On Your Invention Journey: Helping Inventors Be More Successful

VentureLab

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Agenda

- Speaker Background
- Broad overview of medical and pharmaceutical research
- Commercialization Support at GT
  - Enterprise Innovation Institute
    - ATDC and VentureLab
- VentureLab Process
- Questions & Answers

Harold H. Shlevin, PhD

25+ years leadership experience in pharma, medical devices & vaccines companies.

Strong background in R&D through commercial operations

- CEO Solvay Pharmaceuticals, Inc.
- Founder & CEO Tikvah Therapeutics, Inc.
- Founder & SVP CIBA Vision Ophthalmics
- 18+ years with Ciba Geigy Pharmaceuticals in various positions of increasing responsibility

- Ph.D., Univ. of Rochester Medical School
- Postdoc. - Mayo Clinic
- Assistant Professor – Mayo Medical School

Importance of Patents to Pharmaceutical Innovation

INDUSTRY	Would NOT have been Introduced	Would NOT have been Developed
Pharmaceuticals	65	65
Chemicals	30	38
Petroleum	18	25
Machinery	15	17
Electrical Equipment	1	11

Mansfield, *Mgmt Sci*., Feb., 1986

Selected Advances in the 20th Century

Georgia Tech Enterprise Innovation Institute

1900s – 1940s

1900–1929

1900 – U.S. life expectancy is 45
1908 – Tuberculosis vaccine
1922 – Insulin for diabetes
1924 – Tetanus vaccine
1928 – Discovery of penicillin

1930s & 1940s

1932 – First antibiotic (sulfa drugs)
1935 – Discovery of cortisone
1938 – First epilepsy Rx
1948 – First chemotherapy Rxs

1950s – 1970s

1950s

1950 – Discovery of prednisone
1951 – First Rx for depression
1953 – First leukemia Rx
1954 – Polio vaccine
1958 – First diuretic to treat high blood pressure

1960s & 1970s

1963 – Measles vaccine
1967 – First beta blocker
1968 – First anti-rejection medicines for organ transplants
1972 – Advances in anesthesia
1977 – First non-surgical treatment for ulcers
1978 – First biotech product (synthetic human insulin)

1980s – 2000

1980s

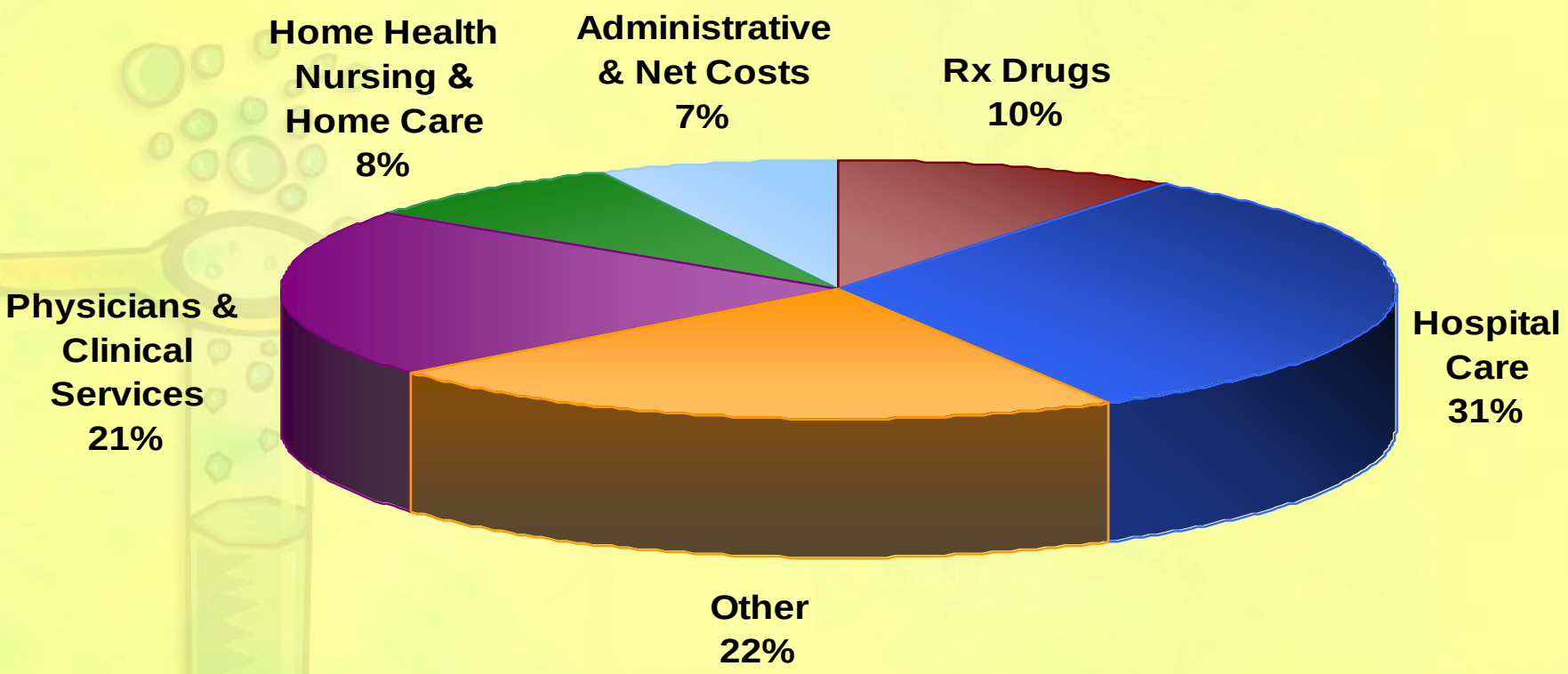
1981 – First ACE inhibitor to treat high blood pressure
1986 – First monoclonal antibody treatment
1987 – New class of depression medicines (SSRIs)
– First AIDS Rx
– First statins to lower cholesterol

1990s

1993 – First Alzheimer's Rx
1994 – New breast cancer Rx
- Polio eradicated in the Americas
1995 – AIDS Rx advance (HAART)
1995–97 – Four new classes of oral diabetes Rxs
1997–98 – Advance in Parkinson's Therapies

Sources: Innovation.org, Great Moments in Innovation, http://www.innovation.org/index.cfm/nonav/Great_Moments_in_Innovation; NIH, National Institute of Allergy and Infectious Disease, Tuberculosis (TB), Age of Optimism, http://www3.niaid.nih.gov/topics/tuberculosis/Research/researchFeatures/history/historical_optimism.htm.

Health Care Dollar Spending



*Note: "Other" includes medical care provided by private employers for employees at their work site, government spending for non-specified medical care by service usually delivered in schools, military field stations, and community centers.

