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Committee Meeting: 8/19/2015

**Board Meeting:** 8/20/2015 Austin, Texas

Wallace L. Hall, Jr., Chairman Ernest Aliseda Alex M. Cranberg Brenda Pejovich Sara Martinez Tucker

	Committee Meeting	Board Meeting	Page
Convene	11:30 a.m. Chairman Hall		
U. T. System Board of Regents: Discussion and appropriate action regarding Consent Agenda items, if any, referred for Committee consideration	11:30 a.m. Action	Action	315
2. U. T. M. D. Anderson Cancer Center: Report on activities related to development of industry research partnerships that advance funding and capabilities in discovery of cancer drugs and therapeutics	11:31 a.m. Report/Discussion President DePinho Dr. Hurn	Not on Agenda	316
3. U. T. Austin: Report on activities related to development of industry research partnerships that advance funding and capabilities of the discovery mission	11:40 a.m. Report/Discussion President Fenves Dr. Hurn	Not on Agenda	330
4. U. T. System: Discussion and appropriate action regarding proposed revision of Regents' <i>Rules and Regulations</i> , Series 90000, concerning Intellectual Property, to amend and combine Rules 90101 - 90106 into a new Rule 90101	11:50 a.m. <b>Action</b> President Karbhari Dr. Hurn	Action	340
5. U. T. System: Update on the U. T. Horizon Fund portfolio	12:00 p.m. Report/Discussion Ms. Goonewardene	Not on Agenda	360
6. U. T. System: Allocation of \$10 million of Available University Funds for the U. T. Horizon Fund	12:20 p.m. <b>Action</b> Dr. Hurn Ms. Goonewardene	Action	373
Adjourn	12:30 p.m.		

### 1. <u>U. T. System Board of Regents: Discussion and appropriate action regarding Consent Agenda items, if any, referred for Committee consideration</u>

#### **RECOMMENDATION**

The proposed Consent Agenda is located at the back of the book.

2. <u>U. T. M. D. Anderson Cancer Center: Report on activities related to development of industry research partnerships that advance funding and capabilities in discovery of cancer drugs and therapeutics</u>

#### **REPORT**

President DePinho will report on activities at U. T. M. D. Anderson Cancer Center related to development of industry research partnerships that advance funding and capabilities in the discovery of cancer drugs and therapeutics. President DePinho's presentation is set forth on the following pages.

# Innovative Partnerships, Agreements, and Sustainability

U. T. System Board of Regents' Meeting Technology Transfer and Research Committee August 2015

Ronald DePinho, M.D. President, U. T. M. D. Anderson Cancer Center



# Building a Sustainable Future To Fulfill Our Mission

Increased Expenses



Decreased Reimbursement



Decreased Grant Funding



Limited Mission Support

#### Proactive measures can close the gap:

- Diversify our revenue stream
- Enhance translation of discoveries via collaboration with the private sector through:
  - Strategic Alliances with Big Pharma
  - Risk-sharing agreements with smaller biotechs
  - Asset Development Corporations (ADCo) for individual drug candidates
  - New Company (NewCo) formation
  - Creative, best-in-class deal structures that maximize value and allow us to retain control
- Move from one-off deals to multi-trial, long-term, innovative agreements

D Anderson

THE UNIVERSITY OF TEXAS

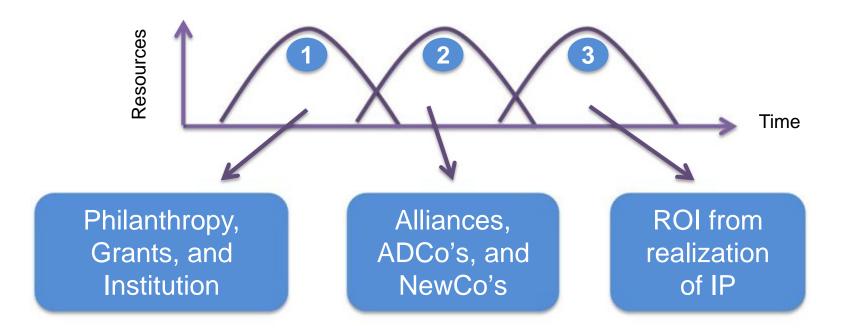
# Fulfilling Our Solemn Responsibility To Our Patients, Future Generations

"Knowing is not enough; we must apply. Willing is not enough; we must do."



Johann Wolfgang von Goethe

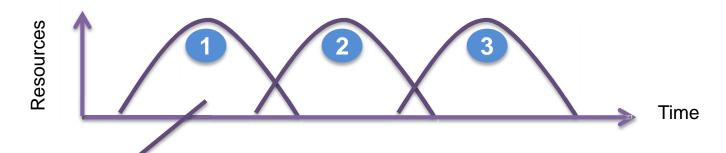
# Developing a Sustainable Model for Mission Support



The most important "return" = increasing number of novel agents for our patients



# Developing a Sustainable Model for Mission Support (cont.)

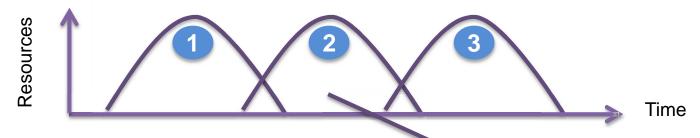


Philanthropy, Grants, and Institution Philanthropy, grants, and institutional support are fundamental to achieve "escape velocity"

- Explore and validate new ideas
- Retain control to ensure more accurate clinical development
- Avoid premature birth of new companies and partnerships



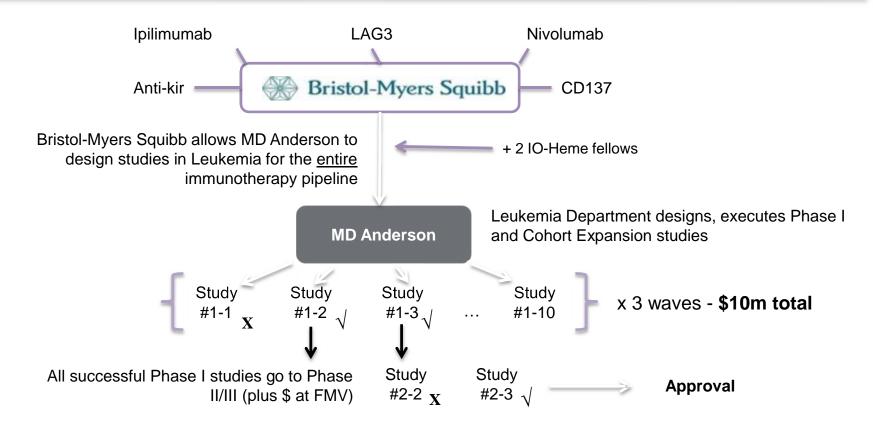
# Developing a Sustainable Model for Mission Support (cont.)



