted with advanced metastatic melanoma who have progressed on the existing FDA-approved treatments have gained access to a novel and effective treatment with adoptive cellular therapy in an ongoing clinical trial at Moffitt. Additional efforts include improving the effectiveness of adoptive cellular therapy as well as applying this promising treatment to other cancer subtypes." – Moffitt Surgical Oncologist Amod Sarnaik, M.D.

SPONSORED RESEARCH

- Extended for three years
- Expanded focus on developing novel ways of increasing TIL production from several solid tumors such as melanoma, lung, head and neck, etc., as well as identifying the functions and efficacy of the increased TIL production

LICENSING

- Moffitt-developed agents and methods to improve TIL therapy

CLINICAL TRIALS

- Expanded to determine the safety of TIL therapy for patients with various metastatic or treatment-refractory tumors (e.g. melanoma, head and neck, and cervical cancers)

MANUFACTURING

- Moffitt's first manufacturing agreement
- Moffitt will manufacture TILs for Iovance Biotherapeutics' clinical trials run both at Moffitt and non-Moffitt sites

Blockbuster Agreements

WITH M2GEN

Blockbuster intellectual property and data agreements have been executed between Moffitt and M2Gen®. Through these agreements, both Moffitt and M2Gen are able to excel in clinical research. The intellectual property agreements include seven patents and patent applications for trial matching, a decision support tool, a healthcare information network, four trademarks and 20 domain names.

M2Gen is a health informatics solutions company focused on the development of personalized medicine. M2Gen was founded in 2006 by Moffitt Cancer Center. William Dalton, Ph.D., M.D., is the Founder and Executive Chair of the Board of M2Gen. Moffitt and M2Gen have developed one of the largest cancer tumor data warehouses in the United States.

M2Gen studies patients throughout their lifetime through the Total Cancer Care® Protocol. The Oncology Research Information Exchange Network® (ORIEN) was launched by M2Gen. ORIEN allows M2Gen to partner with cancer centers nationwide through collaboration. M2Gen is the only company granted the right to commercialize ORIEN's cancer data.

TRIAL MATCHING

Intellectual property that involves determining the molecular profile of a patient who responded to a specific therapy, and then matching a clinical trial for that therapy with patients with the same molecular profile

DECISION SUPPORT TOOL

Intellectual property for identifying and optimizing treatment regimens by comparing a patient's molecular profile with a database of other patients' molecular profiles stored and catalogued by treatment and clinical response

HEALTHCARE INFORMATION NETWORK

Intellectual property that involves a network of facilities that communicate with each other electronically and share patients' clinical and molecular data in order to find the most effective treatment

SAGE Publishing purchased the domain name, trademark and copyrights to *Cancer Control: Journal of the Moffitt Cancer Center®* and its historical records. SAGE Publishing is the fourth largest academic journal publisher in the world, and the world's largest independent, family owned publisher.

SOLD!

CANCER CONTROL JOURNAL

SAGE Publishing contacted Lee Green, Ph.D., Vice President of Diversity and Community Relations at Moffitt about purchasing the peer-reviewed journal. Dr. Green sought assistance from the Office of Innovation and Industry Alliances. After much discussion and thought, Dr. Green concluded, "We are at a point where the resources needed to continue producing the journal may not be worth the ROI." At that point Dr. Green garnered support from Moffitt executive leadership to move ahead with selling this journal.

The idea to produce the oncology journal surfaced with Moffitt leadership in 1993. Production began by 1994 and continued strong as the continuing medical education-containing journal transitioned to solely electronic distribution. Major aims of the journal have been to update oncologists on the spectrum of actions and approaches needed to reduce the impact of cancer and to enhance Moffitt's reputation as a National Cancer Institute-designated Comprehensive Cancer Center. Cancer Control is a member of the Medscape Publishers' Circle®, an alliance of leading medical publishers whose content is featured on Medscape (www.medscape.com).

SAGE Publishing has over 950 journals and partners with nearly 400 society and associations worldwide. Moffitt will remain involved with seats on the editorial board. SAGE Publishing's purchase is financially beneficial to Moffitt and it allows Moffitt to partner with a leading publishing company. The partnership with SAGE enables Moffitt to more efficiently focus on core competencies.

Jarett Rieger (center), Senior Director, Office of Innovation and Industry Alliances, awards patent plaques to David Morse, Ph.D. (left), and Robert Gillies, Ph.D. (right).