Source: CMS, "National Health Expenditures," at http://www.cms.hhs.gov/NationalHealthExpendData, accessed January 6, 2009.

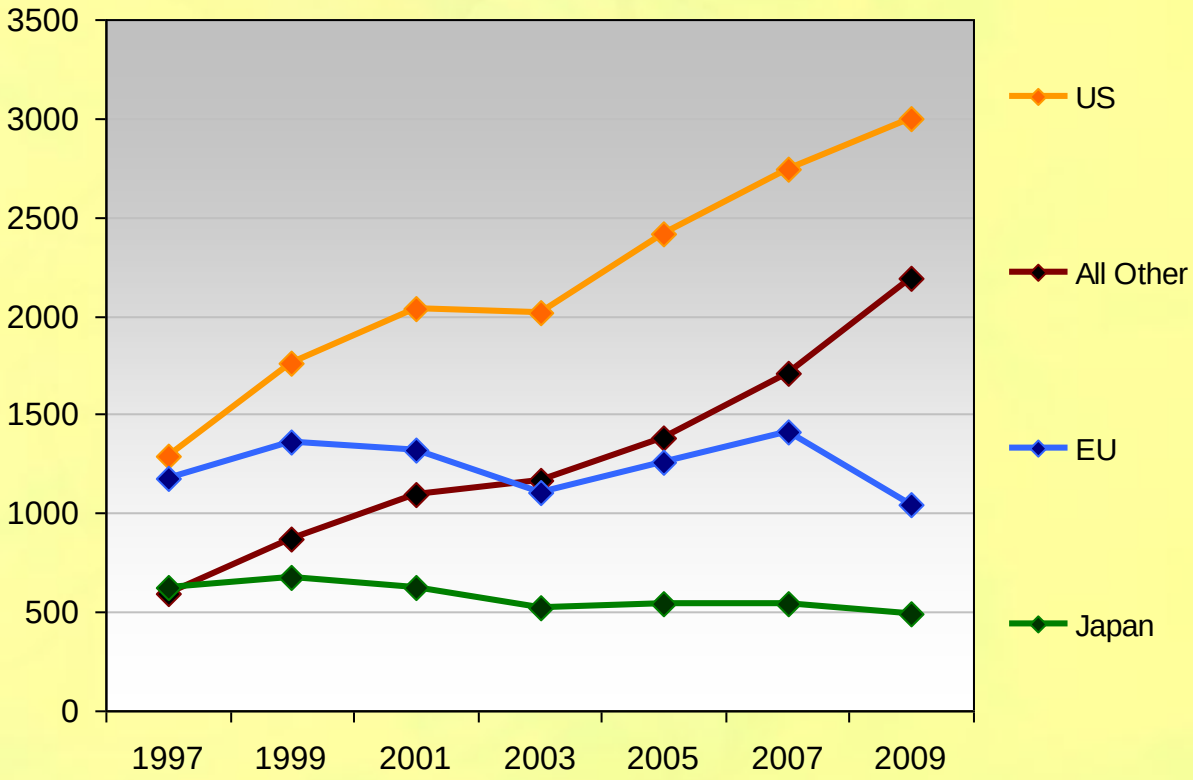
Medical Research in the U.S. Outpaces the Rest Of the World

…in the late 1980s only 41% of the top 50 innovative drugs were of American origin, in the late 1990s…[it had] climbed to 62%....

In 1990, the pharmaceutical industry spent 50% more on research in Europe than in the U.S. In 2001, the situation was reversed with 40% more spent in the U.S.[2]

–Gunter Verheugen, Vice-President of the European Commission for Enterprise and Industry

Number of Compounds in Development, by Region,* 1997–2009[1]

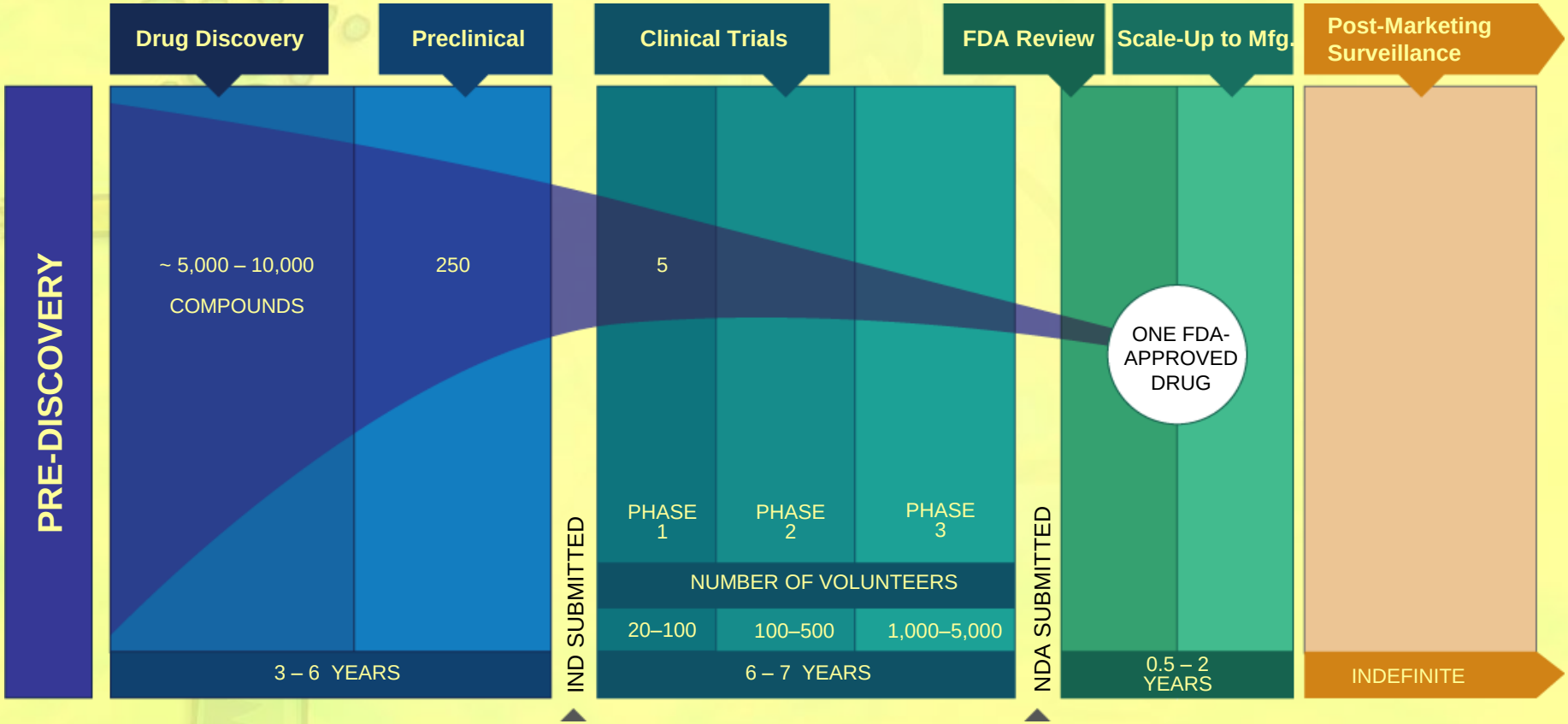


*Note: Reflects the number of compounds in clinical trials or awaiting approval as of June of each year. Compounds in development for multiple regions are counted in each region for which regulatory approval is sought, and multiple indications are counted only once.