- Efficient translation requires productive collaboration with private sector.
- Achieved via Strategic Alliances with Big Pharma, risksharing agreements with smaller biotechs, ADCo's for individual drug candidates, or NewCo formation.
- All arrangements are guided by our conflict of interest rules to preserve research integrity and the safety of our patients.

Alliances, ADCo's, and NewCo's

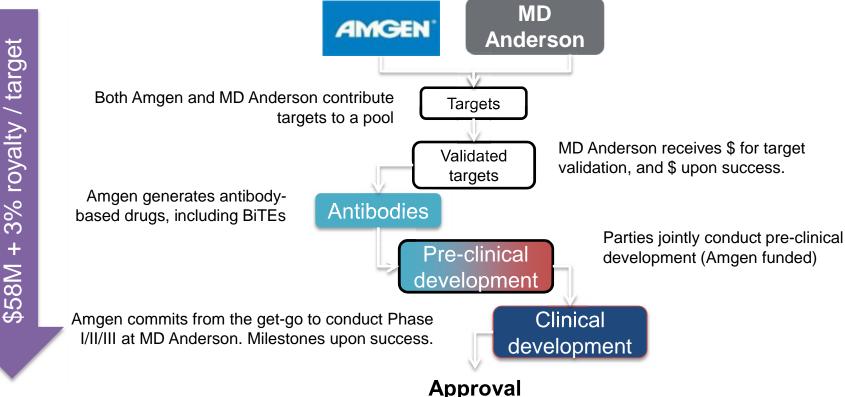
## Strategic Alliance in Leukemia Securing the Bristol-Myers Squibb Pipeline



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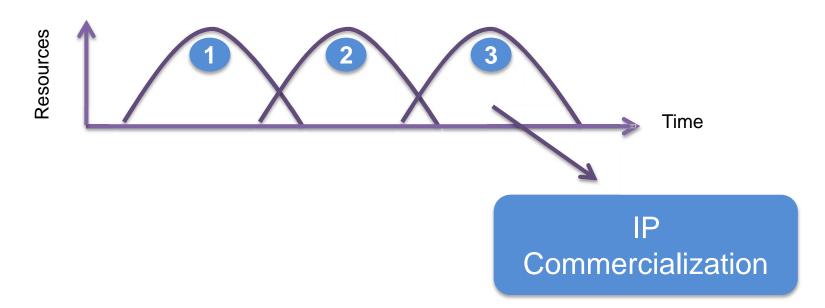
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## Strategic Alliance with Amgen Harnessing Proteomics, Novel Drug Platform





# Developing a Sustainable Model for Mission Support (cont.)





## We're Establishing a Track Record



- 8F4 antibody for myeloid malignancies (pre-IND)
- \$26m in exchange for option to negotiate at FMV in three years



- OX40 immune checkpoint agent (pre-IND)
- \$355m in milestones and singledigit royalty

### INTREXON®

- "Sleeping Beauty" Intellectual Property estate for CAR T-cells
- \$100m upfront + \$45m in funded research





# IP is Being Generated and/or Matured by MD Anderson Platforms

Invest in Business Development



Increase and Develop Faculty Entrepreneurs



Create Professional Platforms

#### **Moonshot Platforms**

Institute for
Applied Cancer
Science
small molecule

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ORBITbiotherapeutics ACT Cellular therapy

Center for Co-clinical Trials

**Drug Discovery and Testing** 

Immunotherapy Monitoring

**Proteomics** 

Research genomics

Clinical genomics

**Data Generation** 

APOLLO BIG DATA

MD Anderson's Oncology Expert Advisor powered by IBM Watson

**Data Aggregation** 

# Long-term, Collaborative Partnerships Help Us Fulfill Our Mission

- ✓ Provide critical resources to further explore and deliver novel therapies and support all mission areas
- ✓ Provide access to some of the most impactful pipelines in the industry
- ✓ Provide lifesaving clinical trial opportunities that attract patients from around the world and maintains U. T. M. D. Anderson Cancer Center as the leader in researchdriven cancer care



## **Special Thanks To...**

Ferran Prat, Ph.D., J.D., Vice President, Strategic Industry Ventures Giulio Draetta, M.D., Ph.D., Director, Institute for Applied Cancer Science Andrew Futreal, Chair *ad interim*, Genomic Medicine Steve Haydon, Associate Vice President, Legal Services Dan Fontaine, J.D., Executive Vice President, Administration Our world-leading faculty Our patients



3. <u>U. T. Austin: Report on activities related to development of industry research partnerships that advance funding and capabilities of the discovery mission</u>

#### **REPORT**

President Fenves will report on activities at U. T. Austin related to development of industry research partnerships that advance funding and capabilities of the discovery mission. President Fenves' presentation is set forth on the following pages.



### U. T. AUSTIN'S DISCOVERY MISSION

Basic research is the foundation of discovery.

The value of research for society is dramatically increased by translation of discoveries to practice.

Industry sponsored research has a critical role in translation and application as engagement moves from tactical to strategic.

Technology commercialization through licensing or spin-out provides rapid translation of research.

