## Facilitating Commercialization May 1, 2017

Jarett Rieger, Senior Director Office of Innovation and Industry Alliances



## **INNOVATION OFFICE SERVICES**

#### PATENTS

Protects intellectual property via patents, trademarks, and copyrights

#### AGREEMENTS

Negotiates Material Transfer, Confidentiality, Data Sharing, Intellectual Property

### INNOVATION OFFICE

#### INDUSTRY ALLIANCES

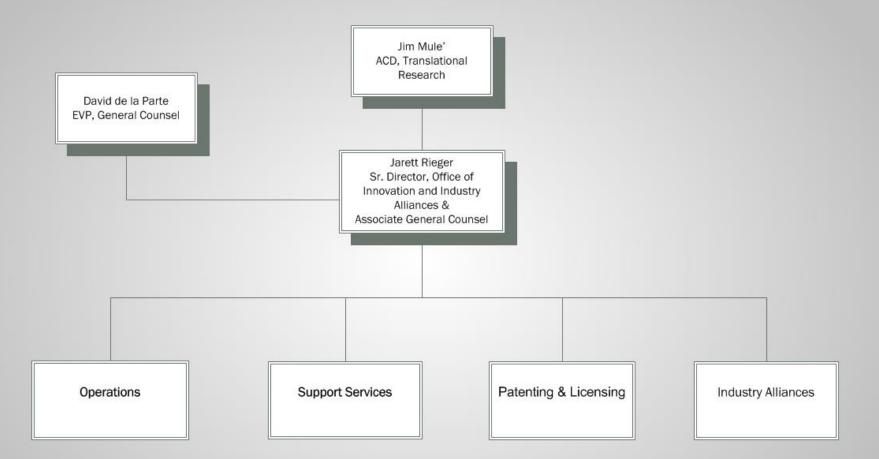
Forges research collaborations to advance Moffitt research

#### LICENSING & STARTUPS

Commercializes technologies by transferring intellectual property to a company



## **INNOVATION OFFICE ORGANIZATIONAL CHART**





## **BUSINESS UNITS FUNCTIONS**

### **OPERATIONS**

- Generate reports
- Market technologies
- Coordinate office programs
- Manage financial functions

### **SUPPORT SERVICES**

- Coordinate intellectual property filings
- Negotiate contracts

#### **PATENTS & LICENSING**

- Protect intellectual property
- License technologies
- Facilitate faculty startups

### **INDUSTRY ALLIANCES**

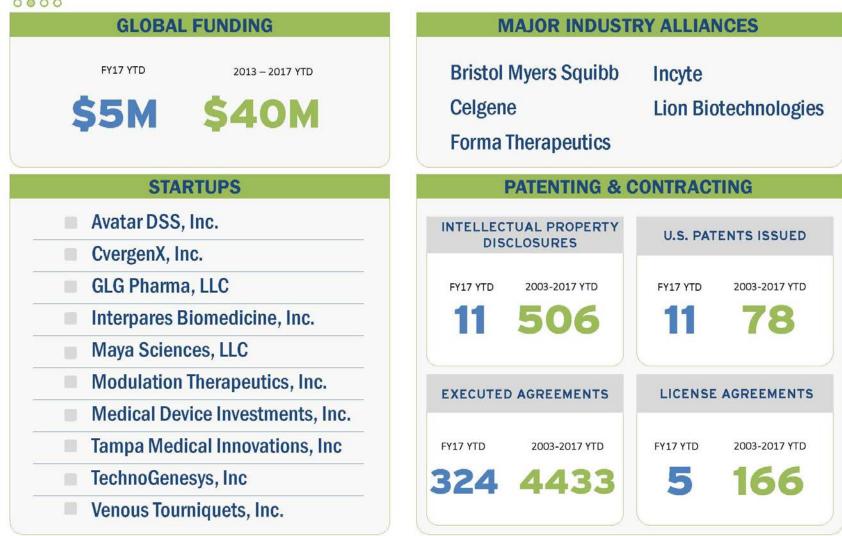
• Identify, evaluate, and forge research collaborations



