New Input Mechanisms into the Commercial Cycle from Universities and Research Institutes

Facilitated Movement of University IP, Translational Research and an Emerging Applied Research Model Leading to Enhanced Delivery of Healthcare

OECD WPB/NESTI Workshop on Biotechnology Impacts and Outputs
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Disclaimer

- Not representative of any official U.S. government position
- Not representative of any U.S. National Academy of Sciences and Engineering position
- Not representative of any official Biotechnology Industry Organization position
- Will not discuss the intracasies of the biotech, pharm and med device industrial tectonic, titanic interactions

Proclaimer

- Current roadblocks to output enhancement from the bioscience academic-industry universe

- Potential solutions
  - Alfred Mann Institutes
  - Data and benchmarks
  - New statistical indicators

U.S. Synopsis

- **September 2006 316 pp Report: "Mind to Market: A Global Analysis of University Biotechnology Transfer and Commercialization"**
  - **DeVol and Bedroussian, Milken Institute**
  - **TT process examined in order to facilitate commercialization and ensure greatest possible returns on public investment**

- **National Institutes of Heath Roadmap for Biomedical Research: Themes**
  - **New Pathways to Discovery**
  - **Research Teams of the Future**
  - **Reengineering the Clinical Research Enterprise**
  - **"The Front Door to Translational Research"**

- **FDA Critical Path to New Medical Products Report**
  - **Better Evaluation Tools**
  - **Biomarkers and Disease Models**
  - **Streamlining Clinical Trials**
  - **Harnessing Bioinformatics**
  - **Moving Manufacturing into the 21 st Century**
  - **Products to Address Urgent Public Health Needs**
  - **At-Risk Populations**

Other Studies

- **Biopharmaceutical Industry Contributions to State and U.S. Economies**

  Ross DeVol, Perry Wong, Armen Bedroussian, Lorna Wallace, Junghoon Ki, Daniela Murphy and Rob Koepp
  October 2004, Milken Institute

- **Capital Access Index 2005: Best Markets for Entrepreneurial Finance and Securitization in Financing Economic Activities**

  James R. Barth, Tong Li, Sangeetha Malaiyandi, Donald McCarthy, Triphon Phumiwasana and Glenn Yago
  October 2005, Milken Institute

- **Business of Innovation: Technology Forecasts**

  November 2005 Battelle

- **Financial Innovations for Accelerating Medical Solutions: A Financial Innovations Lab Report**
  October 2006, Milken Institute

Impediments to Successful Delivery of Health Innovation and Commercialization

- Commercialization “output” from universities has failed to keep pace with research-dollar input
- Interest by faculty to develop research with commercial potential lags behind their desire to perform the search for new knowledge
- Commercial potential of basic research and consequent IP is under-developed and the university, the inventor, and the public provider of research dollars are not receiving the potential benefit of their investments
- Handoff of IP to industry can get bogged down in negotiations, bureaucratic overload, and unrealistic university expectations of returns

	Academia	Industry
Main focus	Generating and disseminating knowledge	Commercialization of ideas for profit
Resources	Limited resources	Often substantial resources available
Financial motivation	Money not the critical incentive for performance	Money important incentive to boost performance
Pace of research	Outcomes driven by desire for high quality research	Time to market and to patient are critical and permeate most every decision
Goals, etc.	Tenure, based on publications not entrepreneurship	Value of research outcome often based mostly on revenue generated
Information exchange	Free exchange of ideas	Intellectual property becomes a predominant corporate asset

The Commercialization of Compelling Ideas is Critical!

- Healthcare innovation fuels entrepreneurial enterprise and is the key to a thriving economy
- As a world, we are failing to develop and commercialize the majority of promising research
- Discoveries that could lead to new medical devices, therapeutic drugs, and other life-saving or life-enhancing technologies are languishing within the walls of our universities…or the university IP resides in the hands of small companies with inadequate capital to expedite it

The Problem: Current Approach to Delivering the Best Science to Patients is Not Optimal

- **$45B spent annually in sponsored research at universities***
- **4,000 patents issued to universities annually**
- **Nearly 30,000 products currently languish 'on the shelf' at universities untapped by traditional tech transfer**
- **11,000 active licenses from universities annually yield only $1B of revenue (a theoretical Return on Investment (ROI) of *less than 3%*)**
  - **Only 25% of universities have 'theoretical ROI' over 1%**
  - **Diversity of university objectives is appropriate; 'theoretical ROI' isn't everything, but it is something; while university goals should remain weighted toward basic research, 'balancing the portfolio' on the commercializable science side also makes sense**

Is there a moral obligation to more effectively translate publicly funded research into products benefiting mankind?