### U. T. AUSTIN INDUSTRY ENGAGEMENT

Research Roadmap Center Funding Master Agreement Joint Licensing Staff Exchange Co-location

Single PI Projects **Proposal Support** Affiliates Programs Equipment/Software

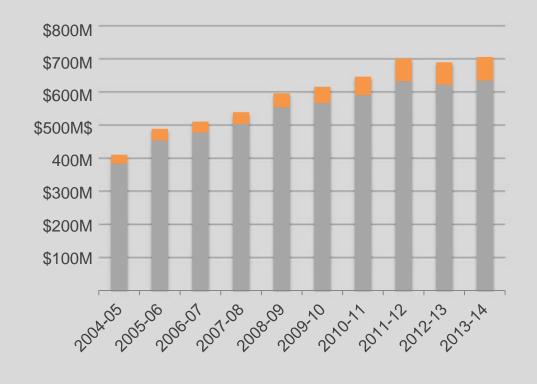
Career Placement Co-op/Internship Seminars/Speakers **Advisory Committees** 

**TRADITIONAL** 

TACTICAL

**STRATEGIC** 

### **R&D EXPENDITURES**



Industry R&D Expenditures

Total R&D Expenditures

### INDUSTRY FUNDING ENERGY SECTOR



Total funding of \$9M over nine years



Multicompany collaboration of >\$50M to date



Funding increased from \$123K in 2003 to \$2.4M in 2013



Invested more than \$3M to date



Multiyear commitment ~ \$5M to date, \$7.5M total over five years

### INDUSTRY FUNDING NON-ENERGY SECTOR



Funding doubled from 2013 to 2014



National Science Foundation Nanosystems Engineering Research Center

- \$775K in annual membership dues paid to NASCENT by 14 industrial partners since Center's creation in Septempber 2012
- Additional \$731K in directed research projects awarded, several from Raytheon
- Leading U. T. Austin's effort to participate in a \$150M+ Flexible
   Hybrid Electronics Manufacturing Innovation Institute

### TECHNOLOGY COMMERCIALIZATION

#### In the past 10 years

- ~1,580 invention disclosures
- \$140M in licensing revenue
- 2,400+ U.S. and foreign patent applications filed
- 64 startup companies 48 in Texas

#### Fiscal Year 2013-2014

- 205 invention disclosures
- \$17.1M in licensing revenue
- 264 U.S. and foreign patent applications filed
- 7 startup companies all in Texas

### ENTREPRENEURAL SUCCESS

#### Molecular Imprints: a nanotech spinout

- Developed at U. T. Austin in 1998; acquired by Canon Corp. in 2014
- Has created 120+ high tech jobs in Austin

## Aeglea BioTherapeutics: drug therapies to fight cancer and inborn errors of metabolism

- Founded in December 2013 by U. T. Austin Professor George Georgiou and Dr. David Lowe
- Raised \$55M in venture financing; been awarded a \$19.8M product development grant from the Cancer Prevention and Research Institute of Texas

#### Drug Dynamics Institute (DDI) in the College of Pharmacy

- A university core lab + service center that provides preclinical drug development services and infrastructure
- THERAPEUTEX (DDI's service core) has generated more than \$300K in revenue in 2013-2014

### RESEARCH IMPACT

Basic research + translation = IMPACT

Research mission is inextricably linked with education mission: training next generation of discoverers.

Good progress in moving from tactical industry engagement to strategic but much more to be done.

Entrepreneurship is becoming the dominant mode of translation of new ideas, and U. T. Austin is positioned to become a leader.

4. <u>U. T. System: Discussion and appropriate action regarding proposed revision of Regents' Rules and Regulations, Series 90000, concerning Intellectual Property, to amend and combine Rules 90101 - 90106 into a new Rule 90101</u>

#### RECOMMENDATION

The Chancellor, the Executive Vice Chancellor for Academic Affairs, and the Executive Vice Chancellor for Health Affairs concur in the recommendation of the Vice Chancellor for Research and Innovation and the Vice Chancellor and General Counsel that the U. T. System Board of Regents approve proposed revision of Regents' *Rules and Regulations*, Series 90000, concerning Intellectual Property, to amend and combine Rules 90101 - 90106 into a new Rule 90101, which is set forth on Pages 341 - 355.

Vice Chancellor Hurn and U. T. Arlington President Karbhari, Co-Chair of the Board of Regents' Task Force on Intellectual Property Issues, will summarize the intent and detail surrounding the proposed revised Regents' *Rules and Regulations*. President Karbhari's presentation is set forth on Pages 356 - 359.

#### **BACKGROUND INFORMATION**

The Task Force on Intellectual Property (IP) Issues, created by Chairman Foster on February 6, 2014, was charged with examining the intent, rationale, current language, workability, and requirements of the U. T. System Board of Regents' *Rules and Regulations* governing the disposition and management of research-derived IP at U. T. System institutions. The Task Force was also charged with recommending changes or revisions to such Regents' Rules.

Five Task Force meetings were held at U. T. System from March through May 2014, and presentations of the Task Force activities, key findings, and recommendations were made to the Technology Transfer and Research Committee on August 20, 2014, and on February 11, 2015. The Board accepted the report and recommendations of the Task Force on February 12, 2015. Many of the recommendations focused on potential actions unrelated to the Regents' *Rules and Regulations*.

The proposed revisions to the Regents' Rules concerning IP simplify the language, clarify the intent, and shorten the policy, while promoting strong and long-standing industry engagements, fostering a philosophy and culture of innovation, assuring U. T. System continues its leading role in discovery, affirming student ownership of student-created IP, and revising the license and equity revenue split to allow for flexibility and to recognize the importance of balancing multi-investigator and multidisciplinary discovery.

#### 1. Title

Intellectual Property: Preamble, Scope, Authority

#### 2. Rule and Regulation

Sec. 1 Preamble. This intellectual property Rule is intended to serve the public good, promote partnerships with the private sector, encourage innovation, promote the engagement of faculty, staff, and students in research, and foster economic development. The Board of Regents recognizes the high importance of discovery commercialization as a core mission. U. T. System recognizes that it will attract more collaborative research supported by industry if timely and efficient processes exist to manage intellectual property.

This Rule is intended to be adaptable to the highly varied circumstances that characterize the private sector and the portfolio of research at U. T. System institutions. In all cases, U. T. System institutions will strive to enable the ease of intellectual property creation, protection, management, and transfer to the private sector and society within an environment that promotes the highest quality and integrity of academic activity, teaching, and research.

