Global Perspective on Biotech Innovation & Perspective on South Africa

Hilary Stiss, Senior Manager, International Affairs
Biotechnology Innovation Organization (BIO)
Outline

- About BIO
- What is Biotechnology?
- Biotechnology: A Key Solution to Global Challenges
- Trends in the Biopharmaceutical Industry
- Benchmarking South Africa
- Recommendations
What is BIO

- World’s Largest Biotechnology Organization
  - About 1000 members, from start ups to large MNCs
  - **Most** are small companies
  - Members from 35 countries
  - Host BIO International Convention annually – c. 18,000 participants in Boston in June 2018. 46,000 one-one meetings

- Covers all three sectors or biotech: Biopharma, Agriculture, industrial/environmental. Common elements:
  - All three use same technologies
  - All involved in addressing some of the most important issues confronting mankind
Serve as Voice of Global Innovative Biotech Sector

➢ Advance the use of biotechnology to solve world’s most pressing problems: Health, Hunger, Sustainable Environment

➢ Define and advance best practices that promote global biotech innovation (regulatory, IP, financial)

➢ Promote partnerships among parties engaged in biotech research and commercialization (the biotech “ecosystem”)

BIO’s Mission
What is Biotechnology?
What is Biotechnology?

The use of living organisms, or parts thereof, to provide useful products, processes and services.

**Cells** are the basic building blocks of living organisms.

Scientists in biotechnology modify cellular DNA to **produce useful proteins & other molecules**.
The Three Sectors of Biotechnology

- Biotechnological Science
- Health (Drugs & Therapies)
- Industrial and Environmental
- Agriculture
Composition of Biotech by # of Firms

Percentage of Biotechnology Firms by Application

- Health 51%
- Agriculture 12%
- Food and beverages 8%
- Natural resources 1%
- Environment 6%
- Industrial processing 9%
- Bioinformatics 4%
- Other 9%

Total 100%
Biotechnology and the United Nations Sustainable Development Goals
Sustainable Development Goals
Agriculture biotechnology is helping to feed the world.

Plants modified from their natural form to be:
- Drought resistant
- Insect resistant
- Nutritionally enhanced
- Longer lasting
Biofuels are contributing to the reduction of greenhouse gas emissions by:

- Countries and cities adopting them as a primary source of energy; and
- Companies committing to increasing the production and use of renewable energy, including biofuels
Applications of biotechnology promote responsible consumption and production:

• Through the recycling and reuse of materials, such as bioplastics; and

• Environmentally sound management of chemicals
Biotechnology can contribute to the preservation of marine ecosystems by:

- Using genomic sciences to provide new foods and food production methods;
- Safeguarding ecosystems at risk; and
- Reducing nutrient run-off into waterways
Biotechnology plays a critical role in saving lives and improving the quality of life for people across the globe.

Health biotechnology includes:
• Therapies and cures
• Vaccines and other tools to prevent and contain epidemics
• Diagnostics
Trends in the Biopharmaceutical Industry
A total of 667 innovative biopharmaceuticals launched in the U.S. over the past 20 years, bringing new treatment options to both small and large groups of patients suffering from specific diseases.

- Personalized medicine
  - Drive toward increasingly personalized medicines
  - Gene therapy and genome editing
  - Improved data infrastructure, collection and analysis

- Increased R&D in biologics versus small molecule therapies
  - Cures are starting to become more realistic
# Promise of Biotech in Human Health Sector: What’s in the Pipeline?

