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Committee Meeting: 5/14/2014

Board Meeting: 5/15/2014 Austin, Texas

Wallace L. Hall, Jr., Chairman Ernest Aliseda Alex M. Cranberg R. Steven Hicks Jeffery D. Hildebrand

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### 1. U. T. M. D. Anderson Cancer Center: Approval to enter into Collaboration Agreement and Amended and Restated Operating Agreement with Noliva Therapeutics, LLC and delegation of authority to the President of U. T. M. D. Anderson Cancer Center to execute documents and take other actions as necessary

# RECOMMENDATION

The Chancellor concurs in the recommendation of the Executive Vice Chancellor for Health Affairs, the Vice Chancellor for Research and Innovation, the Interim Vice Chancellor and General Counsel, and President DePinho that authorization be granted by the U. T. System Board of Regents, on behalf of U. T. M. D. Anderson Cancer Center

- a. to enter into a Collaboration Agreement with Noliva Therapeutics, LLC to develop and commercialize SSP Technology, a novel therapeutic modality involving stapled peptides;
- b. to enter into an Amended and Restated Operating Agreement with Noliva Therapeutics, LLC whereby U. T. M. D. Anderson Cancer Center would participate as a member in a manager-managed limited liability company; and
- c. to delegate authority to the President of U. T. M. D. Anderson Cancer Center or his delegate to execute all documents, instruments, and other agreements, following review and approval by the Executive Vice Chancellor for Health Affairs, the Vice Chancellor for Research and Innovation, and the Interim Vice Chancellor and General Counsel, and to take all further actions necessary or advisable to carry out the purpose and intent of, and to accomplish, the foregoing transactions.

# BACKGROUND INFORMATION

U. T. M. D. Anderson is exploring new ways to undertake research collaboration with industry partners and to realize value for its research beyond the traditional invention licensing model. This transaction contemplates that U. T. M. D. Anderson will perform certain research at its cost on behalf of Noliva Therapeutics, LLC (Noliva). In exchange for its research and the intellectual property-related terms granted to Noliva, U. T. M. D. Anderson will obtain an equity interest in Noliva. This approach will provide U. T. M. D. Anderson with the possibility of realizing value for its research through an equity interest.

Noliva was formed in January 2013 by Renato T. Skerlj, Ph.D., and Andrew C. Good, D. Phil., for the purpose of owning, developing, and commercializing a novel therapeutic modality involving stapled peptides (the SSP Technology) invented by Drs. Skerlj and Good and assigned to Noliva. As an early stage company, Noliva needs assistance in developing and advancing the SSP Technology.

The Institute for Applied Cancer Science (IACS) at U. T. M. D. Anderson is interested in assisting Noliva with the development and advancement of the SSP Technology, and hopes to use its expertise and capabilities to develop initial proof of concept for the SSP Technology to demonstrate superiority over existing technologies and to show clinical applicability of this type of modality.

To jointly develop the SSP Technology, it is proposed that U. T. M. D. Anderson and Noliva enter into a Collaboration Agreement, and that U. T. M. D. Anderson receive a 25% interest in Noliva upon entry into an Amended and Restated Operating Agreement. The Collaboration Agreement will delineate the development work that will be performed by IACS at U. T. M. D. Anderson for the benefit of Noliva. U. T. M. D. Anderson's commitment to perform Development Work is capped at \$500,000, with no obligation to continue to perform development work, although it could choose to do so. In exchange, U. T. M. D. Anderson will receive a twenty-five percent (25%) equity interest in Noliva, potentially subject to dilution in the event Noliva attracts outside financing.

All data arising from U. T. M. D. Anderson's development work will be jointly owned by U. T. M. D. Anderson and Noliva, and Noliva will own outright all inventions resulting from U. T. M. D. Anderson's development work. However, the grant of ownership to Noliva is expressly made subject to applicable law and the tax-exempt bond regulations applicable to U. T. M. D. Anderson's bond-financed buildings. If outright assignment of the inventions to Noliva is not permitted, then Noliva will be granted a royalty-free, nonexclusive license to the invention with an option to negotiate an exclusive, royalty-bearing license. Under either the grant of ownership or the licensing scenario, U. T. M. D. Anderson will have the right to use the invention for internal, noncommercial research, academic, and patient care purposes.

### 2. <u>U. T. System: Approval of \$12.1 million over three years (Fiscal Years 2015-2017)</u> from the Available University Fund to support the three initiatives of the U. T. System Innovation Framework 2014: a) implementation of a U. T. System Entrepreneurship Academy, b) construction of a U. T. Systemwide Research Experts Data Warehouse with big data analytics structures, and c) funding for the Texas FreshAIR program

# RECOMMENDATION

The Chancellor concurs with the Vice Chancellor for Research and Innovation and the Vice Chancellor for Strategic Initiatives that the U. T. System Board of Regents approve \$12.1 million from the Available University Fund (AUF) to be deployed over Fiscal Years 2015-2017 to support three initiatives of the U. T. System Innovation Framework 2014 as follows:

- a. \$2.7 million over three years for implementation of a U. T. System Entrepreneurship Academy;
- b. \$5.54 million over three years for construction of a U. T. Systemwide Research Experts Data Warehouse with big data analytics structures; and
- c. \$3.86 million over three years for the Texas FreshAIR program.

# BACKGROUND INFORMATION

The U. T. System research and commercialization engine drives \$2.5 billion in Research and Development expenditures; receives a U.S. patent every two days; signs a commercialization agreement every three days; and starts a new company every nine days. To advance this discovery enterprise, Innovation Framework 2014 aims to advance discovery, inter-institution research collaboration, and commercialization within the U. T. System institutions through three initiatives described below.