- U. T. System is guided by the following fundamental principles on intellectual property:
- 1.1 The successful deployment of intellectual property developed through teaching, research, discovery, creative activities, and application of knowledge, whether through sponsored research, licensing, or other types of transactions or arrangements, allows for knowledge and technology to be disseminated to benefit the broad public and comports with the mission of the U. T. System;
- 1.2 Sponsored research is very important to the vitality and competitiveness of U. T. System institutions, the State of Texas, and our nation. All U. T. System institutions shall (a) encourage and strengthen

Rule: 90101

university-industry partnerships, (b) efficiently and expeditiously manage intellectual property created from these partnerships, and (c) remain understanding, flexible, and open to the varied circumstances and needs of potential industry sponsors;

- U. T. System institutions should expect that when industry is underwriting sponsored research, industry commences negotiations with the expectation of speed in the execution of critical agreements, clear financial outcomes, and ownership rights in, or appropriate access to, intellectual property resulting from the work;
- 1.4 Sponsored research is frequently tightly integrated with the educational mission at many U. T. System institutions but must not abridge publication and research rights, impinge upon the dissemination of research results, including student theses and dissertations, nor diminish an environment of academic and research integrity;
- 1.5 The primary research-related duties of members of the faculty at U. T. System institutions are to teach, study, investigate, discover, create, disseminate, develop professionally, and infuse new knowledge into their classes and student interaction;
- 1.6 Commercialization of technology enhances the reputation of the U. T. System and enables transformation of knowledge into the marketplace; and
- 1.7 Compliance with all applicable federal laws and regulations, the Texas Constitution, and applicable laws of the State of Texas is essential for successful U. T. System technology commercialization.

- Sec. 2 Ownership of Intellectual Property. Except as set forth in Section 5, the Board of Regents automatically owns the intellectual property created by individuals subject to this Rule, yet recognizes the importance of discovery commercialization. In appropriate circumstances concerning intellectual property resulting from research supported by (a) an entirely private, nongovernmental grant or contract with a nonprofit or for-profit entity, or (b) an entirely private gift or grant to the U. T. System or any U. T. System institution, as set forth in Section 12.1, the U. T. System or a U. T. System institution may enter into an agreement to transfer the Board of Regents' rights in intellectual property to third parties. For purposes of this Rule, intellectual property includes, but is not limited to, any invention, discovery, creation, know-how, trade secret, technology, scientific or technological development, research data, work of authorship and software, regardless of whether subject to protection under patent, trademark, copyright, or other laws.
- Sec. 3 Individuals Subject to this Rule. While students are governed by Section 6, this Rule applies to all persons employed by the U. T. System or any U. T. System institution, as well as to anyone using the facilities or resources of the U. T. System or any U. T. System institution. All individuals subject to this Rule must assign, and do hereby assign, their rights in such intellectual property to the Board of Regents, and such individuals shall promptly execute and deliver all documents and other instruments as are reasonably necessary to reflect the Board of Regents' ownership of such intellectual property. A creator of intellectual property owned by the Board of Regents has no independent right or authority to convey, assign, encumber, or license such intellectual property other than to the Board of Regents. U. T. System institutions may promulgate institutional rules, regulations, or policies defining the course and scope of employment for persons or classes of persons and specifying that authorized outside employment is or is not within an employee's course and scope of employment.
- Sec. 4 Intellectual Property Subject to this Rule. Intellectual property
  (a) developed within the course and scope of employment of the individual, (b) resulting from activities performed on U. T.

  System time or with support of State funds, or (c) resulting from

using facilities or resources owned by the U. T. System or any U. T. System institution (other than incidental use) is owned by the Board of Regents.

- Sec. 5 Intellectual Property Not Subject to this Rule. Intellectual property developed or created by a U. T. System employee outside the course and scope of employment of the individual that is developed or created on his/her own time and without the support of the U. T. System or any U. T. System institution or use of U. T. System facilities or resources, is the exclusive property of the creator.
- Sec. 6 Students and Intellectual Property. A student enrolled at a U. T. System institution, such as in an undergraduate or graduate degree program or certificate program, including a postdoctoral and predoctoral fellow, owns the intellectual property he or she creates (a) in courses, (b) during extracurricular activities, and (c) while using the resources and facilities of U. T. System institutions commonly provided for a student's use and for which a student has paid tuition and fees, unless:
  - 6.1 The student is also an employee of the U. T. System or any U. T. System institution and the intellectual property is developed within the course and scope of his or her employment, in which case the provisions of this Rule relating to employees shall apply;
  - 6.2 The student works on a work-for-hire or institutional project as described by Section 8, in which case Section 8 governs that work;
  - 6.3 The student participates in a research project where any intellectual property created under that project has already been committed to, or encumbered by an agreement with, a governmental, philanthropic, corporate or other sponsor, including a sponsor as described in Section 12.1; or
  - 6.4 The student jointly creates the intellectual property with a non-student, in which case this Rule (other than Section 6) and applicable law dictate ownership

of the intellectual property as if the student was a nonstudent described in Section 3.

Sec. 7 Interest in Certain Copyrights. Notwithstanding Section 2 but subject to Section 12, the Board of Regents will not assert an ownership interest in the copyright of scholarly or educational materials, artworks, musical compositions, and literary works related to the author's academic or professional field, regardless of the medium of expression. Such creators are encouraged to manage their copyrights in accordance with the guidelines concerning management and marketing of copyrighted works consistent with applicable institutional policies.

As the Board of Regents has done historically, as reasonably required for the limited purpose of continuing an institution's scheduled course offerings, the Board of Regents retains for one year following the loss of a course instructor's services a fully paid-up, royalty-free, nonexclusive worldwide license to use, copy, distribute, display, perform, and create derivative works of materials prepared by the instructor (including lectures, lecture notes, syllabi, study guides, bibliographies, visual aids, images, diagrams, multimedia presentations, examinations, web-ready content, and educational software) for use in teaching a course.

- Sec. 8 Works for Hire and Institutional Projects. Notwithstanding any provisions of Sections 6 or 7 to the contrary, the Board of Regents shall have sole ownership of all intellectual property created by (a) an employee, student, or other individual or entity commissioned, required, authorized, or hired specifically to produce such intellectual property by the U. T. System or any U. T. System institution, and (b) an employee, student, or other individual as part of an institutional project. The provisions of Section 11.5 shall not apply to intellectual property governed by this Section unless approved by the institution or U. T. System Administration in a written agreement.
- Sec. 9 Use of Research Data. Research data or results created by an employee are owned by the Board of Regents and except to the extent that rights to such research data are contractually assigned or licensed to another by the Board of Regents, the

creator shall have a nonexclusive license to use such data for patient care, teaching, scholarly, and other academically related purposes and nonprofit research, provided such activities are within the scope of the employee's employment.