Patently Successful

In February, during the annual Faculty Appreciation & Recognition Ceremony, 14 faculty members who were awarded U.S. patents in 2016 were presented plaques commemorating their distinctive accomplishments. Congratulations!

As noted by Moffitt Center Director Thomas Sellers, Ph.D., M.P.H., "patents are an important metric of scientific impact." Since 2004, Moffitt has received 86 new patents for technologies developed by 80 faculty members. Patents provide rights for the owner to exclude competitors from the market and if the patent is licensed, a portion of the revenue is used to support research and innovation at Moffitt. Effective patent protection can therefore offer a licensee protection from competitors, while also stimulating research and investment at Moffitt by use of license proceeds.

The faculty benefits of a patent are far-reaching. Patents help support faculty promotion and tenure, while validating the novelty of a faculty member's research findings. Patents can also be leveraged to attract commercial interest in partnering with Moffitt via a licensing arrangement or industry collaboration. In addition, published patents promote Moffitt's research and create awareness for potential postdoc applicants.

20 U.S. Patents Issued FY 2017

PATENT TITLE	INVENTORS
Immune Gene Signatures in Cancer	James Mulé Domenico Coppola Timothy Yeatman Andrey Loboda Michael Nebozhyn
Transient Hypoxia Inducers and Their Use	Robert Gillies Murali Cherukuri Shingo Matsumoto James Mitchell Kieta Saita
Methods and Materials for Monitoring Myeloma Using Quantitative Mass Spectrometry	John Koomen Mohamad Hussein Kaaron Benson Elizabeth Wood
Inhibitors of Rho Associated Protein Kinases (Rock) And Methods Of Use	Saïd Sebti Ernst Schönbrunn Rongshi Li
Selective Histone Deactylase 6 Inhibitors	Eduardo Sotomayor Alejandro Villagra Joel Berman Alan Kozikowski Karrune Woan
Super Lewis Acidic Borate Esters as 18F Labeled Pet Probes	Haibin Tian Mark McLaughlin
Melanocortin 1 Receptor Ligands and Methods of Use	David Morse Robert Gillies Natalie Barkey Victor Hruby Christian Preihs Jonathan Sessler Kevin Sill Narges Tafreshi Josef Vagner
Method and Apparatus for Detection of Radioactive Isotopes	Kenneth Forster
Method of Identifying Myelodysplastic Syndromes	Alan List Lubomir Sokol
Method of Screening for Colon Cancer Using Biomarkers	David Morse Robert Gillies

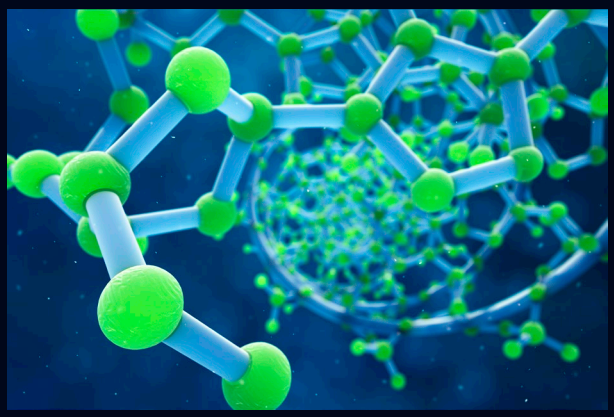
PATENT TITLE	INVENTORS
Novel Drug Targets to Overcome De Novo Drug-Resistance in Multiple Myeloma	Daniel Sullivan Joel Turner David Ostrov Thomas Rowe
Phosphorylation of Histones And Uses Thereof	Nupam Mahajan Kiran Mahajan
Aurora Kinase Inhibitors and Methods of Making and Using Thereof	Saïd Sebti Nicholas Lawrence Harshani Lawrence Ernst Schönbrunn Mathew Martin
Small Molecule Inhibitors of STAT3 with Anti-Tumor Activity	Saïd Sebti Nicholas Lawrence Harshani Lawrence Wayne Guida James Turkson Man Lun Yip Benjamin Greedy
BAD Phosphorylation Determines Ovarian Cancer Chemo-Sensitivity And Patient Survival	Johnathan Lancaster Dung-Tsa Chen Douglas Marchion
Novel Rho Kinase Inhibitors and Methods of Use	Saïd Sebti Nicholas Lawrence Roberta Pireddu
Thiosemicarbazones Inhibitors of Lysophosphatidic Acid Acyltransferase and Uses Thereof	Gregory Springett Saïd Sebti Nicholas Lawrence
Method and Apparatus for Detection of Radioactive Isotopes	Kenneth Forster
Inhibition of Cell Proliferation	Srikumar Chellappan Saïd Sebti Nicholas Lawrence
Symmetrical Marinopyrrole Derivatives as Potential Antibiotic Agents	Rongshi Li Chunwei Cheng Yan Liu Hao Song Yong Qin