#### OFFICE OF INNOVATION AND INDUSTRY ALLIANCES

MID YEAR DASHBOARD FY2017

0000



MOFFITT CANCER CENTER

## **ROAD TO INDUSTRY ALLIANCES**



Funding reductions in Industry R&D and Grants led to

## **New Strategic Plan**

## New Revenue To Date \$50M



## **ADDITIONAL BENEFITS OF INDUSTRY ALLIANCES**



Aligns with Moffitt's research strategic plan



Leads to high impact publications

**Creates licensing opportunities** 

Supports recruitment and retention of top research talent

**Creates local jobs in biotech industry** 

## **INDUSTRY ALLIANCE FUNCTIONS**

CONTRACT

SIGNED

#### **INNOVATION OFFICE**

- Company outreach
- Notification of research opportunities
- Prepare statement of work
- Negotiate areas of collaboration
- Coordinate budget
- Negotiate contract

#### ALLIANCE MANAGEMENT

- Centralized liaison between faculty and industry
- Onboarding alliance members, team development
- Alliance meeting management
- Measure alliance performance
- Alliance decision making process



## **INDUSTRY ALLIANCE TOOLS**





GUIDELINES
FEE SCHEDULE
JUSTIFICATION



• **REVIEW TOOL** 

- LANGUAGE LIBRARY
- FAST FACTS/EXECUTIVE SUMMARY



## **SCORING POTENTIAL INDUSTRY ALLIANCES**





## **ROLE OF EXECUTIVE SPONSORS**

Advocate for the alliance (internally & across the partnership)

**Understand significant contractual responsibilites** 

Resolve escalated disagreements with Company Executive Sponsor & intervene with Company Executive Sponsor in crisis management

**Conduct quarterly alliance meetings** 

**Ensure clarity of decision-making roles & process** 

Facilitate building win-win relationships

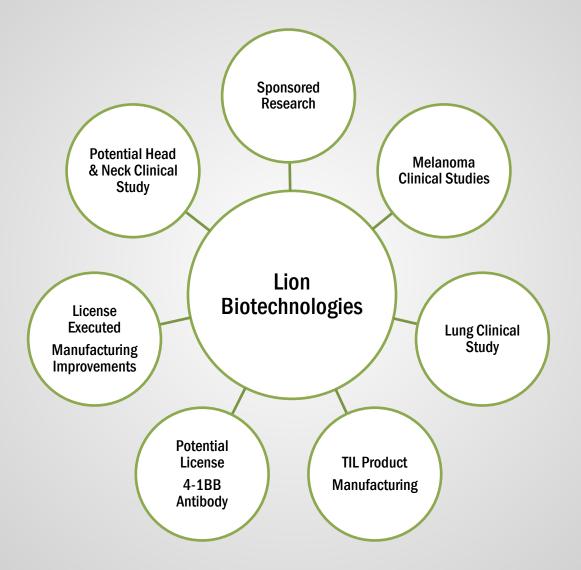
Interface with the Company Executive Sponsor to ensure each company's strategic objectives are served



## **MAJOR INDUSTRY ALLIANCES**



## LION BIOTECHNOLOGIES INDUSTRY ALLIANCE





## LION BIOTECHNOLOGIES RESEARCH

#### **COMPANY PROFILE**

- As of 12/2016 \$166M in cash
- Headquartered in CA with R&D facility in USF Research Park Incubator in Tampa
- Focused on the development and commercialization of novel cancer immunotherapies based on tumor infiltrating lymphocytes (TILs).

#### **BENEFITS TO MOFFITT**

- Provides critical funding to Moffittbased immunotherapy efforts
- Expedites bringing Moffitt's early stage discoveries to clinic and cutting edge therapies to its patients

#### **SCOPE**

- License and commercialize Moffittdeveloped agents and methods to improve tumor infiltrating lymphocyte (TIL) therapy
- Collaboration involves joint translational research projects as well as early phase clinical studies in melanoma and lung cancer



## LION BIOTECHNOLOGIES MANUFACTURING

#### SCOPE

 Supports manufacturing process to be implemented at Moffitt for the production of Tumor Infiltrating Lymphocytes (TIL) to be used in clinical trials at Moffitt and non-Moffitt sites