Sec. 10 Use of Facilities and Resources. Other than in connection with student-owned intellectual property governed by Section 6, U. T. System and U. T. System institution facilities and resources may not be used (a) to create, develop, or commercialize intellectual property outside the course and scope of employment of an individual, or (b) to further develop or commercialize intellectual properties that have been released to an inventor by the Board of Regents under Section 11.2, except as the institution's president may approve in writing where the U. T. System retains an interest under the terms of the release.

#### Sec. 11 Invention Disclosure and Commercialization.

- 11.1 Determination of the Board of Regents' Interest.
  Before intellectual property owned by the Board of Regents is disclosed to any party outside the U. T. System, to the public generally, or for commercial purposes, and before publishing same, the creator shall submit a reasonably complete and detailed invention disclosure of such intellectual property to the president (or designee) of his or her institution for determination of the Board of Regents' interest. The institution will regularly and promptly communicate with the creator during this decision-making process and the creator shall not proceed with any disclosure, commercialization, or publication until that decision is made.
- 11.2 Election Not to Assert Ownership Interest. If the institution's president elects not to assert the Board of Regents' ownership interest, the institution's president shall notify the U. T. System Office of General Counsel and the primary creator in writing within 20 business days after the decision is made that the institution will release the intellectual property to the creator, except where prohibited by law or contractual

obligations or requirements. Thereafter, the creator will be free to obtain and exploit a patent or other intellectual property protection in his or her own right and the U. T. System and U. T. System institutions shall not have any further rights, obligations, or duties with respect thereto except that, in appropriate circumstances, the institution's president may elect to (a) retain income rights, and (b) impose certain limitations or obligations, including, but not limited to, a nonexclusive license for the creator, U. T. System, and any U. T. System institution to use the released invention for patient care, teaching, scholarly, and other academically related purposes, nonprofit research, and to comply with United States government reporting and license requirements.

- 11.3 Later Release of Invention. Except where prohibited by law or contractual obligations or requirements, the institution's president may elect to release an invention to its creator at any time after asserting the Board of Regents' ownership interest, with notice to the U. T. System Office of General Counsel; however, such release must include provisions for the recovery by U. T. System of any patent and licensing expenses as well as the retention of income rights by U. T. System, and may include certain limitations or obligations, including those set forth in Section 11.2.
- 11.4 Protection and Commercialization of Intellectual Property. With respect to intellectual property in which the Board of Regents asserts an interest, the institution's president, or his or her designee, shall decide how, when, and where the intellectual property is to be protected and commercialized. The institution may contract with outside counsel for legal services with the prior consent of the Vice Chancellor and General Counsel and, if required by law, the approval of the Attorney General.
- 11.5 Reimbursement of Licensing Costs and Allocation of Income. In those instances where the U. T. System

or any U. T. System institution licenses rights in intellectual property to third parties, the costs of licensing, including, but not limited to, the costs to operate and support a technology transfer office and the costs of obtaining a patent or other protection for the property on behalf of the Board of Regents must first be recaptured from any royalties or other license payments received by the U. T. System or any U. T. System institution. The remainder of any such income (including, but not limited to, license fees, prepaid royalties, minimum royalties, running royalties, milestone payments, and sublicense payments) shall be divided as follows:

30-50% to creator(s), and 50-70% to U. T. System institutions.

The U. T. System or the U. T. System institution licensing rights in intellectual property to third parties shall decide on a case-by-case basis the allocation of income within these ranges for all creators, with the remainder to be disbursed to and/or retained by the U. T. System or the applicable U. T. System institution. A creator may, however, disclaim his/her interest in such income, in which case the institution shall receive and/or retain the creator's share and shall decide, in its sole discretion, if, how and when to disburse such income. Income received and/or retained by the U. T. System or any U. T. System institution from any intellectual property shall be used by the U. T. System institution where the intellectual property originated.

#### Sec. 12 Sponsored Research.

12.1 Private Sources. Intellectual property resulting from research supported by private sources is owned by the Board of Regents. However, with respect to intellectual property resulting from research entirely supported by (a) a private, nongovernmental grant or contract with a nonprofit or for-profit entity, or (b) a private gift or grant to

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- the U. T. System or any U. T. System institution, if otherwise permitted by this Rule, applicable law and Section 12.3, the U. T. System and U. T. System institutions are permitted and encouraged to negotiate an agreement acceptable to U. T. System Administration or applicable U. T. System institution transferring the Board of Regents' ownership rights or other rights in the intellectual property resulting from such arrangements to the sponsor or the sponsor's designee. Any such agreement shall be negotiated:
- (a) In accordance with the sponsor's needs and preferences, as best may be accomplished;
- (b) With flexibility and adaptability in mind; and
- (c) In a timely, cooperative, and efficient manner.
- 12.2 Public Sources. Intellectual property resulting from research supported by a grant or contract with the government (federal and/or state) or an agency thereof is owned by the Board of Regents.
- 12.3 Nonconformance with Intellectual Property Guidelines. Approval by a U. T. System institution under Section 15.2 of grants and contracts containing ownership and other provisions inconsistent with this Rule and other policies and guidelines adopted by the Board of Regents, including, but not limited to, The University of Texas Systemwide Policy UTS125, Processing of Intellectual Property Agreements is permissible, as it implies a decision that the benefit and value to the U. T. System or any U. T. System institution from receiving the grant or performing the contract outweighs the impact of any nonconforming provisions on the intellectual property policies and guidelines of the U. T. System or any U. T. System institution, such as The University of Texas Systemwide Policy UTS125, Processing of Intellectual Property Agreements.