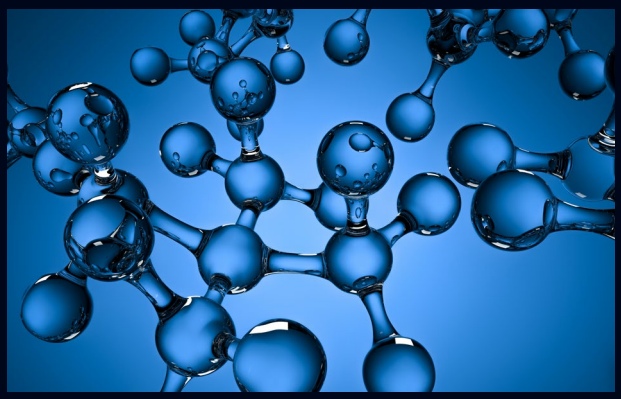
Expanding Horizons

WITH PRESCIENT THERAPEUTICS

MOFFITT IS ENTHUSIASTIC ABOUT AN EXPANDED PARTNERSHIP WITH PRESCIENT THERAPEUTICS LTD. PRESCIENT THERAPEUTICS IS A PUBLICLY TRADED AUSTRALIAN COMPANY DEVELOPING NOVEL DRUG THERAPIES TO TREAT A RANGE OF CANCERS. Prescient is in clinical development with two small molecule cancer therapeutics, an AKT inhibitor (PTX-200) and a GGTI inhibitor (PTX-100). One of the inventors of both drugs is Saïd Sebti, Ph.D., Chair of the Department of Drug Discovery at Moffitt Cancer Center.

There are three clinical trials open at Moffitt studying Prescient's PTX-200 drug in combination with various chemotherapies for treatment of ovarian cancer, breast cancer and leukemia. Prescient is funding correlative biomarker analysis of blood samples from patients participating in a leukemia clinical trial using PTX-200 conducted at Moffitt.





"We are extremely excited about our collaboration with Prescient Therapeutics to develop this assay that could lead to development of new companion diagnostic and therapeutic response assays for PTX-200, a potent small molecule inhibitor of the AKT pathway," said Dr. Sebti, co-developer of PTX-200. The Prescient-Moffitt partnership relies on capabilities and expertise within Moffitt's Translational Research Core.

Moffitt has a license with Prescient involving PTX-100, and Prescient is planning to start clinical trials with PTX-100. PTX-100 is also known as "GGTI-2418," a GGT-1 inhibitor co-developed by Dr. Sebti and Andrew Hamilton, Ph.D., when Dr. Hamilton was at Yale University. Moffitt has licensed to Prescient PTX-100, a companion biomarker that may help determine which breast cancer patients would likely respond to PTX-100.

"We are extremely excited about our collaboration... this assay could lead to development of a potent small molecule inhibitor of the AKT pathway."

TOGETHER, BMS AND MOFFITT

Take On Rare Tumors

IN 2015, MOFFITT AND BRISTOL-MYERS SQUIBB (BMS) JOINED FORCES TO IDENTIFY POTENTIAL TREATMENT OPTIONS FOR PATIENTS WITH RARE TUMORS—DEFINED BY LOW INCIDENCE, SPECIFIC MOLECULAR CHARACTERISTICS, OR DISEASE RESPONSE CRITERIA. Investigator-initiated trials have commenced. The trials include teams of Moffitt clinical researchers working collaboratively, and all involve mentoring of junior faculty members. The trials include correlative molecular analyses on patient tumor samples to help define biomarkers that predict response or specific mechanisms of drug action. Moffitt is one of seven major US cancer centers collaborating with BMS in this Rare Population Malignancy Program.

There are three trials actively recruiting patients and two pending regulatory approval:

Phase 2, Randomized, Multi-institutional Study of Nivolumab and Ipilimumab versus Nivolumab, Ipilimumab and Stereotactic Body Radiation Therapy for Metastatic Merkel Cell Carcinoma.

Sungjune Kim, Principal Investigator

Phase 1 Trial of Hypofractionated Stereotactic Irradiation (HFSRT) Combined with Nivolumab in Patients with Recurrent High Grade Gliomas.