<table>
<thead>
<tr>
<th>Selected Diseases</th>
<th>Medicines in Development*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cancers</td>
<td>1,813</td>
</tr>
<tr>
<td>Cardiovascular disorders</td>
<td>599</td>
</tr>
<tr>
<td>Diabetes</td>
<td>475</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>159</td>
</tr>
<tr>
<td>Immunological disorders</td>
<td>1,120</td>
</tr>
<tr>
<td>Infectious diseases</td>
<td>1,256</td>
</tr>
<tr>
<td>Mental health disorders</td>
<td>511</td>
</tr>
<tr>
<td>Neurological disorders</td>
<td>1,329</td>
</tr>
</tbody>
</table>

**Major Industry Trends**

- Very expensive and long timeline to develop and commercialize biologics
- Majority of projects fail = risky
- Blockbusters are the exception
- Small companies driving global biopharma pipeline
- Increased partnership
  - Nearly three quarters of the molecules were launched by a company different from the one that filed the original patent, reflecting the level of activity in licensing, partnering and acquiring associated with biopharmaceutical innovation.

- Globalization of industry
- Many players to absorb risk
Developing a New Medicine Takes Up to 15 Capital-Intensive Years

Developing a new medicine takes 10–15 years and over $2.5B*
Very expensive and long timeline to develop and commercialize biologics

- Majority of projects fail = risky
- Blockbusters are the exception
- Small companies driving global biopharma pipeline
- Increased partnership
  - Nearly three quarters of the molecules were launched by a company different from the one that filed the original patent, reflecting the level of activity in licensing, partnering and acquiring associated with biopharmaceutical innovation.

Globalization of industry

- Many players to absorb risk
90% of New Drugs in Development Are Expensive Failures

Average Cost to Bring a Single FDA-approved Drug to Market: $2.6 billion

Cost of research and development

The average amount spent to bring a new prescription drug to market more than doubled since it was last estimated 11 years ago.

- Clinical studies: $2,558 billion
- Research & animal testing: $1,643 billion
- $1,098 billion
- $1,044 billion
- $413 billion
- $179 billion

NOTE: All figures are inflation adjusted to 2013 dollars
SOURCE: Tufts Center for the Study of Drug Development
Fewer than 1 in 10 biotechs survive to earn a single dollar in profit.

Biotechnology is uniquely dependent on smart public policy to attract investment.

Source: Factset, BIO Industry Analysis, January 2016
Major Industry Trends

- Very expensive and long timeline to develop and commercialize biologics
- Majority of projects fail = risky
- Blockbusters are the exception
- Small companies driving global biopharma pipeline
- Increased partnership
  - Nearly three quarters of the molecules were launched by a company different from the one that filed the original patent, reflecting the level of activity in licensing, partnering and acquiring associated with biopharmaceutical innovation.
- Globalization of industry
- Many players to absorb risk
Blockbusters Very Much the Exception

- Sales trends for medicines launched over the past 20 years are characterized by a relatively small number of outlier products with significantly higher sales than the majority of products.
  - In each year, the five drugs with the highest cumulative sales in their first five years on the market average 14 times higher sales than the rest of drugs launched that year.

- Only 19 drugs (out of 667) have reached the $1 billion in annual sales mark within their first five years on the market over the past 20 years; 9 of these were launched in the past five years.

- Over the 20-year period, 62% of the launches averaged less than $100 million in average annual sales during their initial five years following launch.
Very expensive and long timeline to develop and commercialize biologics
Majority of projects fail = risky
Blockbusters are the exception
Small companies driving the global biopharma pipeline
Increased partnership
- Nearly three quarters of the molecules were launched by a company different from the one that filed the original patent, reflecting the level of activity in licensing, partnering and acquiring associated with biopharmaceutical innovation.

Globalization of industry
Many players to absorb risk
Small Biotechs Driving Global Biopharma Pipeline

5,293 Clinical Programs

70% from Small Companies

38% Partnered

Source: BIO IndustryAnalysis, BioMedTracker, June 2016
Major Industry Trends

- Very expensive and long timeline to develop and commercialize biologics
- Majority of projects fail = risky
- Blockbusters are the exception
- Small companies driving global biopharma pipeline
- Increased partnership
  - Nearly three quarters of the molecules were launched by a company different from the one that filed the original patent, reflecting the level of activity in licensing, partnering and acquiring associated with biopharmaceutical innovation.
- Globalization of industry
- Many players to absorb risk
Convergence of new technologies across sectors – success in one sector (e.g., agriculture) can more easily be translated to another.