Sources: 1Adis R&D Insight, Custom data run, February 2009, January 2010; [2]G. Verheugen, "Address to the Concluding Session of the European Track" (Lyon) 2005.

Drug Development Takes Longer

Developing a new medicine takes an average of 10–15 years; the Congressional Budget Office reports that "relatively few drugs survive the clinical trial process"



Sources: Drug Discovery and Development: Understanding the R&D Process, www.innovation.org; CBO, *Research and Development in the Pharmaceutical Industry*, 2006.

Georgia Tech Strategic Plan & Vision

Strategic Goal: 3

"Ensure that innovation, entrepreneurship, & public service are fundamental characteristics of our graduates"

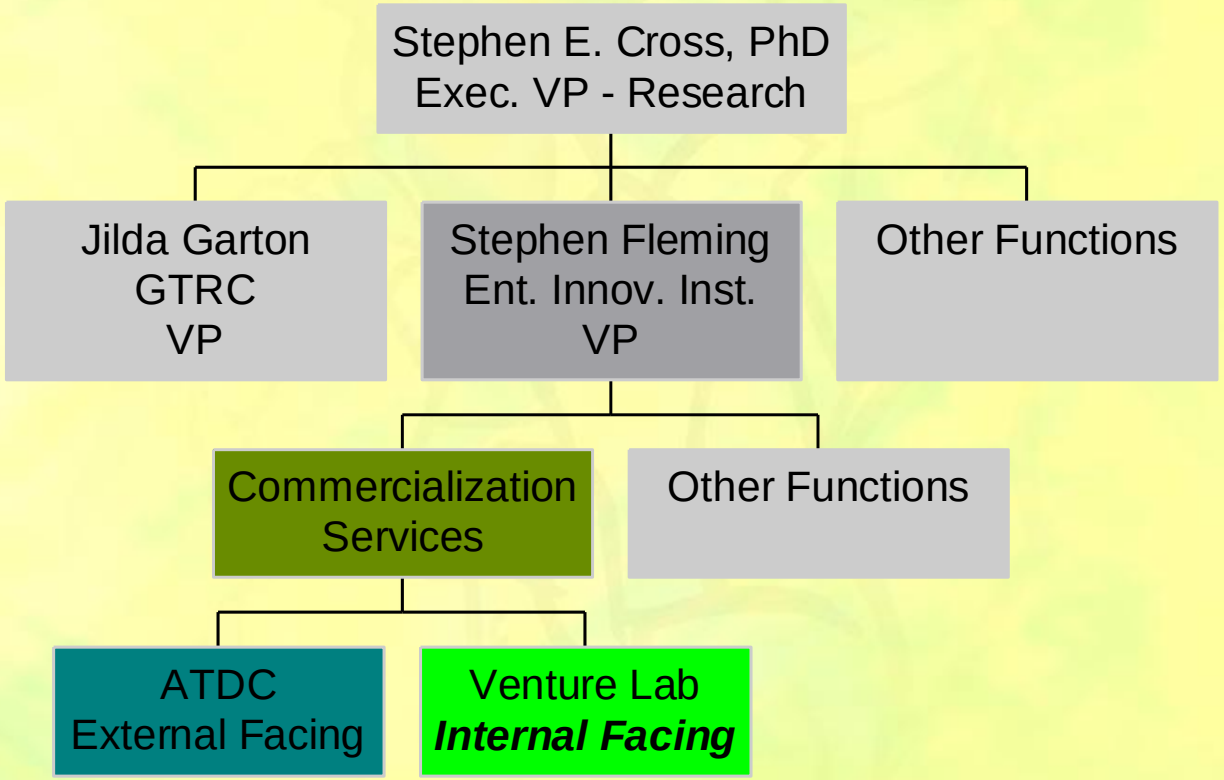
Strategy: 2

- Innovate in how we incentivize & support commercialization
  - "GT will encourage & reward faculty innovation & entrepreneurship in all their manifestations…"
  - "GT will continue to develop the infrastructure that will enable our faculty to perform at the highest levels, from idea generation to commercialization…"

Source: GT Strategic Plan. "Designing the future: A strategic vision and plan"

Enterprise Innovation Institute (EI^2)

Functional Organization



2011 – ATDC and VentureLab have distinct foci

- ATDC
  - Community
  - 450+ members
  - Served by temp. EIRs and Mentors
  - Circles
  - Some space

VentureLab today

- Focused on GT
- Commercialization of GT inventions
- Catalyst coaching & partnering
- Industry expertise
- Experts in starting and managing small new companies
- Partner with inventors

In brief, VentureLab . . . Partners with Faculty for Technology Development

- Provides <u>comprehensive</u> assistance to faculty members, research staff members and graduate students who want to commercialize the technology innovations they have developed.
  - Supports faculty in a consultant-like role related to commercialization
    - Ourselves or through our network
- View research ideas as a “valley of opportunity”; leverages research investment
- *Goals:* Products
  - Successful startup companies
  - Successful commercialization

Georgia Tech VentureLab

- Founded September 2001
  - Now a model for other universities
  - Part of Enterprise Innovation Institute (*EI*^{2})
    - Reports up through Office of the VP of Research
  - Staff has substantial private-sector experience
- Faculty-focused process
  - Risk identification and mitigation
  - Fundable innovations
  - Saying no and why, as appropriate
- Education