- Rule: 90101
- 12.4 Conflicting Provisions. Subject to approval as described in Section 12.3, the intellectual property policies and guidelines of the U. T. System or any U. T. System institution are subject to, and thus amended and superseded by, the specific terms pertaining to intellectual property rights included in state and/or federal grants and contracts, or grants and contracts with nonprofit and for-profit nongovernmental entities or private donors, to the extent of any such conflict.
- 12.5 Cooperation with Necessary Assignments. Those persons subject to this Rule whose intellectual property creations result from (a) a grant or contract with the government (federal and/or state), or any agency thereof, (b) a grant or contract with a nonprofit or for-profit nongovernmental entity, or (c) private gift to the U. T. System or any U. T. System institution, shall promptly execute and deliver such documents and other instruments as are reasonably necessary for the U. T. System or any U. T. System institution to discharge its obligations, expressed or implied, under the particular agreement.
- 12.6 Sharing of Royalty Income. In the event that two or more persons who are entitled to share royalty income or equity cannot agree in writing on an appropriate sharing arrangement, the institution's president shall determine that portion of the royalty income (or equity) to which the creators are entitled under the circumstances and such amount will be distributed (or issued) to them accordingly. In the event that the creators are located at two or more U. T. System institutions and cannot agree. such royalty (or equity) distribution decision shall be made by the involved institutions' presidents (or their respective designees). In the further event that the involved presidents cannot agree, then the Chancellor shall decide and his/her decision shall be binding on the creators.
- 12.7 Geographical Scope of Protection. A decision by the U. T. System or any U. T. System institution to seek

Rule: 90101

patent or other available protection for intellectual property covered by Section 9 shall not obligate the U. T. System or any U. T. System institution to pursue such protection in all national jurisdictions. The U. T. System's decision relating to the geographical scope and duration of such protection shall be final.

#### Sec. 13 Equity Interests.

- 13.1 Agreements with Business Entities. The U. T. System or any U. T. System institution may receive equity interests as partial or total compensation for the conveyance of intellectual property rights. The institution where the intellectual property was created may elect, at its sole option and discretion, to share an equity interest, dividend income, or a percentage of the proceeds of the sale of an equity interest with the creator(s). The U. T. System or any U. T. System institution may also receive equity interests in a business entity as consideration for the institution's role as a founder, or for other contributions made to the business entity other than as a licensor, and institution shall not be obligated to share such equity interests with the creator(s). The U. T. System or any U. T. System institution may also, but shall not be obligated to, negotiate an equity interest on behalf of any employee who conceived, created, discovered, invented, or developed intellectual property owned by the Board of Regents that is the subject of an agreement between the U. T. System or any U. T. System institution and a business entity relating thereto.
- 13.2 Creator Holding Equity and Managing Conflict of Interest. Employees of the U. T. System Administration or any U. T. System institution who conceive, create, discover, invent, or develop intellectual property may hold an equity interest in a business entity that has an agreement with the U. T. System or any U. T. System institution relating to the research, development, licensing, or exploitation of that intellectual property only so long as the institution where the intellectual property was developed is in full compliance with the requirement to

have, implement, and enforce for that employee an effective conflict of interest management plan approved by the institution's president, the Office of General Counsel, and the respective Executive Vice Chancellor as set forth in the U. T. System Office of General Counsel's <u>Procedure for Managing Conflicts of Interest</u>. In any case where an actual conflict of interest is found, the employee may be required to divest the equity interest or terminate affected research.

#### Sec. 14 Conflicts of Interest.

- Approval to Serve as Officer or Director. Any individual 14.1 subject to Sections 2, 3, 4, or 8 who conceives, creates, discovers, invents, or develops intellectual property may serve, in his/her individual capacity, as a member of the board of directors or other governing board or as an officer or an employee (other than as a consultant) of a business entity that has an agreement with the U.T. System or any U. T. System institution relating to the research, development, licensing, or exploitation of that intellectual property only so long as the institution where the intellectual property was developed is in full compliance with the requirement to have, implement, and enforce for that individual an effective conflict of interest management plan approved by the institution's president, the Office of General Counsel, and the appropriate Executive Vice Chancellor as set forth in the U. T. System Office of General Counsel's Procedure for Managing Conflicts of Interest. In any case where an actual conflict of interest is found, the individual may be required to terminate the business relationship or the relevant research.
- 14.2 Request for Employee to Serve as Officer or Director. When requested by the Board of Regents, an employee may serve on behalf of the Board of Regents as a member of the board of directors or other governing board of a business entity that has an agreement with the U. T. System or any U. T. System institution relating to the research, development, licensing, or exploitation of

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- intellectual property, but may not accept any consideration offered for service on such board.
- 14.3 Report of Equity Interest and Service as Officer or Director. Any individual subject to this Rule or this Section must report in writing to the president of the institution the name of any business entity in which the person has an interest or for which the person serves as a director, officer, or employee, and shall be responsible for submitting a revised written report upon any change in the interest or position held by such person in such business entity. The U. T. System institution or its office of technology commercialization will file a report by October 1 of each year with the Office of the Board of Regents for transmittal to the Comptroller of Public Accounts as required by Section 51.912 and Section 51.005, Texas Education Code.
- Sec. 15 Execution of Documents Related to Intellectual Property.
  - 15.1 Execution of Agreements. Agreements that grant an interest in the Board of Regents' intellectual property, including, but not limited to, option and license agreements and contracts with corporate sponsors, may be executed and delivered in accordance with the provisions of Regents' Rule 10501, after any required review by the U. T. System Office of General Counsel.
  - 15.2 Agreements That Do Not Conform to the Rules. Any agreement that deviates substantially from this Rule or other policies and guidelines adopted by the Board of Regents, including, but not limited to, The University of Texas Systemwide Policy <a href="UTS125">UTS125</a>, <a href="Processing of Intellectual Property Agreements">Processing of Intellectual Property Agreements</a> may be executed and delivered as set forth above if, in the judgment of the institution's president and after any required review by the U. T. System Office of General Counsel, the benefits from the level of funding for proposed research and/or other consideration from a sponsor, licensee, or other party outweigh any potential disadvantage that may result from the deviation.