#### **BENEFITS TO MOFFITT**

- Fosters relationship with industry leader in the promising field of immunotherapy
- Expands the bandwidth and capabilities of Moffitt's Cell Therapy Facility
- Further establishes Moffitt as a national leader in Adoptive Cell Therapy for oncology treatment



## **CELGENE CORPORATION INDUSTRY ALLIANCE**

#### **COMPANY PROFILE**

- Publically traded global biopharmaceutical company
- 2016 revenue over \$11B with more than half from its leading blood cancer drug, Revlimid
- Headquartered in NJ with offices in over 50 countries

#### **BENEFITS TO MOFFITT**

- Bring Moffitt's early stage discoveries to the clinic
- Critical funding to various Moffitt research studies
- Interaction with Celgene's 2000+ R&D team
- Prominent support from highly regarded biotech industry leader

#### **SCOPE**

- License Moffitt's new myelodysplastic syndrome (MDS) treatments
- Fund 5 Moffitt research projects on new therapeutic targets in immune modulation and cell signaling



## University of Florida Office of Technology Licensing

Where Science Meets Business

*David L. Day*, former Assistant Vice President and Director, Office of Technology Licensing





Office of Technology Licensing

- UF's Office of Technology Licensing (OTL) consistently ranks among the top universities for startup launches and licensing. In the past 16 years, UF OTL has launched *195 startups*, generating more than \$1 billion in private investment.
- In fiscal year 2015-16, OTL received 311 invention disclosures on \$724 million in UF research.
- OTL also signed a record *122 licenses and options* and launched 17 startup companies in fiscal year 2015-16, topping the previous year's total of 85 licenses by 43 %.
- According to the most recent statistics from the *Association of University Technology Managers* UF ranked *Third* in the nation for licenses and options completed.





# Sid Martin Biotechnology Institute

Sid Martin Biotechnology Institute (SMBI), the biotechnology incubator of the University of Florida, has been awarded the Randall M. Whaley Incubator of the Year award for 2017, the highest award given by the International Business Innovation Association (InBIA) from among more than 7,500 incubators worldwide.

Sid Martin has graduated over 50 companies who garnered over \$1.5B in revenues, grants, and M&A activity. The average Sid Martin Biotech company raises **\$24 million** in investment. **Eighty-one percent** of SMBI companies were still operating five years after graduating from our program. **Fifteen percent** of SMBI companies were acquired within seven years of graduation.

The above Incubator award was the second time the Sid Martin has won this award, the only incubator to do so in the 31 year history of the award.





# UF #3 Technology Transfer University

- Concept to Commercialization: The Best Universities for Technology Transfer
- A new *Milken Institute* research report highlights the vital role played by research universities and argues research funding should be a top priority for enhancing economic growth in the United States.
- The report 'Concept to Commercialization: The Best Universities for Technology Transfer' ranks more than 200 U.S. research institutions. The Index focuses on four key indicators of technology transfer success: patents issued, licenses issued, licensing income, and start-ups formed. Further, to address the productivity of commercialization activity, it normalizes each of these outcome measures by research expenditures at each institution.
- **From the report t**he University of Florida is third, up from fifth in 2006. At 97.81, the University of Florida is just 0.12 points below Columbia. Many are aware of the tremendous source of income that Gatorade provided the university, but Florida's overall success is due to much more than one product. Over the past four years reported in the AUTM survey, Florida generated 395 patents, 547 licenses, \$127.9 million in income, and 62 start-ups.



#### UNIVERSITY OF FLORIDA STATEWIDE ECONOMIC IMPACT : FY 2014-2015



#### TECHNOLOGY LICENSING FROM UF









# ViewRay – UF cancer treatment spinoff

- ViewRay designs, manufactures, and markets the MRIdian® radiation therapy system which employs MRI-based technology to provide real-time imaging that clearly defines the targeted tumor from the surrounding soft tissue and other critical organs during radiation treatment.
- MRIdian allows physicians to record the level of radiation exposure that the tumor has received and adapt the prescription as needed.
- ViewRay believes this combination of enhanced visualization, online adapting and accurate dose recording will significantly improve the safety and efficacy of radiation therapy, leading to better outcomes for patients.