- *Goal:* Products based on Georgia Tech research and its collaborative partners

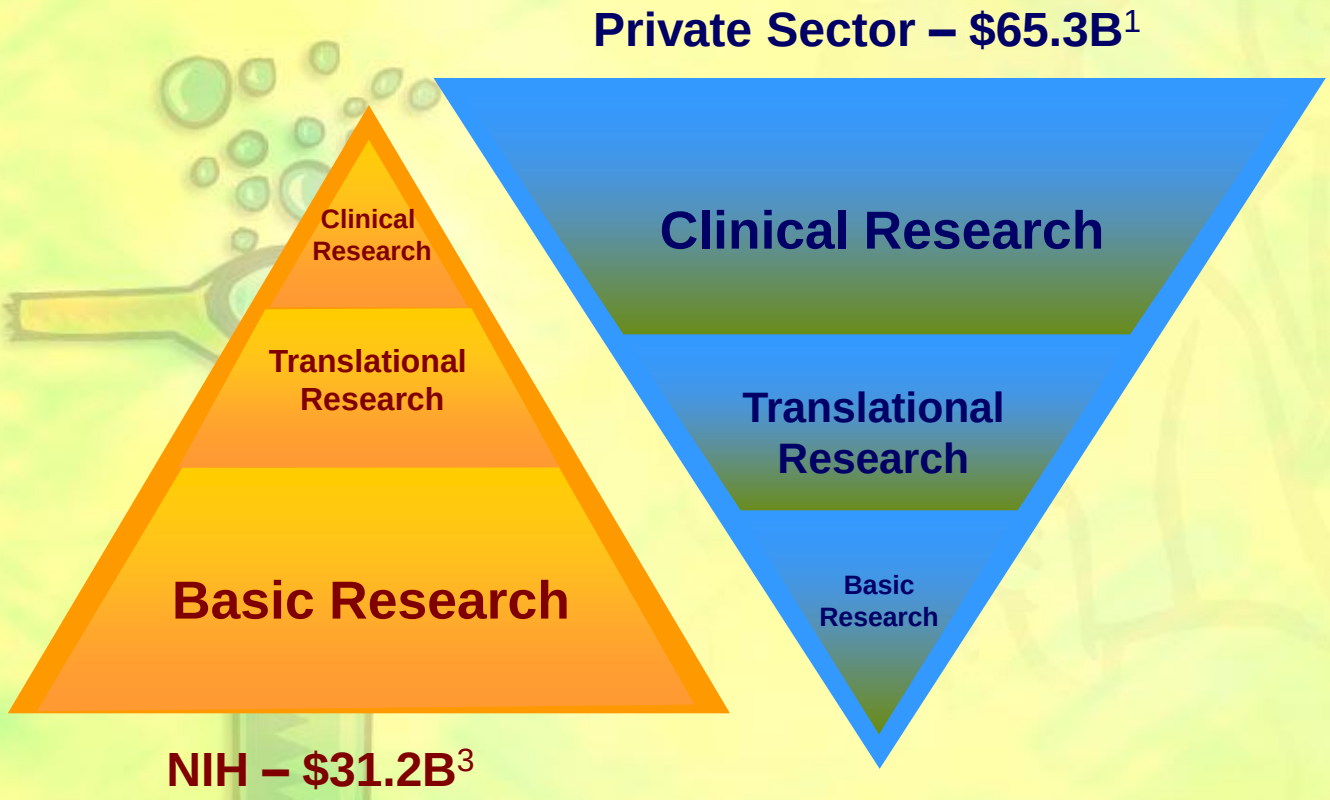
Inventive capacity of Georgia Tech is enormous

- Invention disclosures ~400 (*)
- Startup ideas ~250
- License ideas ~200

- Value is realized as PRODUCTs which leverage the research investments

Federal & Industry Roles in Research and Development

Government and biopharmaceutical industry research are complementary



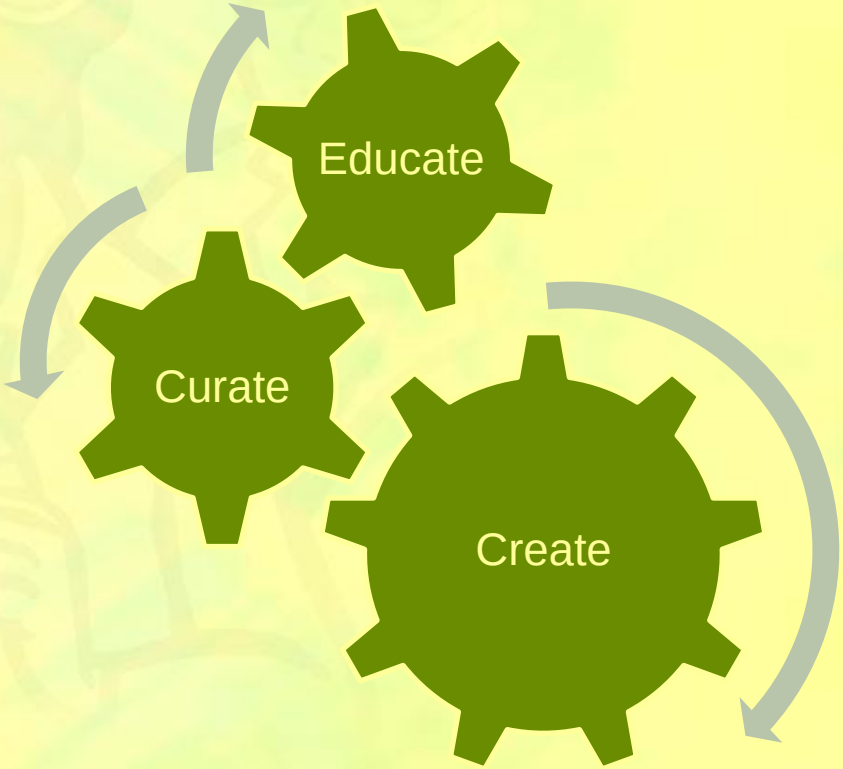
There is an ecosystem of science and biotechnology. Public organizations, patient organizations, universities, Congress, FDA, all of this is an ecosystem that is envied in the rest of the world.

– E. Zerhouni, Director of NIH

Sources: [1]Burrill & Company, analysis for PhRMA, 2010 (Includes PhRMA research associates and nonmembers) in PhRMA, "Profile 2010, Pharmaceutical Industry;" PhRMA, "PhRMA Annual Membership Survey," 2010; [2]Adapted from E. Zerhouni, Presentation at Transforming Health: Fulfilling the Promise of Research, 2007; [3]NIH Office of the Budget, "Natiional Institutes of Health: Enacted Appropriations for FY 2008-FY 2010," http://officeofbudget.od.nih.gov/pdfs/FY11/FY%202010%20Enacted%20Appropriations.pdf.