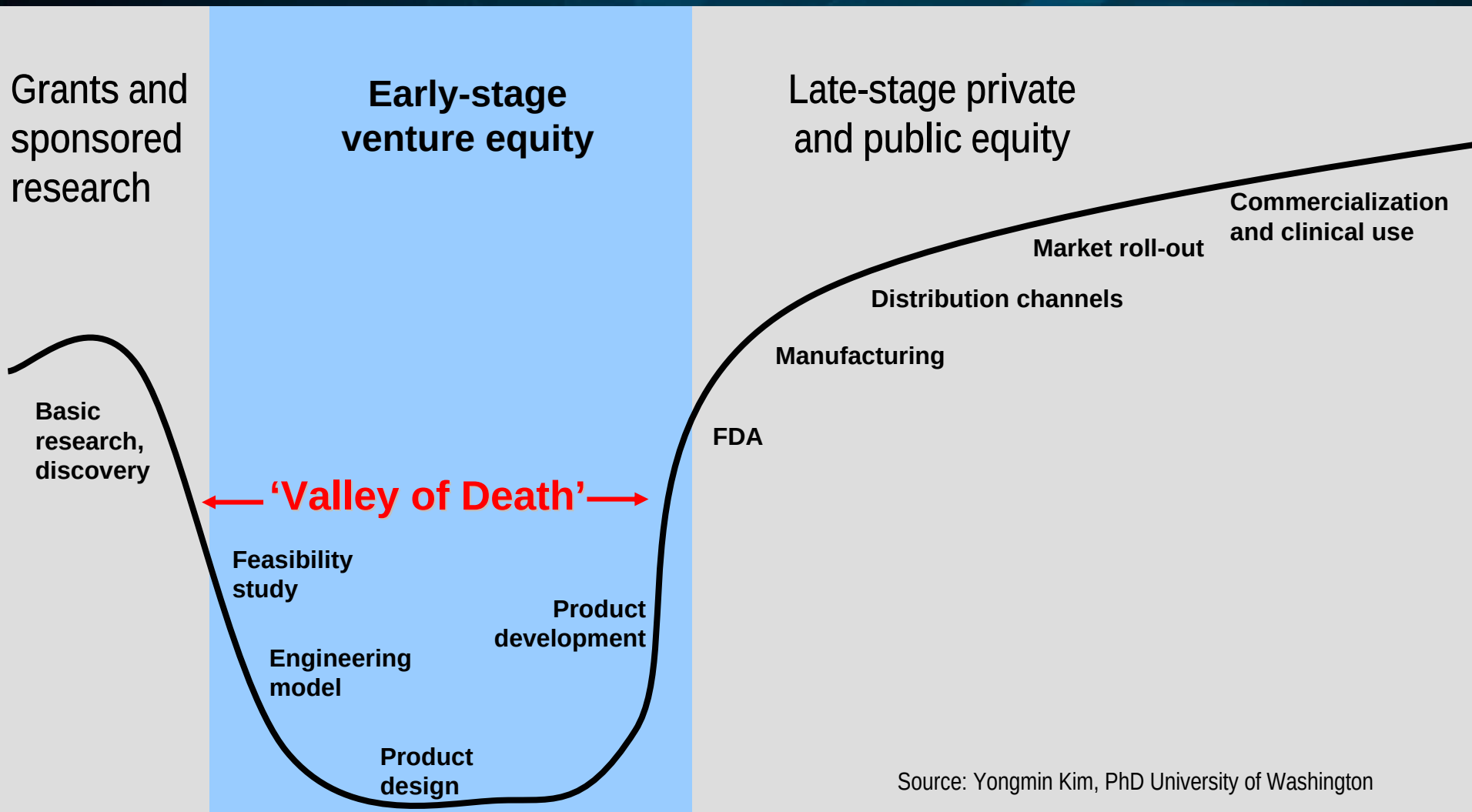
*AUTM Data: Association of University Technology Managers

Changes in the Venture Capital (VC) Industry Exacerbate the Problem

Year	Venture Capital Available	Average VC Fund Size
1975	$1B	$100 M
2005	$300B	$500 M

- **Unprecedented levels of venture cash have built up in VC funds**
- **VCs have traditionally made smaller investments (up to ~ $3M) to 'bridge' the early stage funding gap between university research and commercialization**
- **Today, based on the need to invest larger amounts of cash, venture capital is directed at later stage investments that consequently have higher valuations**
- **This change in VC strategy creates a funding void for universities, and SME's**

The Funding Gap



Source: Yongmin Kim, PhD University of Washington

Solution: Mann Institutes

- $2.1b -> new biomedical product commercialization institutes, initially:
  - 12-15 in the U.S.
  - 3-5 outside the US
- Designed to move IP further along the value chain to expedite delivery to the benefit of the patient and mankind
- ~50 universities to be examined, 2 funded per year at $100m-$200m each with additional $50m in OE each
- 40-70 staff from industry working on highly select projects
- Selection...data…data...benchmarking
- Alfred Mann
- Why?

The Alfred Mann Institutes

Alfred Mann's vision:

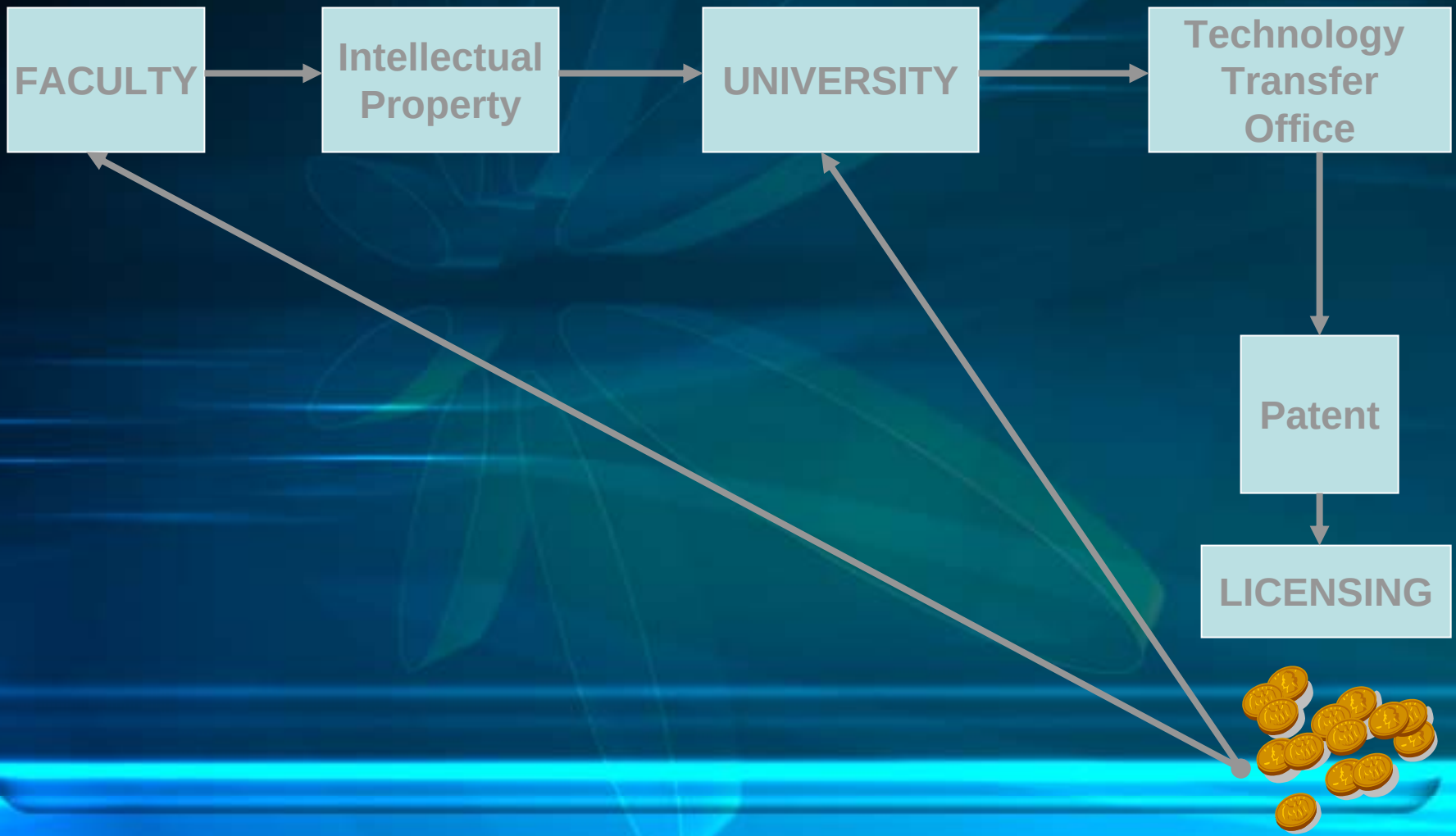
To enhance the flow of university biomedical research of into the stream of commercialization by speeding the transfer of technology.

Alfred Mann's plan:

To create Institutes for Biomedical Development at selected elite universities and to provide the financial and business resources to guide the commercialization of promising research…with funding of $150 m to $200 m each. The Alfred Mann Institute at USC is the first of these, followed by the Technion University, followed by…...

