

Commercialization of University IP: Translational Research Leading to Company Formation

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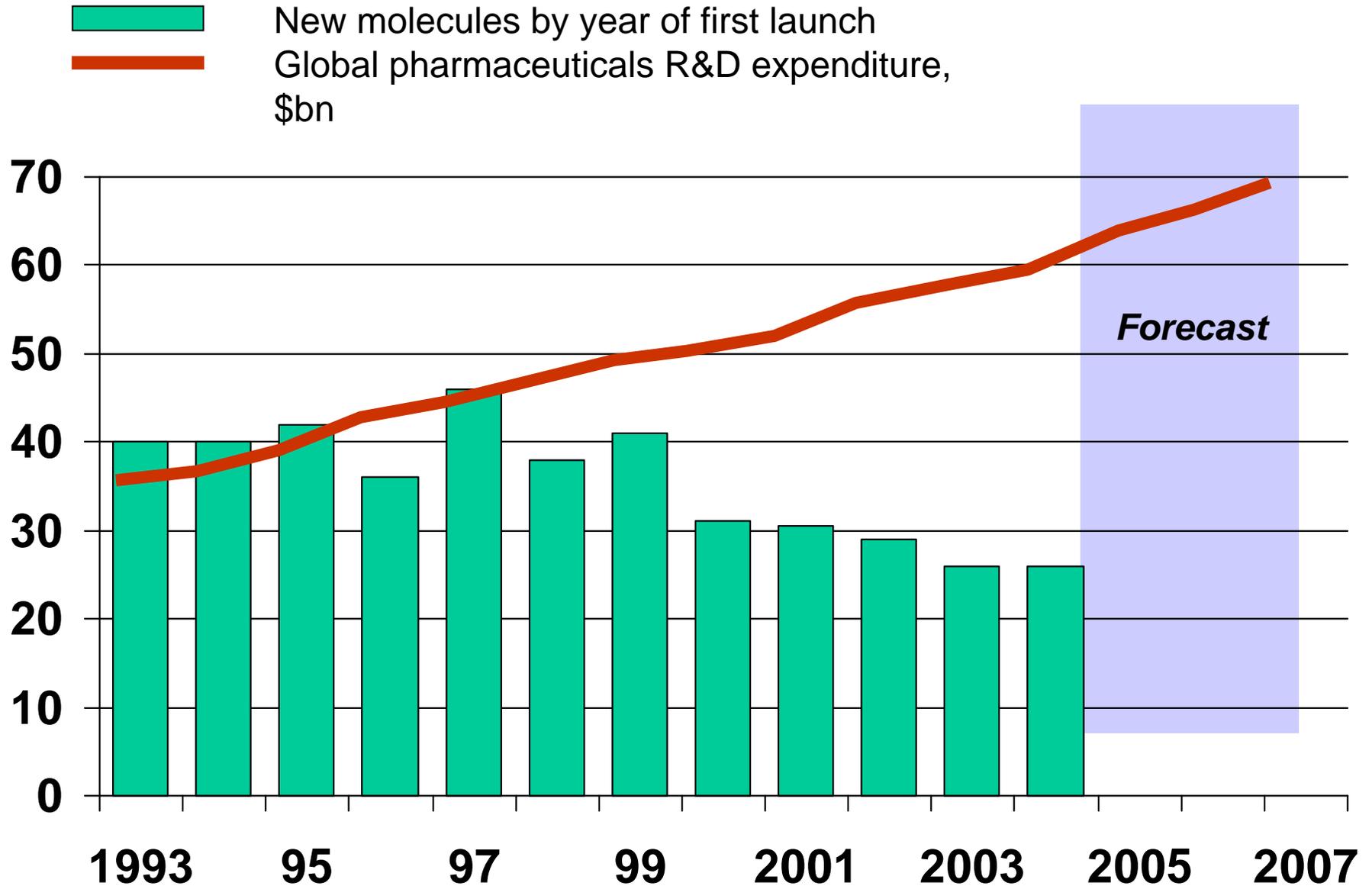


Big Pharma is Facing Major Challenges

- **Lack of new drugs in the pipeline**
- **High-profile medicines withdrawn**
- **“Blockbuster” drugs facing generic competition**
- **Drug-company sales, which increased by 10-15% a year the 1990s, have slowed to single-digit growth**



Spending more, getting less



R&D Expenditures & Risks

- R&D spending increased 6% a year since 1995 to a forecast total of \$55 billion by the end of 2005.
- Average of 12 years to develop a drug, with the biggest rise in the clinical-trials phase.
- For 10,000 molecules screened, around 250 enter pre-clinical testing, ten make it through to clinical trials, and one is approved by the regulator.
- Since the mid-1990s, average success rates have declined at the later stages of clinical testing due to issues of safety or efficacy.