New technologies like CRISPR are less expensive and easier to learn to use.

Cross-border collaboration in research and commercialization is increasing (e.g., huge rise in partnering meetings). *In other words, globalization of technology is accelerating.*
Very expensive and long timeline to develop and commercialize biologics

Majority of projects fail = risky

Blockbusters are the exception

Small companies driving global biopharma pipeline

Increased partnership
- Nearly three quarters of the molecules were launched by a company different from the one that filed the original patent, reflecting the level of activity in licensing, partnering and acquiring associated with biopharmaceutical innovation.

Globalization of industry

Many players to absorb risk
South Africa and Global Benchmarking
Building strong biotech/biomedical sector = strategic priority for many economies. Many have created a blueprint for biotech innovation.
Building a Bioeconomy in South Africa
Annex 1 – Additional Biotech Input and Output indicators
Contents

Biotech Input Indicators

• Number of Researchers
• R&D Spending as a % of GDP
• Scientific American Worldview
• R&D Incentives

Biotech Output Indicators

• Scientific Publications
• Biotech Patents
• Biotech Triadic Patents
• FDI
• Biopharmaceutical R&D FDI
• Venture Capital
Summary of Pugatch Findings: Input Indicators

Human Capital
Low number of researchers, with no significant increase over the years

R&D Capacity
R&D Spending low, stagnating over the last 20 years

R&D capacity
Relatively good performance in terms of Biotech Innovation Potential

R&D incentives
Among the lowest levels of support to business R&D
Summary of Pugatch Findings: Output Indicators

Scientific Publications
Relatively low but increasing and good quality publications

Biotech patents
Constant, limited share of biotech patents globally

Biotech triadic patents
Low number of triadic patents

Foreign Direct Investment
SA is lagging its counterparts in FDI

Biopharmaceutical R&D FDI
SA is not a significant contender for R&D Investment

Venture Capital
Positive trend registered in 2016 in VC activities
## Scientific American Worldview Scorecard Metrics

### Productivity
- Public company revenues
- **Number of public companies**

### Intellectual property
- Scope and strength of IP protection
- Perceived IP protection

### Intensity
- Public companies per population
- Public company employees per capita
- Public company revenues per GDP
- Biotechnology patents / all patents
- Biotechnology VC per GDP
- Biotechnology R&D per total R&D
- Proportion of public companies

### Education/Workforce
- Post-secondary science graduates / capita
- PhD graduates in life sciences per capita
- R&D personnel per thousand employment
- Talent Retention
- Brain Gain

### Foundations
- Biotechnology R&D spend
- Business Expenditures on R&D / GDP
- Government support of R&D / GDP
- Infrastructure Quality
- Entrepreneurship and Opportunity

### Policy and Stability
- Political stability & absence of violence/terrorism
- Government effectiveness
- Regulatory quality
- Rule of law

The U.S. leads, but global activity is growing

South Africa is just below middle of the pack
Recommendations
Broad Policy Recommendations (I)

- Develop a national multisectoral biotech development plan: “All of Government” approach critical

- Mechanisms for translating research to commercial application critical

- Link into global capital markets

- Strategy should have an **outward, global (as opposed to inward looking) perspective**. If industry is not globally competitive, it is not sustainable.
  - Need to be positioned for global competition and collaboration
Broad Policy Recommendations (2)

- Need state of the art regulatory regime – adopt global best practices

- Ensure enforceable IP rights, following global best practice. Without it, investment will wither.

- Adopt public communications campaign to build understanding of the new technology and its promise. Fight ignorance and fear.
Thank you

hstiss@bio.org
Senior Manager, BIO