Technology Transfer of Yesterday

OLD MODEL

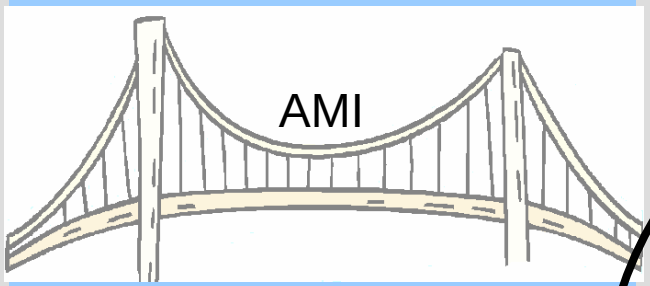


The Funding Gap

Grants and sponsored research

Private equity

Late-stage private and public equity



Basic research, discovery

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Feasibility study

Engineering model

Product design

Product development

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Manufacturing

Distribution channels

Market roll-out

Commercialization and clinical use

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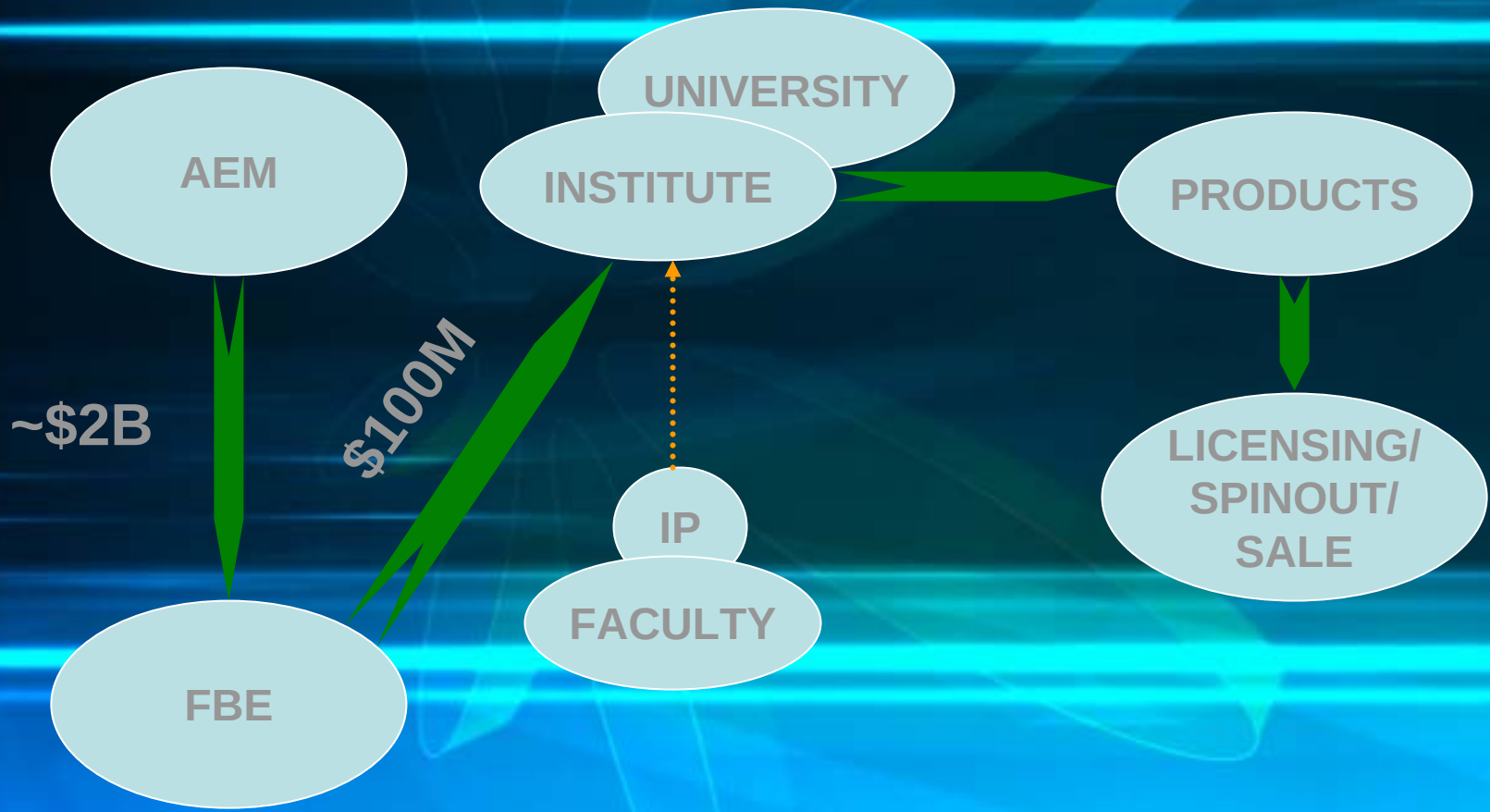
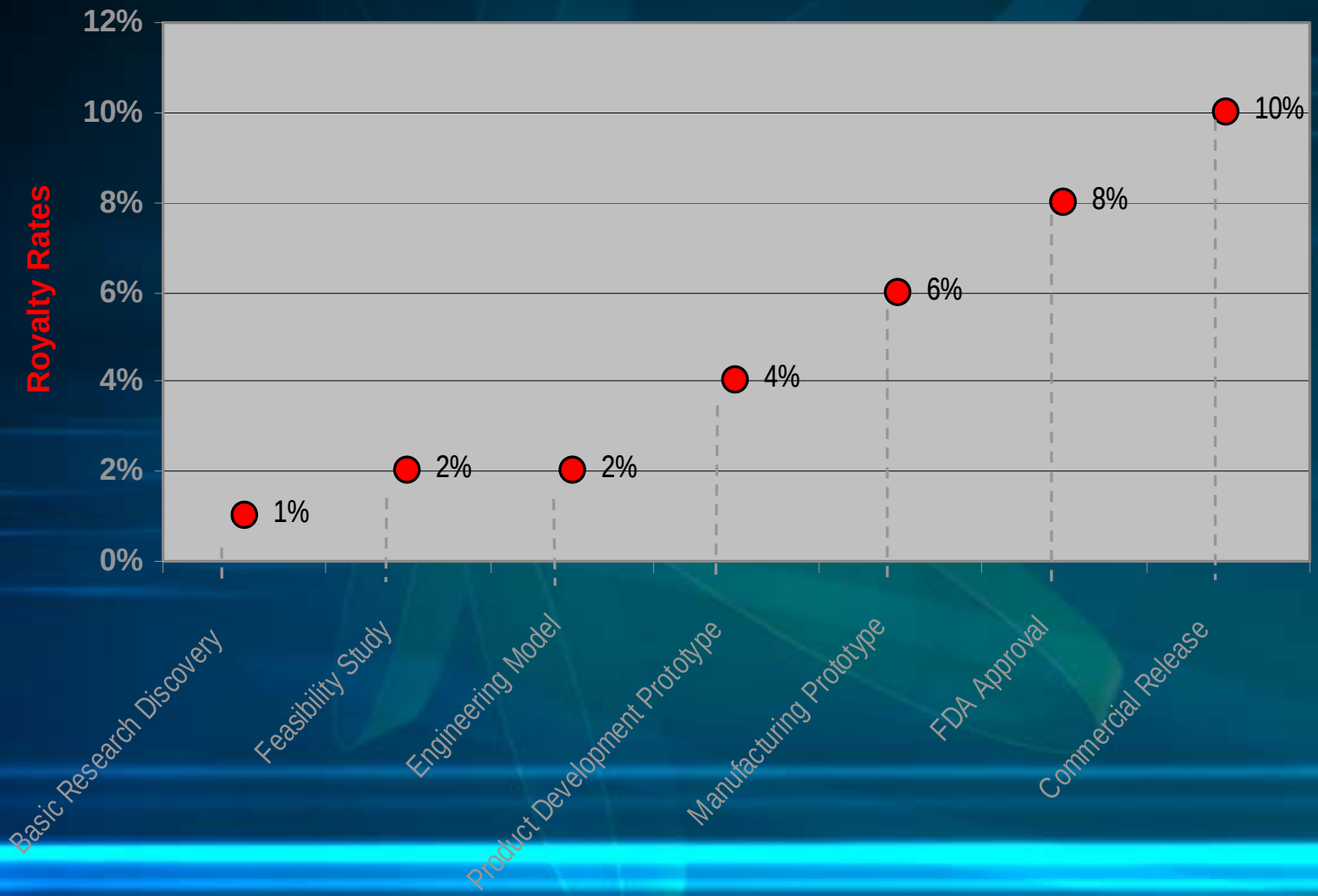
Alfred E. Mann Institutes for Biomedical Development