Solmaz Sahebjam, Principal Investigator

Phase 2 Investigator Sponsored Study of Nivolumab in Patients with Advanced Refractory Biliary Tract Cancers.

Richard Kim, Principal Investigator

Combination Immunotherapy with Ipilimumab and Nivolumab Plus a Dendritic Cell Based p53 Vaccine (Ad.p53-DC) in Patients with Relapsed Small Cell Lung Cancer (pending activation).

Alberto Chiappori, Principal Investigator

CD40-L Blockade for Prevention of Acute Graft-Versus-Host Disease. (pending activation).

Farhad Khimani, Principal Investigator

Partnering For The Future!

MOFFITT CANCER CENTER HELD ITS 11TH ANNUAL BUSINESS OF BIOTECH CONFERENCE FEBRUARY 24, 2017, DRAWING A RECORD-BREAKING 375 ATTENDEES.

With a captivating keynote interview, four information-packed breakout sessions, and plenty of time for networking, eager attendees received ample opportunities to discuss innovation and collaboration in biotechnology. An increasing amount of people have traveled from all over the globe to attend the conference each year.

"The goal of Business of Biotech is to foster the exchange of ideas," said Thomas Sellers, Ph.D., M.P.H., Moffitt Center Director and Executive Vice President. "It helps explore possibilities for the commercialization of Moffitt discoveries and form partnerships to synergize the respective skills and expertise resident in academia and industry."

"The goal of Business of Biotech is to foster the exchange of ideas."

The keynote speaker, George Golumbeski, Ph.D., Executive Vice President of Business Development for Celgene, was interviewed in a fireside chat format by Sam Donaldson, former ABC News correspondent and current Moffitt Board of Advisors member. Attendees heard a fascinating account of the art of deal-making, how to maintain a biotech company culture and a biopharma approach, and how Dr. Golumbeski envisions the future cancer cure landscape. United States-FL Senator, Marco Rubio prepared a conference welcoming video that was shown during the opening session.

In addition, the conference included four diverse education sessions:

- **Efficiencies of Molecular Medicine: Delivery with Nanoparticles**
- **Targeted Clinical Trials and the Oncology Research Information Exchange Network® (ORIEN)**
- **The Portrait of a Partnership: Pharma and Academia**
- **The Genomics Era: Patent Strategies to Avoid the Slippery Slope**

Leading up to the conference, Moffitt held a partnering forum that matched its scientists with potential industry partners and current partners.

A crowd gathers in Moffitt's conference atrium.

George Golumbeski, Ph.D., Executive Vice President at Celgene (right), answers former ABC news correspondent and current member of Moffitt's Board of Advisors, Sam Donaldson's interview question.

SAVE THE DATE:
Discovering Tomorrow's Cancer Cures

12th Business of Biotech Conference March 2, 2018

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

Above: Thomas Sellers, Ph.D., Moffitt Center Director, welcomes the audience to the 2017 conference.

Audience members listen to George Golumbeski, Ph.D., Executive Vice President at Celgene.

PARTNERING FORUM

Showcasing Faculty and Industry

The networking activity began before the Business of Biotech conference itself. At a successful partnering forum held in the days leading up to the conference Moffitt faculty members met with industry representatives to discuss potential new research collaborations and extensions of established ones.

During the 2017 conference partnering forum, over 60 meetings took place with 45 Moffitt faculty members and 20 industry representatives.

This opportunity to showcase the benefits of Moffitt's facilities and faculty to partners is integral to emerging collaborations. The forum brings together industry and academia for a one-on-one interaction while simultaneously establishing the Tampa Bay community as a landing space for industry alliances.

Bruce Ruggeri, Ph.D., Incyte Corporation Senior Director, Pharmacology, states, "The Partnering Forum at the Business of Biotech conference provided an excellent venue to engage in very informal yet extremely informative one-on-one interactions with individuals from academia and start-up biotech companies to explore potential opportunities and areas of mutual interest scientifically. I was pleasantly surprised at the turnout for this event and the level of engagement that was possible at this forum – kudos to the Moffitt Cancer Center..."

The Innovation Office is intent on creating partnerships with industry that drive science and focus on the mission of contributing to the prevention and cure of cancer. The partnering forum, paired with the Business of Biotech conference, provides the fertile ground for these fruitful industry partnerships to grow.

"The Partnering Forum at the Business of Biotech conference provided an excellent venue to engage in very informal yet extremely informative one-on-one interactions with individuals from academia and start-up biotech companies... "

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