ViewRay

## Full Year 2016 Highlights:

- Total revenue of \$22.2 million, up from \$10.4 million in 2015
- Received 13 new orders for MRIdian Systems, totaling \$77.0 million, up from 7 new orders totaling \$40.1 million 2015
- Venture investors include: Aisling Capital, Fidelity Investments, Kearny Venture Partners and OrbiMed
- ViewRay went Public on Apr 10, 2015. Total Equity Funding of \$181.99M in 10 Rounds from 6 Investors



## Entrinsic Health Solutions, Inc.

## Harnessing the power of amino acids

- Innovative consumer healthcare company developing and commercializing first-in-class solutions | Proprietary amino acid platform addressing multi-billion dollar markets
  - Founded in 2012, headquartered in Norwood, MA with R&D laboratory at University of Florida
  - Seasoned management team & world class advisory board
  - Proprietary, customizable amino acid based formulations that promote healthy epithelium via 3 distinct mechanisms of action
  - Established human clinical proof-of-concept in 2 programs and extensive preclinical supporting evidence across robust pipeline

### • Initial focus around 3 key areas of consumer health

- Oncology (supportive care)
- Digestive health (in collaboration with Johnson & Johnson)
- Medical rehydration





**Entrinsic Health Solutions, Inc.** Harnessing the power of amino acids

- Executing initial commercial launch in the U.S. oncology market with its flagship advanced oncology formula, enterade<sup>®</sup>
  - Regional launch program initiated in Florida, with subsequent expansion in key cancer care states (i.e. Texas, Massachusetts)

## Robust R&D pipeline across different epithelial tissues

- Skin care (severe dry skin (eczema), anti-aging)
- Pulmonary (cystic fibrosis, chronic obstructive pulmonary disease, asthma)
- GI tract (inflammatory bowel disease, pediatric short bowel syndrome)
- Animal health (scours (diarrhea) in calves and piglets)

### • \$22.1 million raised to date



### **Initial Validation Studies**

#### **Preclinical and clinical supporting studies**

Study	Year	Туре	Key Findings
Ĭċ	2014	Preclinical	Improved hydration in damaged GI tract compared to glucose-containing beverage
University of Florida	2015	Preclinical	Unique amino acid combinations with electrolytes provide more efficient sodium absorption
NASA	2014	Preclinical	Specific amino acids <b>provide increased crypt</b> cell count and villous height
	2016	Preclinical	Specific amino acids provide <b>GI tract barrier</b> restoration
Iowa State	2015	Preclinical	Specific amino acid <b>decrease mortality and</b> <b>diarrhea in PEDV</b> (porcine epidemic diarrhea virus) inflicted pigs
	2016	Preclinical	Specific amino acids <b>reduce asthma related</b> <b>inflammation</b> and improve airway hyper responsiveness
21st Century Oncology	2016	Clinical	Oncology patients reported significant composite score <b>improvement in diarrhea</b> , <b>dehydration</b> <b>and weight maintenance</b> following cytotoxic treatments
U.S. ARMY	2016	Clinical	Unique amino acid formulation provides <b>superior</b> <b>whole body hydration</b> and fluid volume and retention <b>compared to Gatorade</b>

#### Summary



**Optimal amino acid formulations have been identified** that deliver total hydration, cellular regeneration, and barrier restoration



The  $A_2CT^{TM}$  platform is a **highly customizable transport system** that addresses multiple target conditions and disease states



Scientific evidence supports mechanism of action, efficacy, and safety across a range of studies



# enterade<sup>®</sup> Advanced Oncology Formula

## The newest advancement in supportive care in oncology

- A new amino acid-based medical food product for alleviation of GI toxicity associated with cancer therapy
- Commercial launch initiated in Florida (initial market sampling program in Q3 2016 regional commercial launch in early 2017), with subsequent expansion in key cancer care states (i.e. Texas, Massachusetts) | Commercial channels: specialty pharmacies and direct-to-consumer e-commerce
- 2800 cancer patients have used enterade<sup>®</sup> to date
- 150 oncology clinics are using enterade<sup>®</sup> and 500 HCP are recommending the product







## Working Together For A Better Tomorrow