Enhancement of Royalty Rates as a Function of Commercialization Stage



Data and Benchmarking

Return on Investment

- $37 billion of total sponsored research conducted by 164 U.S. universities, research institutes, and hospitals in 2004

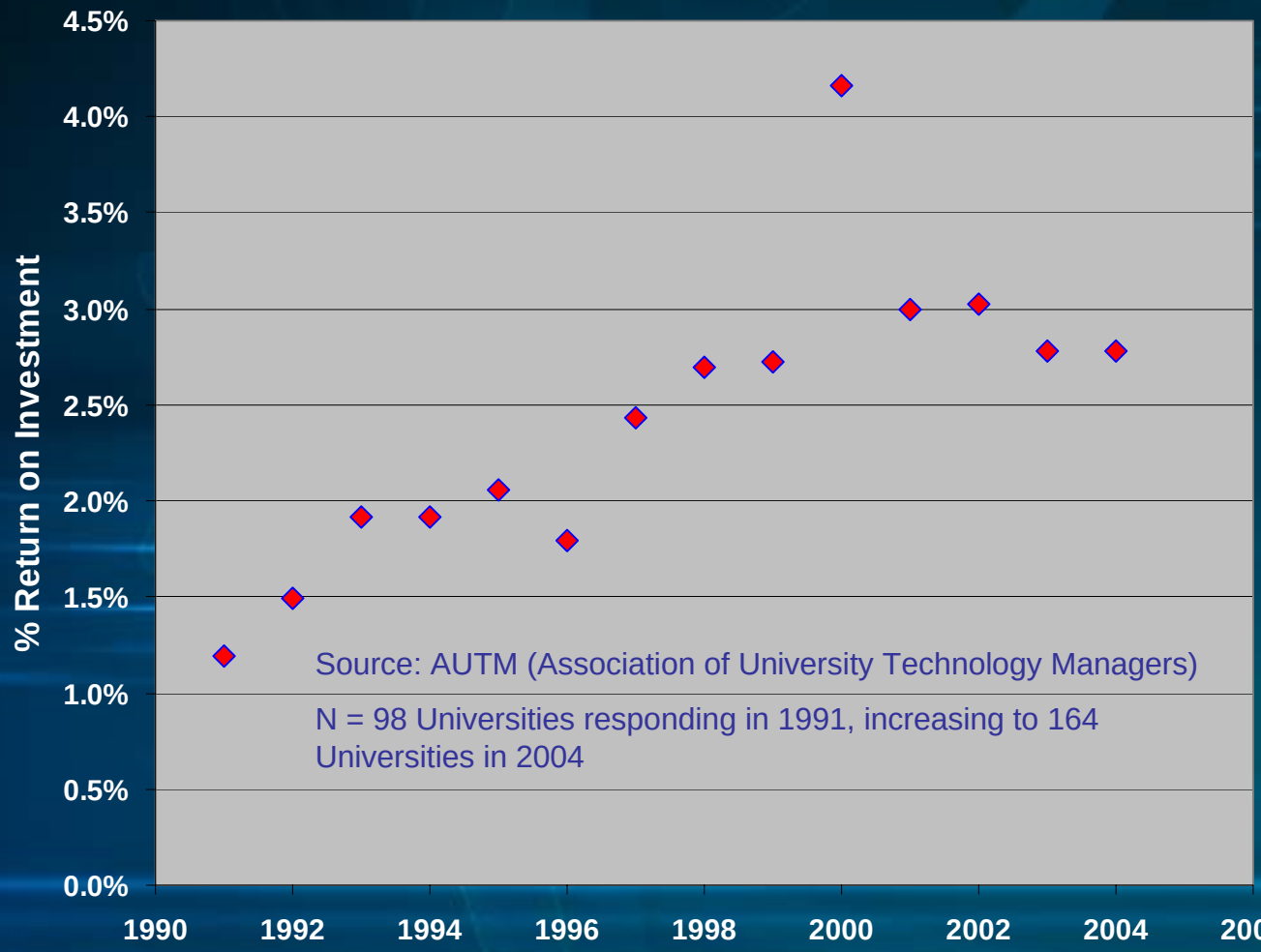
- $1,034 million of licensing and royalty income

ROI of 2.8%

- The best minds are being funded (largely with public dollars) on research which is focused on achieving “breakthroughs” for the benefit of mankind…yet sufficient delivery of health innovation and commercializable outcomes have not been attained

AUTM (Association of University Technology Managers)

ROI: US Universities' Net Income as a % of Total Sponsored Research Expenditures



NIH Outputs

- Intramural Research: ~$2b/$30b NIH Budget
  - # Disclosures ~400/yr
  - ROI = 0.25%
- Extramural Research
  - 53/57 Top selling drugs, not created with NIH funding

Data on TT

- Total Research Expenditures
- Total License Income
- Return on Investment
- License/Options Yielding Income
- Average Income per License
- Invention Disclosures
- New US Patent Applications
- US Patents Issued
- Licenses/Options Executed
- Startup Companies
- Tech Transfer Program Launch Start Date
- Licensing FTEs
- Active Licenses Generating greater than $1 Million