Mission of VentureLab

- **Educate**
- **Curate**
- **Create**



Educate

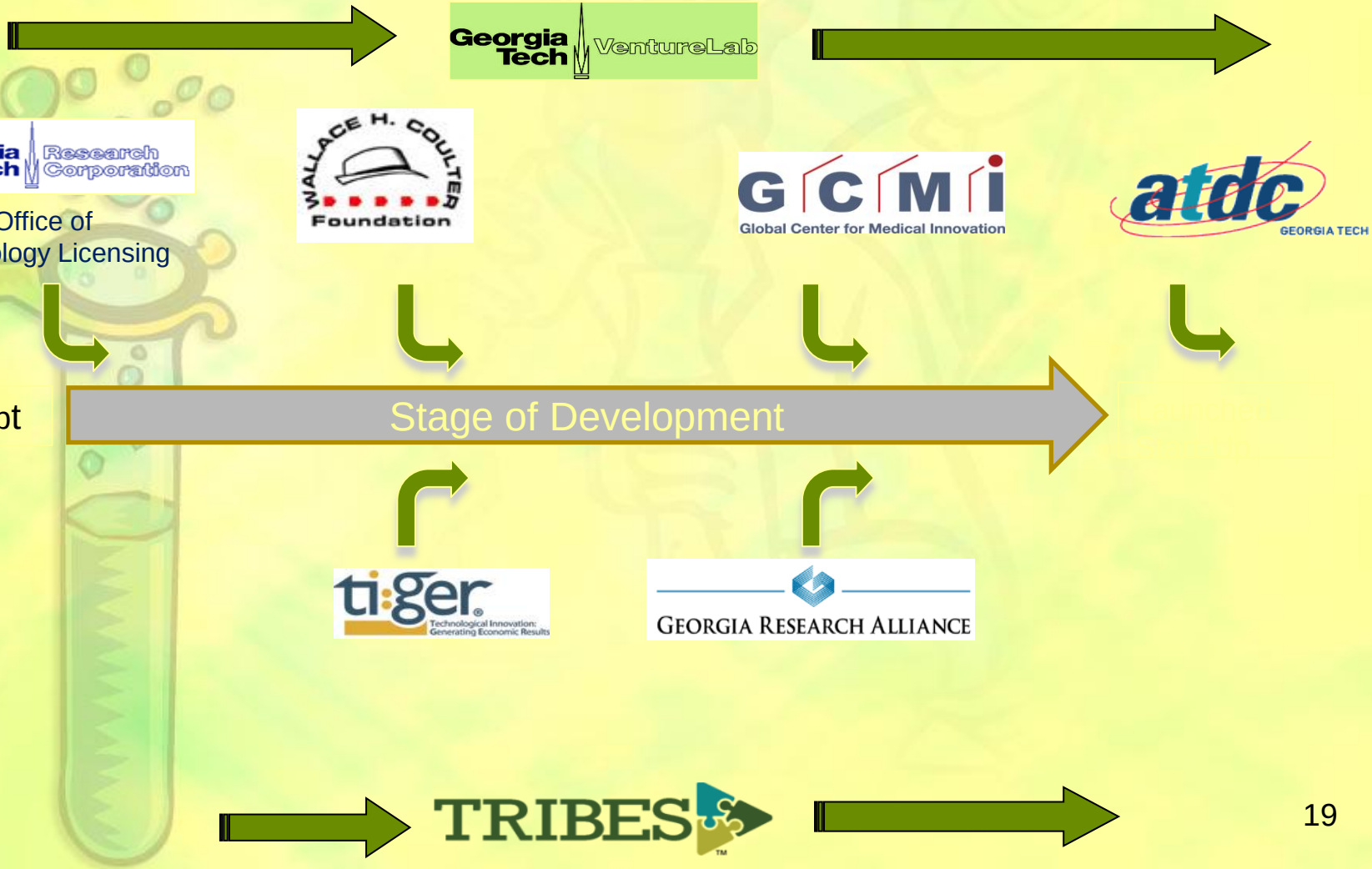
- Two-way street toward understanding and alignment
  - Invention
  - Path to commercialization
    - Science is critical to attract greater business interest
    - Business aspects (market, milestones, meetings, management & money)
    - Risk identification & mitigation
      - Product Development
      - Business Development
- Meet with faculty individually or with groups/ teams

Curate

- Become aware of potential opportunities early in the research process
  - viz., well before the traditional invention disclosure is considered
  - A lot of good ideas stay undeveloped
  - Little tweaks can often better define the commercial potential
- Active process
  - Commercialization takes time & requires capital
- Internally driven by industry experts
- Operate across other translational elements and functions

