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


<table>
<thead>
<tr>
<th>INDUSTRY</th>
<th>Would NOT have been Introduced</th>
<th>Would NOT have been Developed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmaceuticals</td>
<td>65</td>
<td>65</td>
</tr>
<tr>
<td>Chemicals</td>
<td>30</td>
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<tr>
<td>Petroleum</td>
<td>18</td>
<td>25</td>
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<tr>
<td>Machinery</td>
<td>15</td>
<td>17</td>
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<tr>
<td>Electrical Equipment</td>
<td>1</td>
<td>11</td>
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## Selected Advances in the 20th Century

### 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

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*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.

...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

*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; ²G. Verheugen, “Address to the Concluding Session of the European Track” (Lyon) 2005.
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”
Georgia Tech Strategic Plan & Vision

Strategic Goal: 3

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

- 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 (EI²)

Functional Organization

Stephen E. Cross, PhD
Exec. VP - Research

Jilda Garton
GTRC
VP

Stephen Fleming
Ent. Innov. Inst.
VP

Other Functions

Commercialization
Services

ATDC
External Facing

Venture Lab
Internal Facing

Other Functions
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 comprehensive 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
• Founded September 2001
  • Now a model for other universities
  • Part of Enterprise Innovation Institute (EI²)
    • 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
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

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
CURATE

Commercialization Process is iterative and continuous, building 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

Trademark, Marketing, White Paper

Standard Templates

COI Review

Conflict of Interest Plan

Business Plan

Georgia Research Alliance

VentureLab

Funding & CEO?

Term Sheet Negotiation

Compliance Review

License Negotiation

External Counsel

Licensee?

Funding & CEO?

Licensee?

Rights to Faculty?

Rights to Faculty?

Rights to Faculty?

Industrial License

Startup / Spinout

Consulting

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
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

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

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

• 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
“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
• Founded September 2001
  • Now a model for other universities
  • Part of Enterprise Innovation Institute (EI²)
    • 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
- GT startups are a bit less high risk
- Equity in early rounds
- Return
  - Equity on sale
  - Royalty/Milestones from license
- Successful License

Failure rates ~ 90%
Failure rates ~ 70%
Later dilution

1/3 to inventors
1/3 to department
1/3 to Georgia Tech
2009 ATDC Serving the Georgia Entrepreneurial Community

<table>
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<tr>
<th>Community Startups</th>
<th>University Start Ups</th>
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<tbody>
<tr>
<td>• Explosive Growth</td>
<td>• Everything</td>
</tr>
<tr>
<td>• ~ 450 companies</td>
<td>• GRA funding</td>
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<tr>
<td>• + 3 to 5 per week</td>
<td>• Limited lab space</td>
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<td>• Services</td>
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<tr>
<td>• Educational programs</td>
<td>• Inward Facing</td>
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<tr>
<td>• Incubation space</td>
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<tr>
<td>• Outreach circles</td>
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<td>• Mentoring</td>
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