	Med School	Institution Name	FY04 Total Research Expnditures	FY04 Total License Income	2004 Return on Invstmnt	FY04 Lic/ Optns Yielding Income	2004 Ave Income per License	FY04 Invention Disclosures	2004 New US Patent App	FY04 U.S. Patents Issued	FY03 U.S. Patents Issued	FY04 Licenses/ Options Executed	FY03 Licenses/ Options Executed	FY04 Startup Companies	Tech Transfer Program Launch Start Date	FY04 Licensing FTEs	FY04 Active Licenses Generating > $1 Mi
1		New York Univ.	$244M	$109.2M	44.7%	52	$2.1**M**	94	46	23	21	30	24	4	1989	4	2
2		Wake Forest Univ.	$138M	$34.3M	24.9%	30	$1.1**M**	30	9	9	9	7	12	1	1985	3	3
3	No	Brigham Young Univ.	$24M	$4.8M	19.7%	116	$41K	113	33	6	8	28	22	5	1986	4	0
4		Michigan State Univ.	$325M	$36.6M	11.2%	109	$336K	152	64	45	39	44	28	5	1992	6	2
5		Univ. of Rochester	$306M	$33.7M	11.0%	28	$1.2**M**	139	102	24	22	23	12	7	1980	7	1
6		Univ. of Minnesota	$515M	$46.2M	9.0%	225	$205K	224	83	38	54	100	56	3	1957	9	2
7		Univ. of Florida	$428M	$37.4M	8.7%	150	$250K	278	233	53	50	64	55	8	1983	13	3
8		Ohio Univ.	$30M	$2.4M	8.0%	6	$400K	26	16	3	6	1	2	0	1991	2	1
9		Univ. of Massachusetts	$346M	$26.5M	7.7%	123	$215K	141	108	16	18	36	40	2	1995	6	3
10		Stanford Univ.	$694M	$49.5M	7.1%	474	$104K	350	313	87	117	89	128	9	1970	13	6
11	No	Univ. of Mississippi	$45M	$3.2M	7.0%	6	$531K	17	8	3	0	4	5	2	1992	1	1
12		Florida State Univ.	$205M	$14.3M	7.0%	15	$954K	54	25	22	18	6	12	0	1996	2	1
13		Emory Univ.	$326M	$22.7M	7.0%	41	$553K	93	54	22	32	27	16	2	1985	5	2
14	No	The Salk Inst. for Biological Studies	$75M	$5.2M	6.9%	158	$33K	19	16	25		27		2	1969	5	1
15		Univ. of Wisconsin at Madison	$764M	$48M	6.3%	261	$184K	405	163	93	87	203	177	2	1925	19	8
16		Univ. of Colorado	$571M	$34.1M	6.0%	62	$551K	147	68	18	23	41	34	9	1993	8	1
17		Univ. of Utah	$290M	$15M	5.2%	72	$209K	161	48	23	25	33	30	3	1968	7	3
18		Tulane Univ.	$133M	$6M	4.6%	26	$233K	49	13	10	6	5	4	0	1985	3	2
19		Case Western Reserve Univ.	$262M	$11M	4.2%	31	$356K	135	56	21	18	18	15	4	1986	9	2
20		St. Louis Univ.	$48M	$2M	4.1%	29	$67.7K	25	27	8	4	6	3	1	1998	1	0
21		Harvard Univ.	$591M	$23.6M	4.0%	253	$93K	160	73	35	59	50	69	4	1977	8	2
22		Ctr.	$314M	$12M	3.8%	89	$135K	88	27	35	19	34	33	0	1990	7	3
23		Univ. of Iowa Research Fdn.	$313M	$10.7M	3.4%	116	$93K	86	49	32	26	46	44	1	1975	5	2
24		East Carolina Univ.	$13M	$419K	3.1%	7	$60K	14	5	5	3	1	2	0	1995	2	0
25	No	Ctr.	$57M	$1.7M	3.1%	15	$116K	37	11	5	8	0	7	0	1986	3	0
26	No	Northeastern Univ.	$49M	$1.5M	3.1%	13	$115K	47	37	4	4	3	5	1	2000	2	0
27		Fdn.	$834M	$25M	3.0%	322	$78K	233	73	38	46	70	67	7	1983	17	5
28	No	(MIT)	$1.0B	$30M	2.9%	410	$73K	515	287	159	152	134	114	20	1940	15	4
29		NYU	$246M	$7M	2.8%	20	$350K	67	23	14	18	13	8	1	1991	4	1
30		Univ. of California System	$2.8B	$79.3M	2.8%	906	$87K	1,196	515	270	323	273	208	5	1979	63	15
31	No	Miami Univ.	$18M	$500K	2.8%	3	$167K	14	1	1		1		0	N.A.	0	
32	No	Univ. of Georgia	$313M	$8.7M	2.8%	107	$81K	103	59	17	36	71	96	3	1979	5	5
33		Univ. of Chicago/UCTech	$326M	$8.9M	2.7%	78	$115K	116	35	23	67	26	21	0	1986	6	1