Demise of the Blockbuster Model?

- Too many untested leads
- Too many costly late-stage failures of drugs or devices in Phase III or on the market
- Proliferation of new types of therapeutics: large molecule proteins, nanoparticles, gene therapy, stem cells
- Demand for genomics-guided personalized medicine
- Focus on orphan diseases and disease differentiation results in limited population targeted markets
- Use of genetic or protein markers for disease diagnosis and tracking remission or cure



Funding R&D to Reduce Technical Risk

- Translational research or proof of concept within the university environment (NIH, corporate, internal or external commercialization fund) - BioGenerator
- New company created (SBIRs, angel investors, seed and early-stage venture funds, federal and corporate grants, state subsidies, licenses, service contracts, university collaborations) - BioGenerator
- Clinical trials and commercialization (venture funds, IPO/private equity, joint ventures/partnering, state subsidies, federal grants, licensing, contracting out)



Importance of Creating New Companies From University IP

- **Create greater value for larger company acquisition by qualifying and de-risking the technology**
- **Accelerate the development process by providing a more flexible, innovative and efficient environment**
- **Save development costs by eliminating non-productive (efficacy) or problem (toxicity) approaches early on**
- **Enhance discoveries through translational and clinical research by experienced investigators**
- **Move technology from lab to potential commercialization**



Essential elements for growing your own companies

- 1) World-class Research Institutions
- 2) Effective Tech Transfer
- 3) Access to Capital
- 4) Appropriate R&D Facilities
- 5) Experienced Entrepreneurial Talent
- 6) Educated Workforce
- 7) Knowledgeable Service Providers
- 8) Entrepreneurial Culture Supporting Innovation
- 9) Engaged Public Sector
- 10) Quality of Life Attractive to Creative Class



Stage of company development determines necessary resources and services

- Invention Phase
- Company Creation Phase
- Company Development Phase
- High Growth Phase
- Established Company Phase



Life Science Value Chain Analysis

Essential Elements	Invention Phase	Company Creation Phase	Company Development Phase	High Growth Phase	Established Company Phase
1) World-class Research Institutions	Green	Orange	Yellow	Yellow	Green
2) Effective Tech Transfer	Orange	Orange	Yellow	Yellow	Yellow
3) Access to capital	Yellow	Orange	Orange	Red	Yellow
4) Appropriate R&D Facilities	Yellow	Yellow	Orange	Orange	Orange
5) Experienced Entrepreneurial Talent	Orange	Orange	Yellow	Red	Orange
6) Educated Workforce	Yellow	Green	Yellow	Red	Yellow
7) Knowledgeable Service Providers	Green	Green	Green	Green	Green
8) Entrepreneurial Culture Supporting innovation	Orange	Orange	Orange	Orange	Orange
9) Engaged Public Sector	Red	Red	Red	Red	Orange
10) Quality of Life Attractive to Creative Class	Yellow	Orange	Orange	Orange	Orange

Key:	On Target	Deficiencies	Major Deficiencies	Crisis
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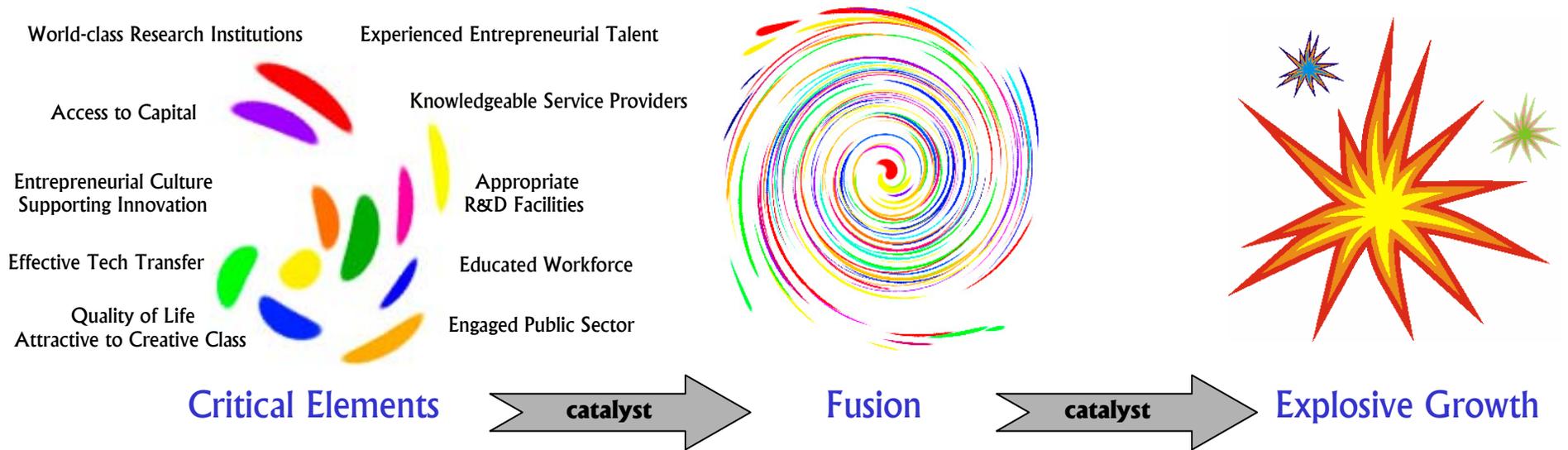
Life Science Value Chain Analysis