Support for Technology Translation
Business Evaluation Programs

Access to Technology



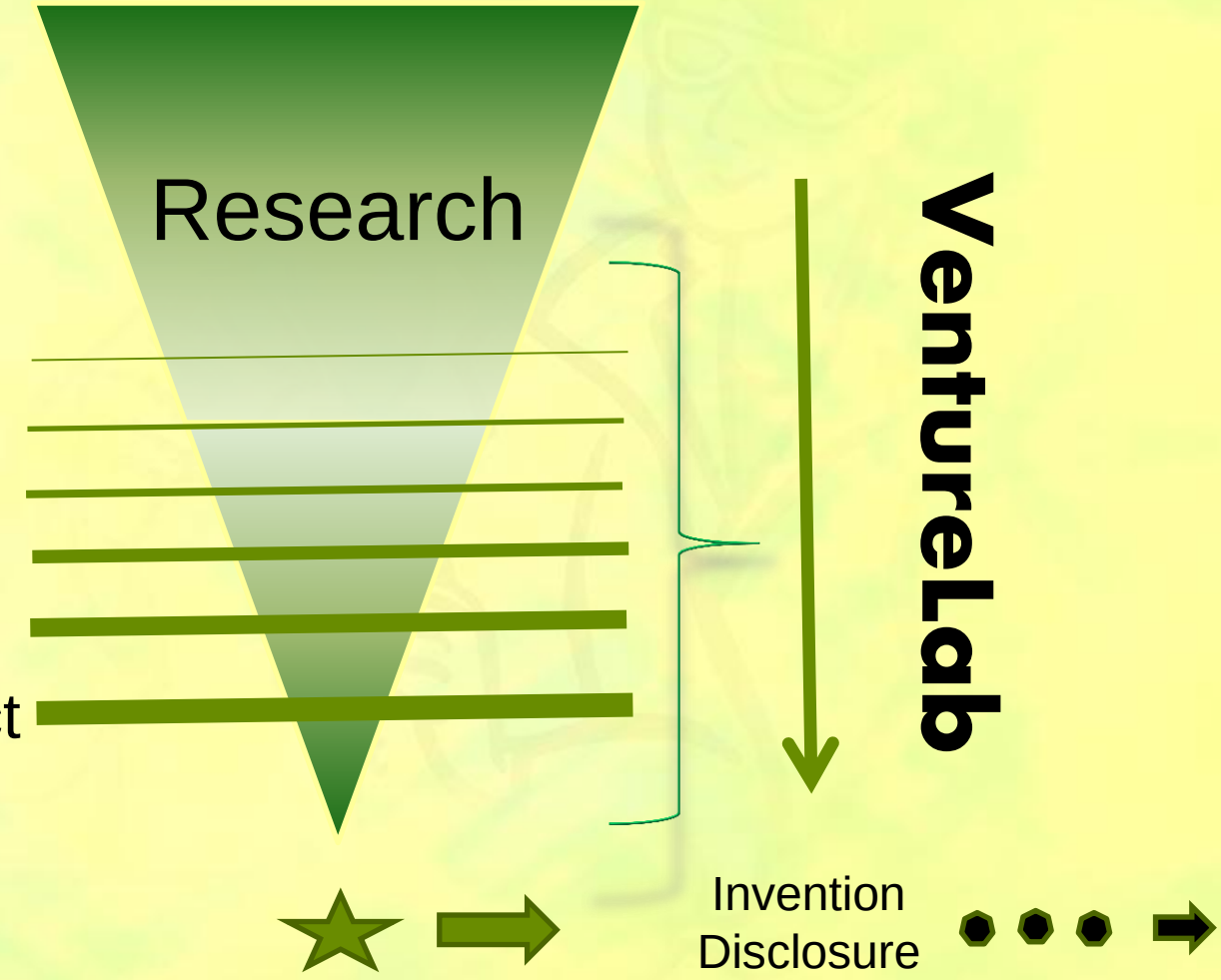
CURATE

Commercialization Process is

- iterative
- continuous
- builds value

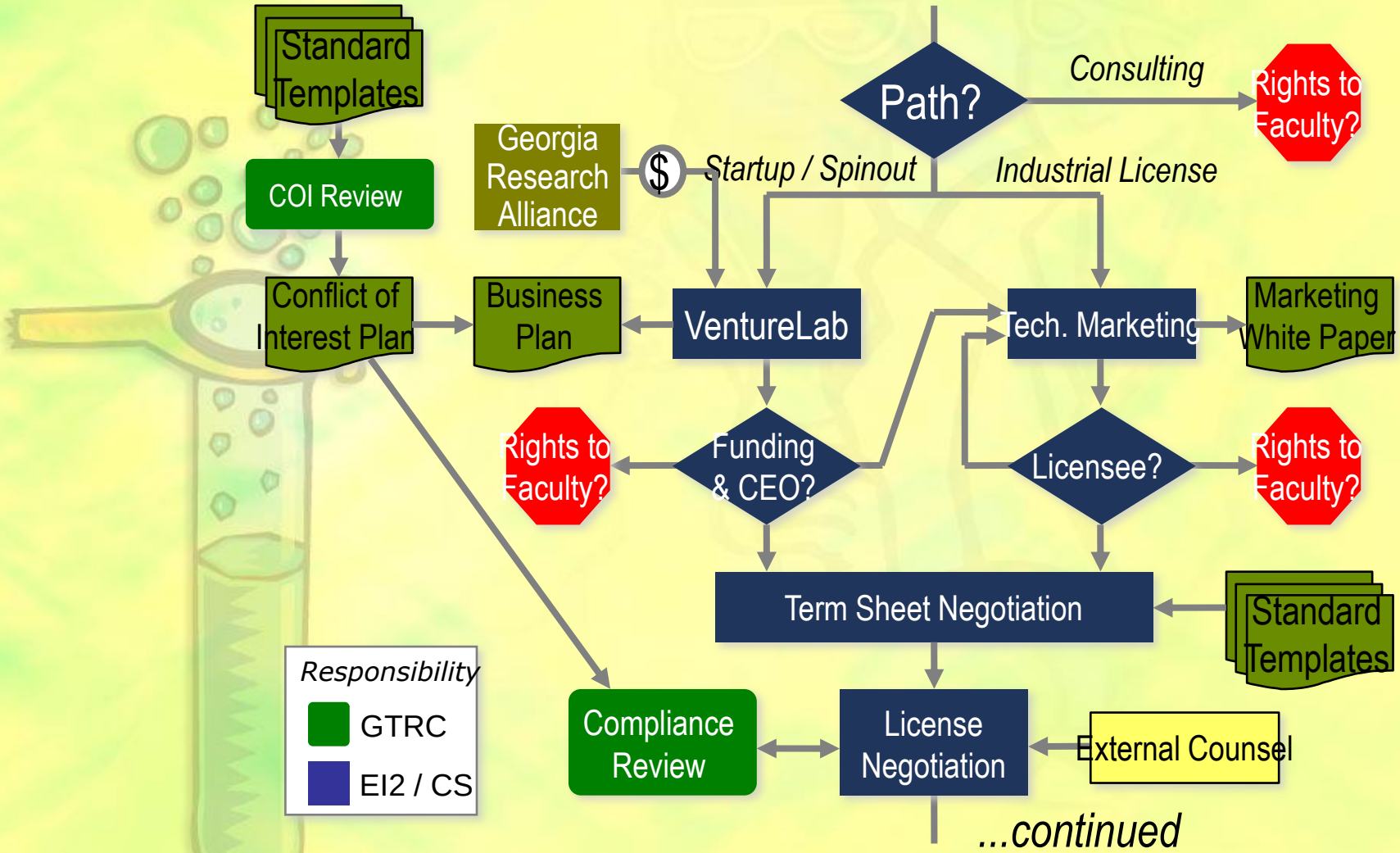
Early commercial insight can help build significant value or kill a project early