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15.3 Delegation of Authority. The Chancellor, the Deputy Chancellor, the appropriate Executive Vice Chancellor, or the Vice Chancellor and General Counsel may execute, on behalf of the Board of Regents, legal documents relating to the Board of Regents' rights in intellectual property, including, but not limited to, assignments of ownership, applications, declarations, affidavits, powers of attorney, disclaimers, and other such documents relating to patents and copyrights; applications, declarations, affidavits, affidavits of use, powers of attorney, and other such documents relating to trademarks; and corporate documents related to the formation of new companies. In addition, the institution's president may execute, on behalf of the Board of Regents, (a) institutional applications for registration or recordation of transfers of ownership and other such documents relating to copyrights, and (b) corporate documents related to the formation of new companies if first reviewed and approved by (i) the U. T. System Office of General Counsel, or (ii) institution's outside counsel working under a U. T. System Office of General Counselapproved outside counsel agreement.

#### 3. Definitions

None

#### 4. Relevant Federal and State Statutes

35 U.S.C. 18 – Patent Rights in Inventions Made with Federal Assistance (The Bayh Dole Act of 1980, as amended)

Texas Education Code Section 51.005 – Reports

Texas Education Code Section 51.912 – Equity Ownership: Business Participation

*Texas Education Code*, <u>Chapter 153</u> – Centers for Technology Development and Transfer

## The University of Texas System Rules and Regulations of the Board of Regents

#### 5. Relevant System Policies, Procedures and Forms

Regents' *Rules and Regulations*, <u>Rule 10501</u> – Delegation to Act on Behalf of the Board of Regents

The University of Texas Systemwide Policy <u>UTS125</u>, <u>Processing of Intellectual Property Agreements</u>

U. T. System Office of General Counsel's <u>Procedure for Managing</u> Conflicts of Interest

#### 6. Who Should Know

Administrators Faculty Staff Students

#### 7. U. T. System Administration Office(s) Responsible for Rule

Office of General Counsel

#### 8. Dates Approved or Amended

August 20, 2015 (Rules 90101 - Rule 90106 combined into one new Rule 90101)

#### 9. Contact Information

Questions or comments regarding this Rule should be directed to:

• bor@utsystem.edu

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# Proposed Revisions of Regents' Rules and Regulations, Series 90000, concerning Intellectual Property (IP)

Vistasp Karbhari, Ph.D.

Co-Chair of the Board of Regents' Task Force on Intellectual Property Issues

President, U. T. Arlington

U. T. System Board of Regents' Meeting
Technology Transfer and Research Committee
August 2015



# The Regental Task Force on Intellectual Property Issues

- Purpose: Examine the intent, rationale, language, and workability of the 90000 Series of the U. T. System Board of Regents' Rules and Regulations
- The Task Force recommended the development of new language for the Rules and subsequent presentation of revisions to the Board of Regents for approval
- The Rules should be rewritten to:
  - Promote industry engagement
  - Foster a philosophy and culture of innovation
  - Assure that U. T. System continues its leading role in discovery
  - Enhance brevity, simplicity of language, and clarity of intent
  - Affirm student ownership of student-created IP



# Summary of Proposed Revisions to Series 90000

#### 1. New Preamble and Clarifying Language

- Emphasizes openness to partnerships with the private sector
- Reflects intent to accelerate processes of IP creation, protection, management, and transfer to society
- States that sponsored research is very important to the vitality and competitiveness of U. T. institutions, the State of Texas, and our nation
- Provides that all U. T. institutions shall (a) encourage and strengthen university-industry partnerships; (b) efficiently and expeditiously manage IP created from these partnerships; and (c) remain understanding, flexible, and open to the varied circumstances and needs of potential industry sponsors
- U. T. institutions should expect that when industry is underwriting sponsored research, industry commences negotiations with the expectation of speed in the execution of critical agreements, clear financial outcomes, and ownership rights in, or appropriate access to, IP resulting from the work



# Summary of Proposed Revisions to Series 90000 (cont.)

- Clarifies Position on Student-Owned IP
  - Enrolled students, including pre- and post-doctoral fellows, own the IP created in courses, during extracurricular activities, and while using resources and facilities commonly provided for student use
  - Exceptions are clearly stated: e.g., student employees, works for hire, institutional projects, third-party sponsors, etc.
- 3. Revises the License and Equity Revenue Split
  - New language provides for local decision-making, emphasizing the flexibility necessary to enable better coverage of multi-investigator and multidisciplinary discovery



#### 5. U. T. System: Update on the U. T. Horizon Fund portfolio

#### **REPORT**

Ms. Julie Goonewardene, Associate Vice Chancellor for Innovation and Strategic Investment and Managing Director of the U. T. Horizon Fund, will provide an update on the U. T. Horizon Fund portfolio.

The presentation, set forth on the following pages, will highlight performance and status of entities selected for U. T. Horizon Fund support.

In addition, Slide 10 on Page 370 identifies an exited investment in Cerevast Therapeutics, Inc. On August 8, 2012, U. T. System invested \$100,007.30 from the U. T. Horizon Fund in Cerevast Therapeutics, Inc., a company engaged in improving vascular repair outcomes through innovations in vascular regeneration technology. On May 14, 2015, Cerevast Therapeutics informed the U. T. System Office of Technology Commercialization that it had received negative outcomes following the second interim analysis of the Phase 3 clinical trial and, as a result, had taken steps to shut down the trial. During the ensuing liquidation process, U. T. System received proceeds in the amount of \$23,094.00. The U. T. System Office of the Controller will adjust the financials of U. T. System to reflect a realized loss of \$76,913.30 for the investment in Cerevast Therapeutics, Inc.

Ms. Julie Goonewardene, Associate Vice Chancellor for Innovation and Strategic Investment and Managing Director of the U. T. Horizon Fund

U. T. System Board of Regents' MeetingTechnology Transfer and Research CommitteeAugust 2015



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# Agenda

- Mission and Approach
- U. T. Horizon Fund Team
- Recent Transactions
- Positive Results
- Conclusion



# Horizon Fund Mission and Approach

#### Mission

- Help commercialize innovations of U. T. System institutions
- Generate a positive return on investment

# Approach

- Invest in companies where U. T. System has equity
- Leverage private sector investors
- Advisory services



# **Background and Evolution**

- Established by U. T. System Board of Regents in 2011
- Funded with equal installments of \$10M over 5 years (\$50M in total commitments)
- Three of the five installments have been authorized by the Regents
- The Horizon Fund has invested in 16 companies to date