Essential Elements	Invention Phase	Company Creation Phase	Company Development Phase	High Growth Phase	Established Company Phase
1) World-class Research Institutions	On Target	Deficiencies	Deficiencies	Deficiencies	On Target
2) Effective Tech Transfer	Deficiencies	Deficiencies	Deficiencies	Deficiencies	Deficiencies
3) Access to Capital	Deficiencies	Deficiencies	Deficiencies	Major Deficiencies	Deficiencies
4) Appropriate R&D Facilities	Deficiencies	Deficiencies	Deficiencies	Deficiencies	Deficiencies
5) Experienced Entrepreneurial Talent	Deficiencies	Deficiencies	Deficiencies	Major Deficiencies	Deficiencies
6) Educated Workforce	Deficiencies	On Target	Deficiencies	Major Deficiencies	Deficiencies
7) Knowledgeable Service Providers	On Target	On Target	On Target	On Target	On Target
8) Entrepreneurial Culture Supporting Innovation	Deficiencies	Deficiencies	Deficiencies	Deficiencies	Deficiencies
9) Engaged Public Sector	Major Deficiencies	Major Deficiencies	Major Deficiencies	Major Deficiencies	Deficiencies
10) Quality of Life Attractive to Creative Class	Deficiencies	Deficiencies	Deficiencies	Deficiencies	Deficiencies

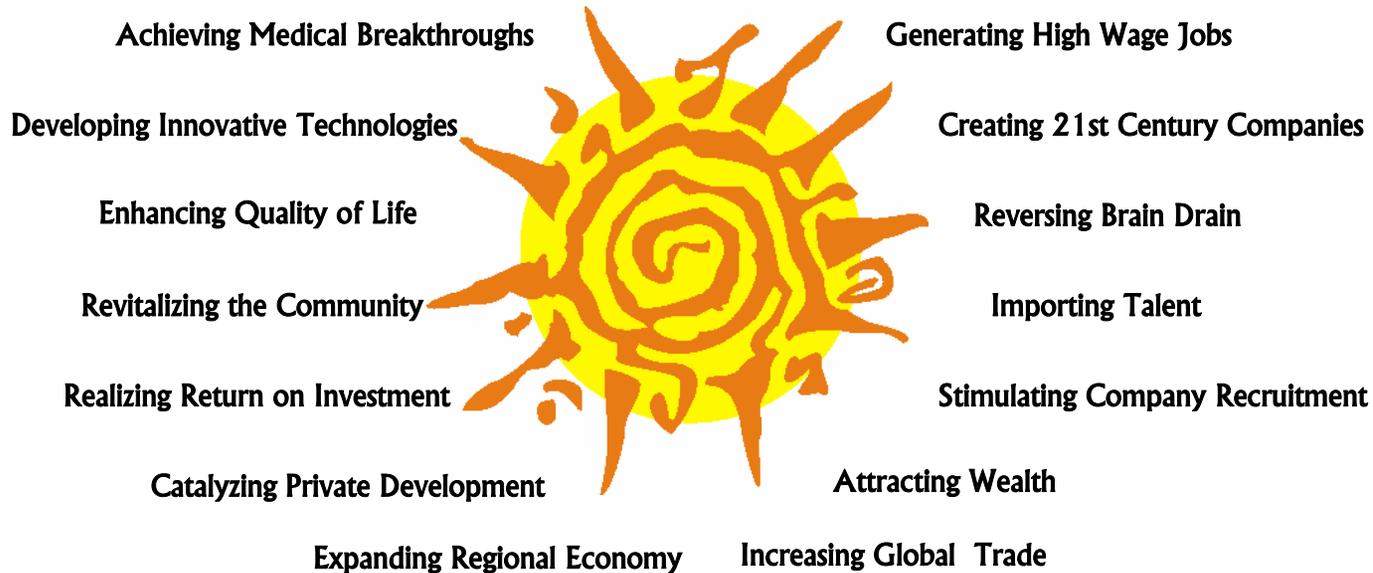
Key:	On Target	Deficiencies	Major Deficiencies	Crisis
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Fusion of Critical Elements Generates Economic Vitality