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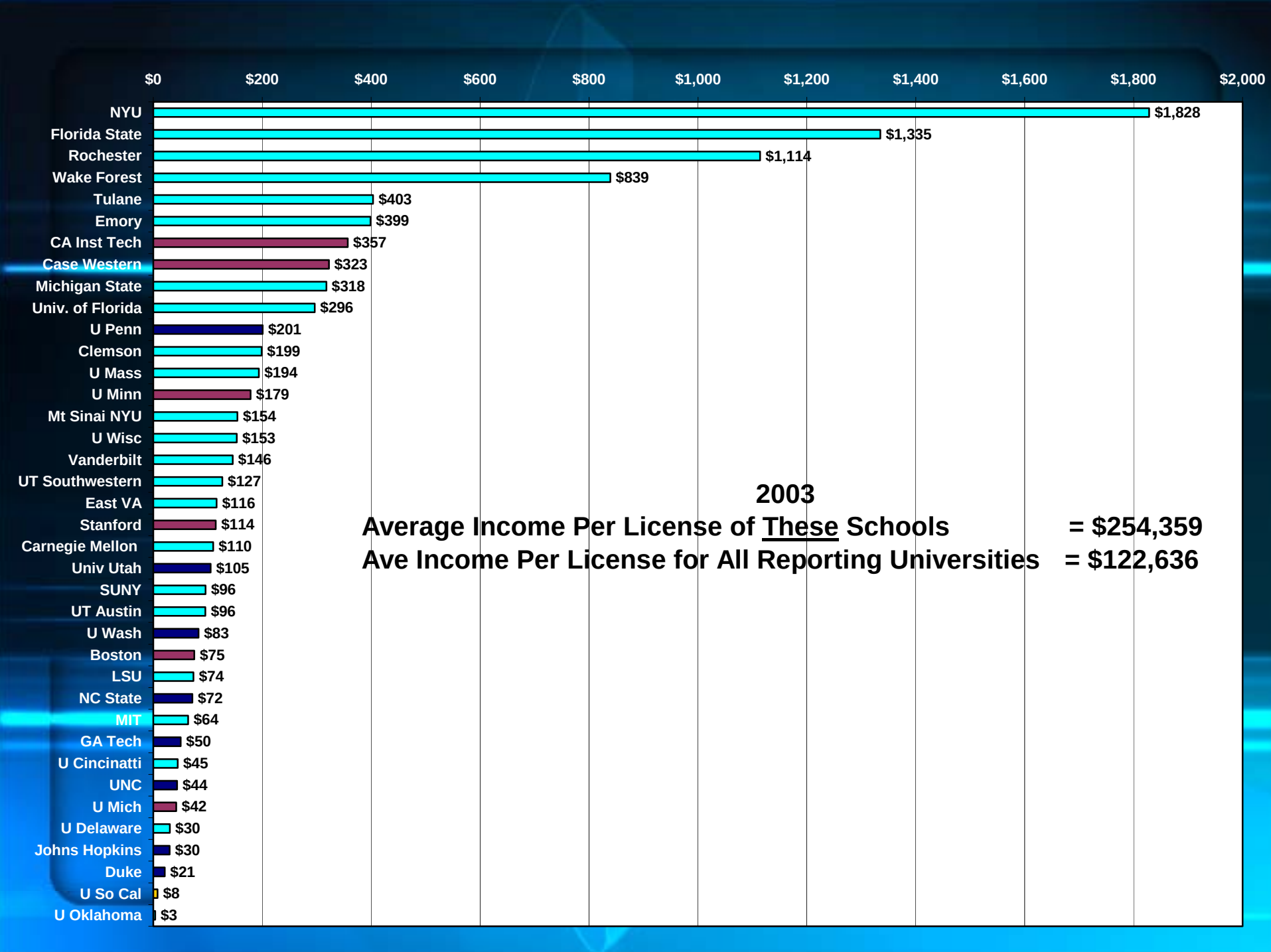
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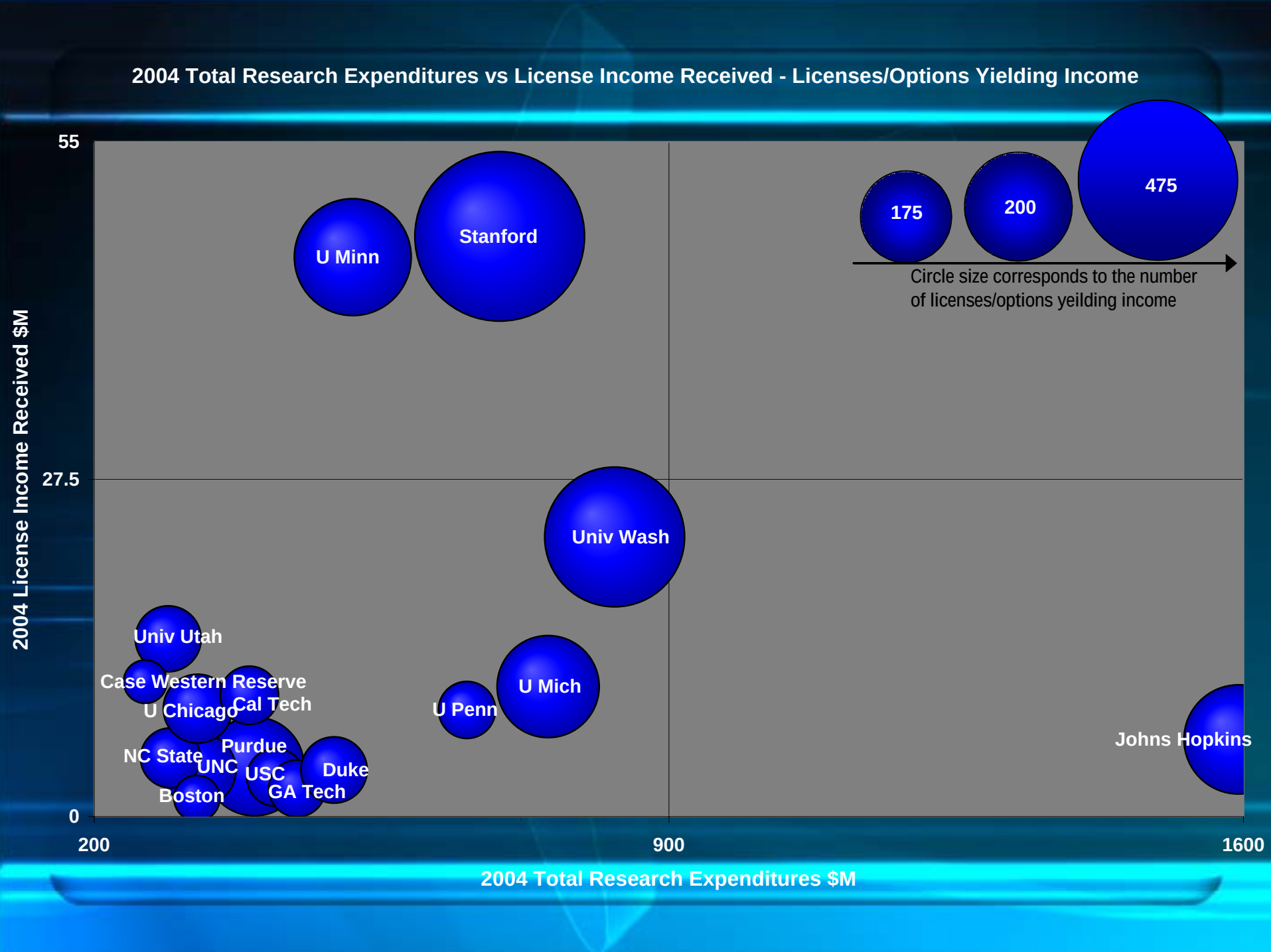
Florida State $1,335
Rochester $1,114
Wake Forest $839
Tulane $403
Emory $399
CA Inst Tech $357
Case Western $323
Michigan State $318
Univ. of Florida $296
U Penn $201
Clemson $199
U Mass $194
U Minn $179
Mt Sinai NYU $154
U Wisc $153
Vanderbilt $146
UT Southwestern $127
East VA $116
Stanford $114
Carnegie Mellon $110
Univ Utah $105
SUNY $96
UT Austin $96
U Wash $83
Boston $75
LSU $74
NC State $72
MIT $64
GA Tech $50
U Cincinatti $45
UNC $44
U Mich $42
U Delaware $30
Johns Hopkins $30
Duke $21
U So Cal $8
U Oklahoma $3
2003
Average Income Per License of These Schools = $254,359
Ave Income Per License for All Reporting Universities = $122,636