Feedback to inventors is critical



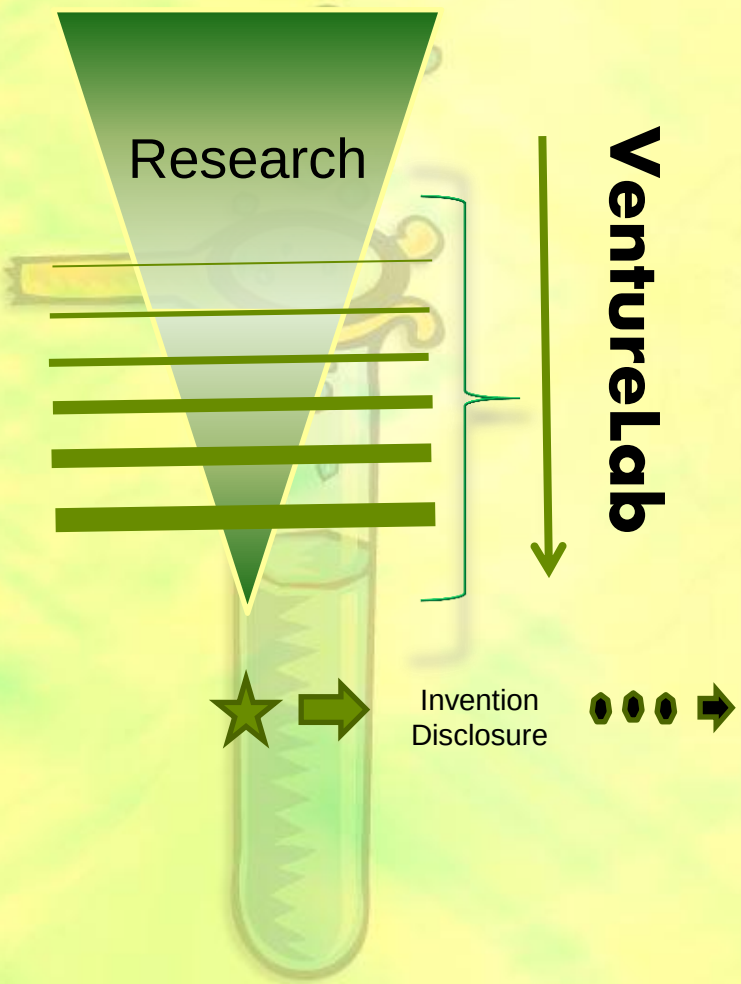
Georgia Tech Invention Disclosure & Licensing Process are Multi-Factorial

Part 1 of 3+ parts



Source: GTRC website www.gtrc.gatech.edu

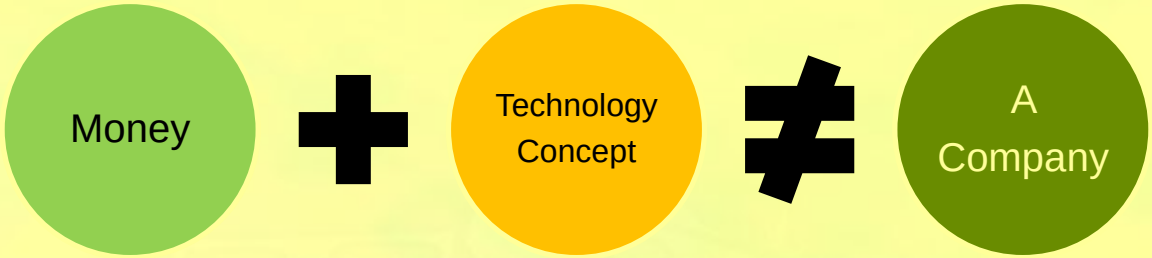
Message to Faculty/Inventors…



Invention Disclosures
Are NOT
the starting point
for
Commercialization

You are !

Business Realities

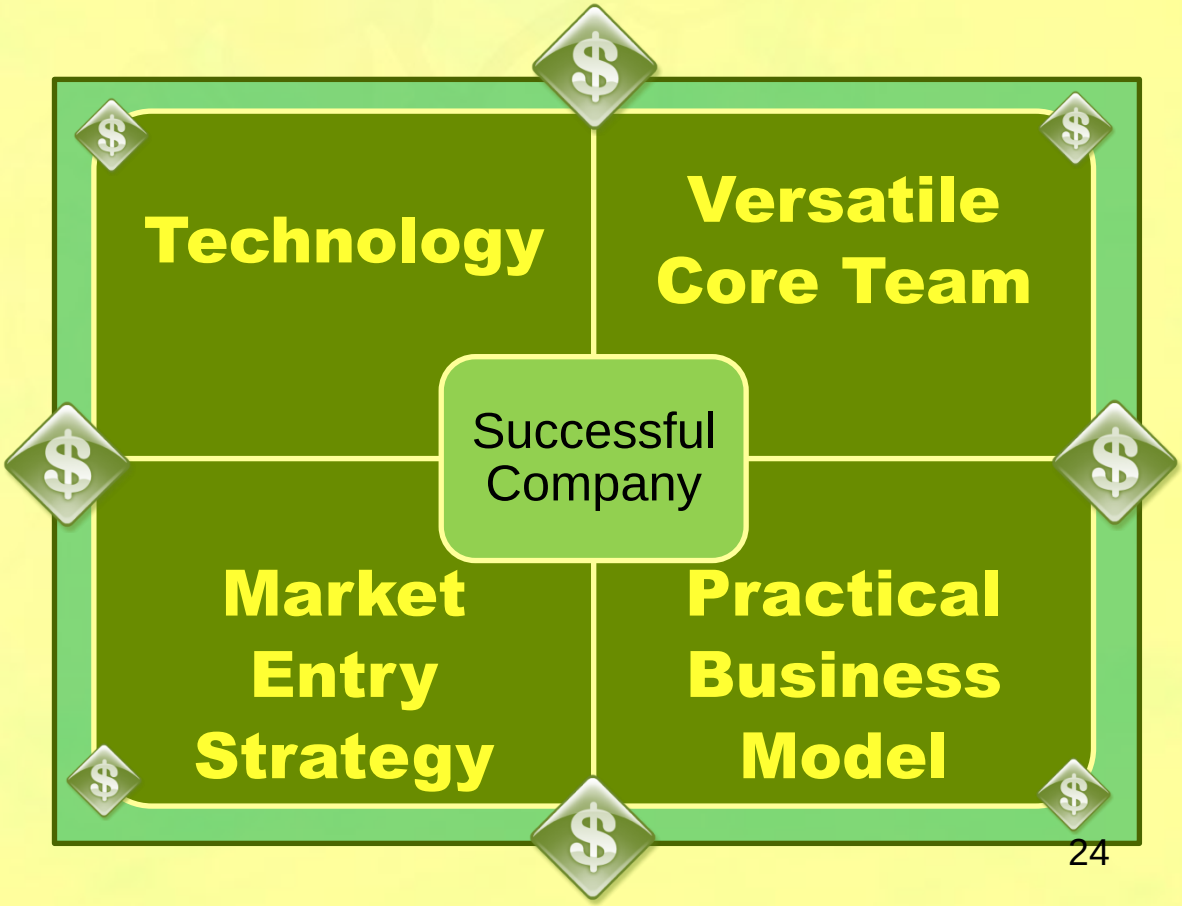


Lots of good ideas stay undeveloped

- Commercialization takes time and requires capital

Key Success Factors

- Technology
- Versatile core team
- Market entry strategy
- Product development strategy
- Money
- Practical business model



Opportunities from the “Valley”

- Return from exceptional startups
- Return from all startups
- Return from Proof of Concept Companies
- Return from GT IP Portfolio companies

Georgia Tech VentureLab

Business Plan

- Market
- Milestones
- Meetings
- Management
- Money

Business Plan

- Classic startup questions—*Who, What, Where, When, Why, How:*
  - Who is the customer?
    - What is the pain they are trying to eliminate?
    - Who/What will pay for the product?
  - Why is your technology the right answer?
  - When will effective competition emerge?
  - What are the growth trends?
  - Product Development Plan & Costs
  - Who are potential partners?
    - Exits ?