Transformation to Sustainable Economic Vitality



Benefits for the region - Direct

- Generating high wage jobs
- Creating 21st Century companies
- Stimulating company recruitment
- Attracting wealth
- Developing innovative technologies
- Catalyzing private development
- Expanding regional economy



Benefits for the region - Indirect

- Reversing brain drain
- Importing talent
- Increasing global trade
- Achieving medical breakthroughs
- Enhancing quality of life
- Revitalizing the community
- Realizing return on investment



Role of incubators and research parks in technology commercialization

1. Facilitate tech transfer, company formation, company-university, and company-company collaborations
2. Stimulate establishment of critical elements
3. Develop affordable specialized facilities
4. Support business and technology development
5. Assist companies in obtaining sources of funding
6. Foster creation of regional technology industry clusters



Benefits for Universities

- Opportunities for entrepreneurial faculty to start or consult with companies
- Investigators' satisfaction from impact of new discoveries on people's lives
- Internships and career opportunities for students
- Funding for sponsored research
- Collaborators in grant applications
- Outlet for publicly funded research to benefit society
- Access to state-of-the-art equipment
- Stimulation of new ideas for research
- Sources of adjunct faculty



Summary of Issues

Universities

- Mission of universities is basic not applied or translational research
- Little public or private funding for proof of concept or prototype
 - NCI and others are redirecting some grant dollars to translational research but total NIH funding is becoming more limited
 - Few places have internal or community funds for translational grants to faculty
 - More faculty interest in SBIR and STTR grants
- Reluctance of TT offices to do start-ups and unrealistic expectations
- Concerns over liability and conflicts of interest and commitment



Summary of Issues

Big Pharma

- Major drugs are coming off patent and little R&D is dedicated to developing significant new advancements
- Traditional model is based on producing and marketing block busters
- University discoveries are too numerous and too unproven to be useful for large companies – prefer to acquire technologies developed by a small company through Phase 2A, but provide limited funding to support development
- See biologics as a growth area but are not geared to do targeted marketing to limited populations



Summary of Issues

Commercialization

- Difficult to obtain funding, experienced entrepreneurs and affordable space for new start-ups
- Difficult and time consuming for faculty to license their own technology to create a company
- Conflict of interest limitations on funding additional research in the university lab
- Hard to raise angel and venture capital outside California and the North East



Summary of Issues

Government

- New and changing FDA requirements: orphan drugs, using biomarkers for an end point, differentiating targeted populations for clinical trials, genetic testing kits, continued patient tracking
- Tax incentives designed for larger, traditional companies
- Miss-information and fear of new technologies (Stem cells, pharmaceuticals from plants, genetically engineered crops)
- Politics-driven funding programs (bioterrorism, breast cancer)



Summary of Issues

Community and private sector

- Limited small bio-production facilities for clinical trials and regulatory expertise to get companies through clinical trials and FDA approvals
- Workforce is critical, particularly for management and highly technical positions
- Incubators and research parks are often not well planned or effectively managed
- Lack of knowledge and understanding among business and political leadership can be problematic
- New types of foundations are being created by individuals to fund translational research



Value Created by CET 1998 – 2006

Investment



City - \$2.2 M



State - \$6.3 M



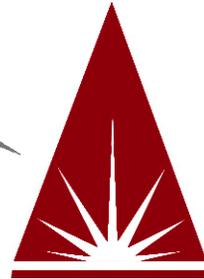
Fed - \$7.1 M



UMSL - \$1 M



Private - \$10.5 M (Incl. \$4.4 M debt)



\$27.1 M
Invested in CET

Resulted in **\$710 M**
of Attracted Capital
&

\$1 B in Economic Impact

Direct Results

Companies - 25



Jobs - 300



Payroll - \$117 M



Attracted Capital - \$710 M



Economic Impact

Construction Jobs - 75



Indirect Jobs - 735



State & Local Taxes - \$66.8 M

Economic Impact - \$1 B



CORTEX

(Center Of Research, Technology and Entrepreneurial eXchange)
A Life Science Research and Development District

 CORTEX East and West Development Districts



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