### Initiative 1: Implementation of a U. T. System Entrepreneurship Academy

In response to recommendations from the Chancellor's Technology Commercialization and Industry Cabinet, the proposed U. T. System Entrepreneurship Academy will be a multigeographical site consortium that will provide mentored programs for U. T. System students and faculty who wish to develop inventions into the commercial space, likely through start-up companies. Sites will be selected through a Request for Proposal process, solicited from all U. T. System institutions, and funded through a grant-like process overseen by the U. T. System Office of Technology Commercialization. Key funding criteria will include:

 The ability to provide educationally sound, innovative, team-based educational experiences that will lead to capstone outcomes, such as applying for National Institutes of Health-funded Small Business Innovation Research or Small Business Technology Transfer funding and/or participating in Systemwide business plan competitions with an opportunity to gain the interest of investors and advisors;

- 2. Direct and sustained mentorship by successful local entrepreneurs;
- 3. The ability to provide the educational experience to a multi-institution audience;
- 4. The ability to accelerate entrepreneurship in Science, Technology, Engineering and Mathematics (STEM) fields or other fields of excellence; and
- 5. An emphasis on health-academic collaborations, e.g., mobile health care apps, software technology, medical devices, and innovative, low capital intensive projects.

Both in-person and blended/online methodologies are desirable.

# Initiative 2: Construction of a U. T. Systemwide Research Experts Data Warehouse with big data analytics structures

There is currently no systematic accounting of the "research products" emerging from ongoing research and commercialization missions across the U. T. System. To understand research "product inventory," the current capabilities of the U. T. System Productivity Dashboard will be extended through the creation of a Research Experts Data Warehouse with big data analytics structures that serve many stakeholders.

- <u>Phase 1</u> of this initiative will utilize publicly available data from federal and state search engines, data from currently implemented SciVal and Academic Analytics at the health and academic institutions, respectively, and data that the Office of Strategic Initiatives (OSI) currently has in the SAS database (timeframe for Phase 1 deliverables is 18 months after approval and funding). Deliverables are to include:
  - Business and Industry Search Engine A central site that can be easily queried using keyword searches to allow business and industry to easily search for and contact experts within the U. T. System.
  - Internal Collaborations Engine A central site for academic and health institutions allows for more in-depth querying of data to facilitate collaborations within an institution and across the U. T. System institutions.

Both engines will provide more exposure of university achievements by highlighting researchers' accomplishments through the public display of faculty profiles to other universities, industry, governmental agencies, and to the public.

<u>Phase 2</u> will focus on data discovery unique to each U. T. System institution and inclusion of the data into the warehouse (timeframe for deliverables is 30 months after approval and funding). OSI staff will lead the data discovery effort and will work with data stewards at the 15 U. T. System institutions to ensure all data are captured. Deliverables include a catalog of locally held data at U. T. System institutions, incorporation of all new data into the research data collection to complete a fully constructed warehouse, and expanded collaboration and query tools. In addition, Phase 2 will include exploration of the potential to automate updates to the U. T. System central database through live connections to existing systems within institutional Offices of Sponsored Projects.

### Initiative 3: Funding for Texas FreshAIR

Texas Fresh**AIR** (**A**cademia-Industry **R**oundtable) is a strategic initiative launched in late 2012; its first phase focused on fostering collaborations between the pharmaceutical industry and the U. T. System health institutions. Texas FreshAIR was successful in bringing 11 major biopharmaceutical companies to the table and harvested 23 recommendations to enhance U. T. System-industry partnerships in the areas of biopharmaceuticals and biomedical engineering devices.

The new initiative will implement two prioritized recommendations, including 1) the creation of a centralized network and "hub and spoke model" for clinical trials across U. T. System to enhance speed and decrease administrative complexity for trial initiation and management and to increase the number of multisite clinical trial, and 2) implementation of regional and statewide FreshAIR events that connect U. T. System researchers and students with the life sciences industry.

#### 3. <u>U. T. System: Update on the U. T. Horizon Fund portfolio, including discussion of</u> recent investment in Lynx Laboratories, Inc.

### **REPORT**

Mr. Jeet Vijay, Interim Executive Director of Technology Commercialization, will report on the progress of the U. T. Horizon Fund portfolio. He will also discuss a recent investment in Lynx Laboratories Inc., a U. T. Austin startup company. Lynx Laboratories, Inc. previously presented to the Committee on May 8, 2013.

### 4. U. T. System: Report on a commercialization success story, Apollo Endosurgery, Inc.

# <u>REPORT</u>

Mr. Jeet Vijay, Interim Executive Director of Technology Commercialization, will introduce Mr. Dennis L. McWilliams, CEO and Founder of Apollo Endosurgery, Inc., to provide a brief overview of Apollo Endosurgery, Inc., a commercialization success story.

Mr. McWilliams will briefly discuss the growth and success of Apollo Endosurgery, Inc., highlighting the following points:

- Acquired the obesity division of Allergan Health, which includes the world's leading obesity treatment device, the LAP-BAND® system;
- Will generate in excess of \$100 million in revenue and will sell its products in over 100 countries and support over 120 direct jobs;
- Importance of seed funding in early stage life sciences and role of the U. T. Horizon Fund; and
- Challenges in creating university based startups.

### BACKGROUND INFORMATION

Apollo Endosurgery, Inc. is dedicated to revolutionizing patient care through the development of endoscopic surgery, which is emerging from the convergence of laparoscopic surgery and therapeutic gastroenterology.

The company was cofounded with a unique collaboration of physicians from the Mayo Clinic, Johns Hopkins University, the Medical University of South Carolina, The University of Texas Medical Branch at Galveston, and the Chinese University of Hong Kong. U. T. Medical Branch -Galveston helped create the company with Mr. McWilliams and provided early seed capital.