# Horizon Fund Team

- Julie Goonewardene, Associate Vice Chancellor for Innovation and Strategic Investment, Office of Technology Commercialization
  - Entrepreneur, National Advisory Council on Innovation and Entrepreneurship, American Medical Association, Personalized Medicine Coalition
- Nick Tulloh, Senior Investment Analyst, Office of Technology Commercialization
  - Economic/Finance, pursuing Certified Financial Analyst Designation
- Matt Sorenson, Ph.D., Investment Analyst, Office of Technology Commercialization
  - Molecular genetics, U. T. Venture Lab
- Evan Fitzmaurice, J.D., Office of General Counsel
  - Corporate and securities law











# Horizon Fund Investment Council

- Phyllis Whiteley, Ph.D.
  - Venture Partner with Mohr Davidow Ventures
- Armen Shanafelt, Ph.D.
  - General Partner with Lilly Ventures
- Robert Metcalfe, Ph.D.
  - Founded 3Com Corporation (now part of HP)
- Alex De Winter, Ph.D.
  - Director at GE Ventures











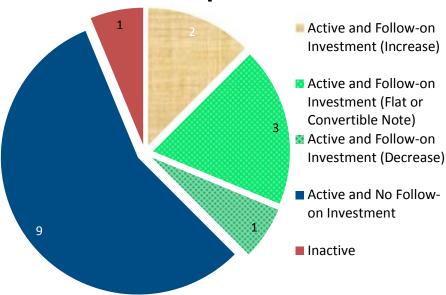
	Business Development Indicators			Financial Strength Indicators	
Company/Variables	Key Regulatory Approvals	Commercial Product	Generating Revenue	Strategic Industry Investors	Strategic Financial Investor
Apollo Endosurgery	✓	✓	✓	✓	✓
Cardiovate					
EMIT Corporation	✓	✓	✓		✓
FibeRio	Not Applicable	✓	✓	✓	✓
Latakoo	Not Applicable	✓	✓		
Lung Therapeutics					
Lynx Labs	Not Applicable	✓	✓		✓
M-87	Not Applicable	✓		✓	✓
MicroTransponder	✓				✓
PLx	✓				✓
Rapamycin Holdings					
Molecular Match	Not Applicable				✓
Aeglea BioTherapeutics				✓	✓
Decisio Health	✓	✓	<u> </u>		
Admittance Technologies					✓



# Performance Analysis

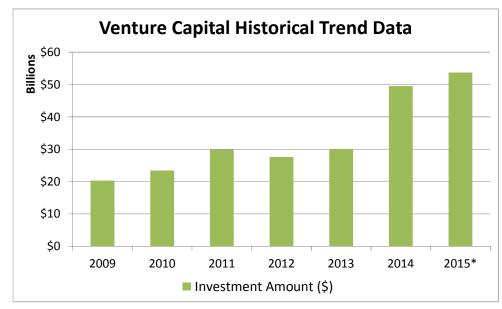
 Approximately 1/3 of the companies in the portfolio have experienced follow-on investment





# Trends in Venture Capital Investing

- 2014 Venture Investment
  - \$48.4B total investment
  - \$8.6B life sciences investment(29% increase over 2013)
  - \$10.9M average life
    sciences deal size
    (32% increase over 2013)

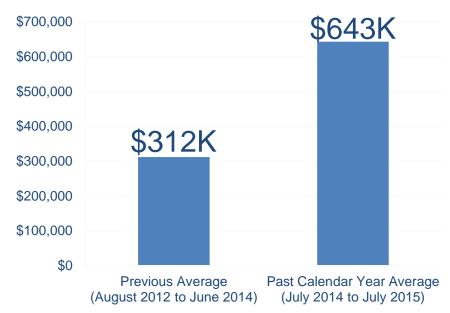


\*2015 is an estimate using first quarter actual data Source: PwC / NVCA MoneyTree™ Report, Data: Thomson Reuters

# **Recent Transactions**

- New Investments:
  - Decisio Health
  - Admittance Technologies
- Follow-on Investments:
  - Lung Therapeutics
  - M87
  - Aeglea BioTherapeutics
- Exited Investments:
  - Cerevast Therapeutics

# Average Investment Size Has Increased



# Positive Results

- Aeglea BioTherapeutics
  - U. T. Austin
  - Developing human enzymes to fight cancer
  - Horizon Fund has invested \$2.2M

### Austin firm Aeglea BioTherapeutics sets IPO, aims to raise \$86 million

O 1:43 p.m. Wednesday, June 17, 2015 | Filed in: Business

Austin biotech company Aeglea BioTherapeutics has decided to go public, filing for an initial public offering of stock.

The company, which develops drug therapies to fight cancer, hopes to raise \$86

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# Conclusion

- Established a lean and efficient team
- Actively investing
- Realizing success
- Poised for future success



# 6. <u>U. T. System: Allocation of \$10 million of Available University Funds for the U. T. Horizon Fund</u>

#### **RECOMMENDATION**

The Chancellor concurs with the recommendation of the Vice Chancellor for Research and Innovation and the Executive Vice Chancellor for Business Affairs that the U. T. System Board of Regents approve and authorize \$10 million from Available University Funds (AUF) as the third allocation under a four-year plan to continue and enhance the goals of the U. T. Horizon Fund. Each year, the funding for the U. T. Horizon Fund is subject to approval and authorization by the Board upon receipt of a satisfactory report of activities undertaken as a result of the previous year's allocation.

#### **BACKGROUND INFORMATION**

The U. T. Horizon Fund, a strategic investment fund for the U. T. System, was initially approved by the Board of Regents on August 25, 2011, and was capitalized with \$10 million of AUF (Phase I). On February 14, 2013, the U. T. Horizon Fund was reauthorized with expanded funding from AUF (Phase II) to be disbursed in four annual installments of \$10 million each. The total committed capital of the U. T. Horizon Fund from both Phase I and Phase II is \$50 million.

The U. T. Horizon Fund's primary mission is to commercialize innovations of U. T. System institutions to generate a positive return on investment. The U. T. Horizon Fund utilizes existing U. T. System rights where possible, leverages the collective resources of private sector investors, enhances partnerships by attending and supporting entrepreneurial events, and strives to add value by connecting entrepreneurs with investors, subject-matter experts, advisors, and potential customers.