Business Plan

- It's far too easy to focus on the technology promise, and ignore the "details":
  - When will you have a prototype?
  - When will you have a paying customer?
  - How many people do you need to hire?
  - How much money do you need at first?
    - When does that run out?
    - How much will you need after that?
  - How do you know when you are winning?

Early Stage Funding

sbir GA
SBIR Assistance Program for the State of Georgia

- Assistance with small-business grants from eleven Federal agencies.

GEORGIA RESEARCH ALLIANCE

- Grants and loans to startups based on Georgia university research.

GEORGIA TECH EDISON FUND

- Equity investments in startups with a connection to Georgia Tech.

One-Stop Center for Technology Development & Commercialization

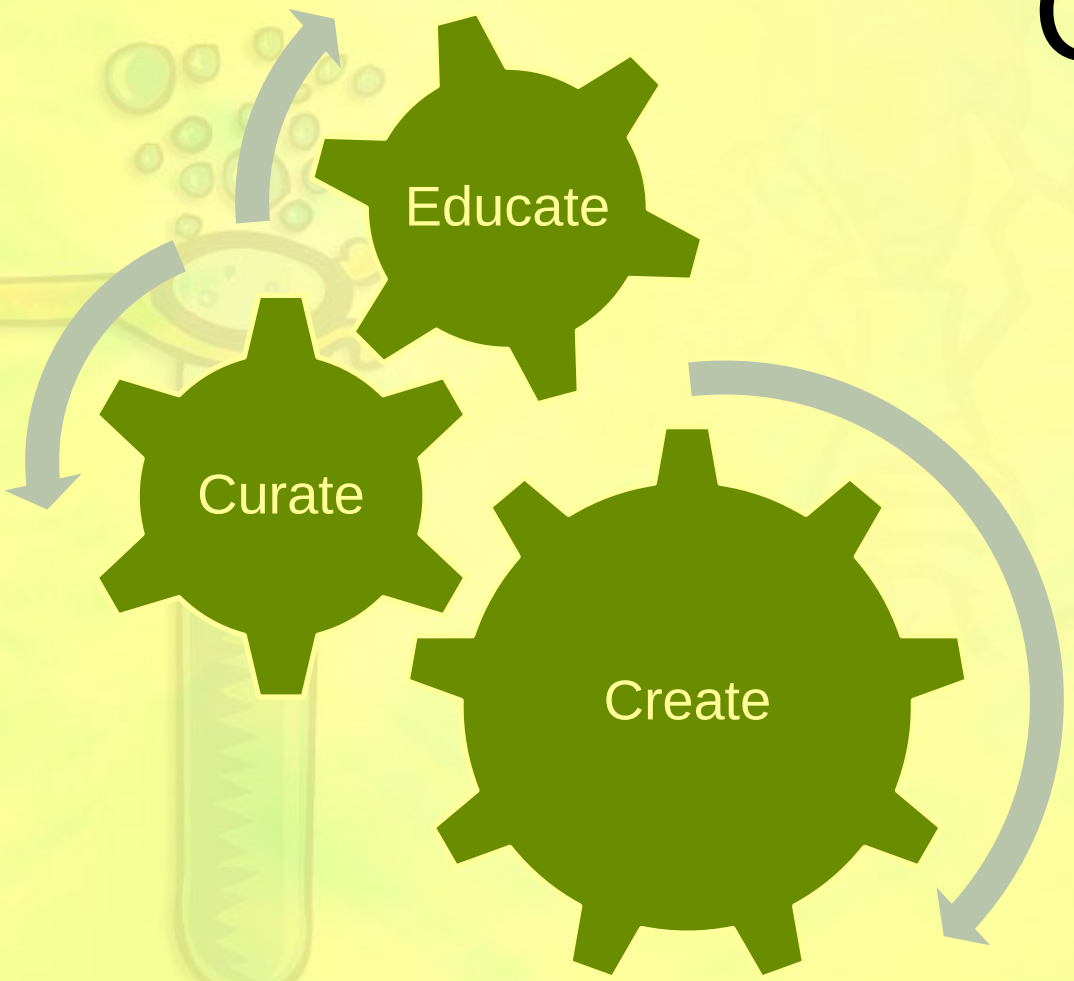
- Clear pathway from laboratory innovation to the commercial market
- VentureLab specialists help faculty transform innovations into early-stage companies / licenses
  - Assist in product development plan,
  - Assist in business plan development,
  - Assist in connecting the innovators with experienced entrepreneurs, partners, etc.,
  - Assist in locating sources of early-stage financing and preparing the new companies for the business world,
  - Wet-lab space in an on-campus incubator
- Experienced industry experts guiding the processes and educating
  - Saying “no” and why, when appropriate

What is Innovation?

"Research is the transformation of money into knowledge.

Innovation is the transformation of knowledge into money."

Geoff Nicholson, Ph.D.
(Post-it® note inventor)



Questions & Answers

Georgia Tech VentureLab

- Founded September 2001
  - Now a model for other universities
  - Part of Enterprise Innovation Institute (*EI*^{2})
    - Reports up through Office of the VP of Research
  - Staff has substantial private-sector experience
- Faculty-focused process
  - Risk identification and mitigation
  - Venture-backable innovations

- *Goal:* Successful startup companies based on Georgia Tech research
  - Successful commercialization

Background

- ATDC is ~30 years old (estb. 1980)
- VentureLab was established in 2001
- In 2009,
  - ATDC was opened up to the community of entrepreneurs across the State
  - VentureLab was merged into ATDC
- July 2011 – VentureLab was separated from ATDC …
  - Better focus on commercialization of Georgia Tech related inventions
  - Consistent with Gtech's strategic focus on commercialization

Returns

- Startups are very high risk — Failure rates ~ 90%
- GT startups are a bit less high risk — Failure rates ~ 70%
- Equity in early rounds — Later dilution
- Return
  - Equity on sale
  - Royalty/Milestones from license
- Successful License
  - 1/3 to inventors
  - 1/3 to department
  - 1/3 to Georgia Tech

2009 ATDC Serving the Georgia Entrepreneurial Community

Community Startups

- Explosive Growth
  - ~ 450 companies
  - + 3 to 5 per week
- Services
  - Educational programs
  - Incubation space
  - Outreach circles
  - Mentoring
  - Catalyst coaching
- Outward Facing

University Start Ups

- Everything
- GRA funding
- Limited lab space
- Inward Facing