2004 Total Research Expenditures vs License Income Received - Licenses/Options Yielding Income
55
27.5
0
2004 License Income Received $M
200
900
1600
2004 Total Research Expenditures $M
U Minn
Stanford
Univ Wash
Univ Utah
Case Western Reserve
U Chicago
Cal Tech
Purdue
NC State
UNC
USC
GA Tech
Duke
Boston
U Penn
U Mich
Johns Hopkins
175
200
475
Circle size corresponds to the number
of licenses/options yeilding income

AMI Contribution

Product Planning & Design
Product Development
Commercial Prototypes
Production Prototypes

PRODUCT DEVELOPMENT
- Corporate/Venture

Value $

Transfer Out

Corporate

University

Clinical Feasibility
Engineering Model
Application Evidence

TRANSLATIONAL RESEARCH I
- NIH Funding
- University Funding
- Grant

BASIC RESEARCH
- NIH Funding
- University Funding
- Grant

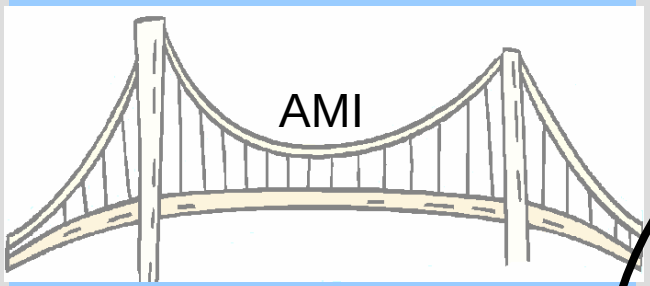
Data
Preliminary Models

The Funding Gap

Grants and sponsored research

Private equity

Late-stage private and public equity



Basic research, discovery

'Valley of Death'

Feasibility study

Engineering model

Product design

Product development

FDA

Manufacturing

Distribution channels

Market roll-out

Commercialization and clinical use

Source: Yongmin Kim, PhD University of Washington

Alfred E. Mann Institute Model

- **Following the model of the first Alfred E. Mann Institutes at University of Southern California and the Technion University**
  - **Institutes will operate under affiliation agreements with their universities**
  - **Institutes will operate as a 501c3 under the umbrella of the university, with university co-governance**
  - **Institutes will function as nonprofit angel investors, shepherding new technologies through the development process, using undiluted capital**
  - **Products, developed with undiluted capital, will be commercialized via license agreements or the establishment of new start-up ventures**

The AMI's

- **Industrial-style biomedical product commercialization entities with funded projects at the selected universities will include medical devices, pharmaceuticals and biotechnology products**
- **Function to perfect and substantially increase the value of university IP**
- **Designed to function in an "evergreen", perpetual mode to benefit manking and decrease "time to patient"**
- **Serve as a new model for enhancing commercialization and ROI**
- **Generating a new mode of thinking (Australian Room Document #3)**
  - **Conceptual Model**
  - **Demand for Data**
  - **Requirement Statistical Indicators, in Particular New Ones**
  - **Supply of Data to Meet Demand for Creating New Strategies**

What is Next for TT on Steroids?

- **12-15 more Institutes after 5-7 years?**
- **Mann peer activities?**
- **International activities**
- **Larger scale projects**
  - **Regional AMI's**
  - **NIH**
  - **Federal labs**
  - **AMI Consortia**
  - **Regional accelerator funds**

Biomedical Philanthropy

BIOMEDICAL PHILANTHROPY

Alfred E. Mann Foundation for Scientific Research 1985

Alfred E. Mann Foundation for Biomedical Engineering 2005

Alfred E. Mann Institutes for Biomedical Research


USC 2001


Technion 2007

Pending
Fall 2007

Pending
Spring 2008

+ ~10 more

Framework for Future Programs

- New Models for Accelerating Commercialization
- Regional Accelerator Funding
- Seed Capital Funds
- Clinical Trial Status
- “Follow the Money” -> “Follow the Patents”
- R&D vs. R&d vs. r&D
- Socio-economic Impacts: **THE TIME TO PATIENT**
- Biomedical Philanthropy of Philanthropreners