

CREATE AMERICAN JOBS

“Do not let a recession go to waste, think growth, don’t think retrenchment”

– Lynda Applegate, HBS Innovation Professor

“The fundamental element of any good strategy is to build it upon your strengths”

– Cynthia Montgomery, HBS strategy Professor

Definitions:

- (a) Life Sciences term includes biotechnology, pharmaceutical and medical device companies
- (b) Biopharma includes biotechnology and pharmaceutical companies. Please note that all Top 15 pharmaceutical companies are now also biotech companies. BigPharma became Big BioPharma.
- (c) Puerto Rico’s installed base of pharmaceuticals is smoothly transitioning from Pharma to Biotechnology sites making us a powerhouse in “Big BioPharma”

I. Current Context – Industrial (Puerto Rico)

PUERTO RICO’S STRENGTH

- A. Puerto Rico’s Economy:
 - GDP= \$103.6 billion
 - GMP=69.2 billion
 - GDP per Capita=\$28,850
 - Exports= \$62.3 billion
 - Imports = \$47.9 billion
- B. Puerto Rico’s manufacturing represents 48% of its total GDP
- C. Manufacturing industry in Puerto Rico segmentation:
 - Biopharmaceutical - 50.5%
 - Computer & Electronics – 21.3%
 - Basic Chemicals – 14.0%
 - Medical devices – 4.3%
 - Beverage – 2.9%
 - Food – 2.1%
 - Electrical Equipment – 1.6%
 - Other – 1.4%
 - Petroleum & Coal - 0.7%
 - Machinery - 0.5%
 - Metal Products - 0.5%
 - Apparel 0.3%

Industry

A. Biopharmaceutical Industry Contribution to Puerto Rico:

- Biopharma generates 30% of GDP directly (over 40% of GDP including indirectly) – only primary economic activity in PR of relevance (next is Tourism with 7%, which includes business travelers)
- Biopharma generates 61% of total manufacturing activity
- Biopharma exports in 2013 were \$44 Billions
- 9 out of the top 14 Biopharma companies have manufacturing sites
- Produce 9 of the top 25 products sold in the US
- Biopharma represents over 33% of total government revenues collected (2015)
- Average salary \$62,000, all other Puerto Rico industries combined average salary of \$18,000
- Biopharma assets base in Puerto Rico have a valuation of over \$10 billion
- Biopharma Capital Expenditure (CapEx) on maintaining current asset base is between \$500-\$700 million yearly. Note: This yearly investment excludes new technologies, new products, expansions, etc.).

B. Puerto Rico is the 5th largest Biopharmaceutical manufacturing hub in the world (by Pharmaceutical Executive January 2016)

C. PR has over 50 years of Life Sciences' manufacturing experience

- Biotechnology Learning Center (BLC)
- Center of Excellence for Advanced Technology (CEAT)
- Puerto Rican Industrial Development Corporation (PRIDCO)
- INDUNIV

D. Leading industrial sector in PR since the 1970's

E. More than five decades of FDA regulatory compliance experience

F. Biopharma products manufactured and distributed to over 100 countries

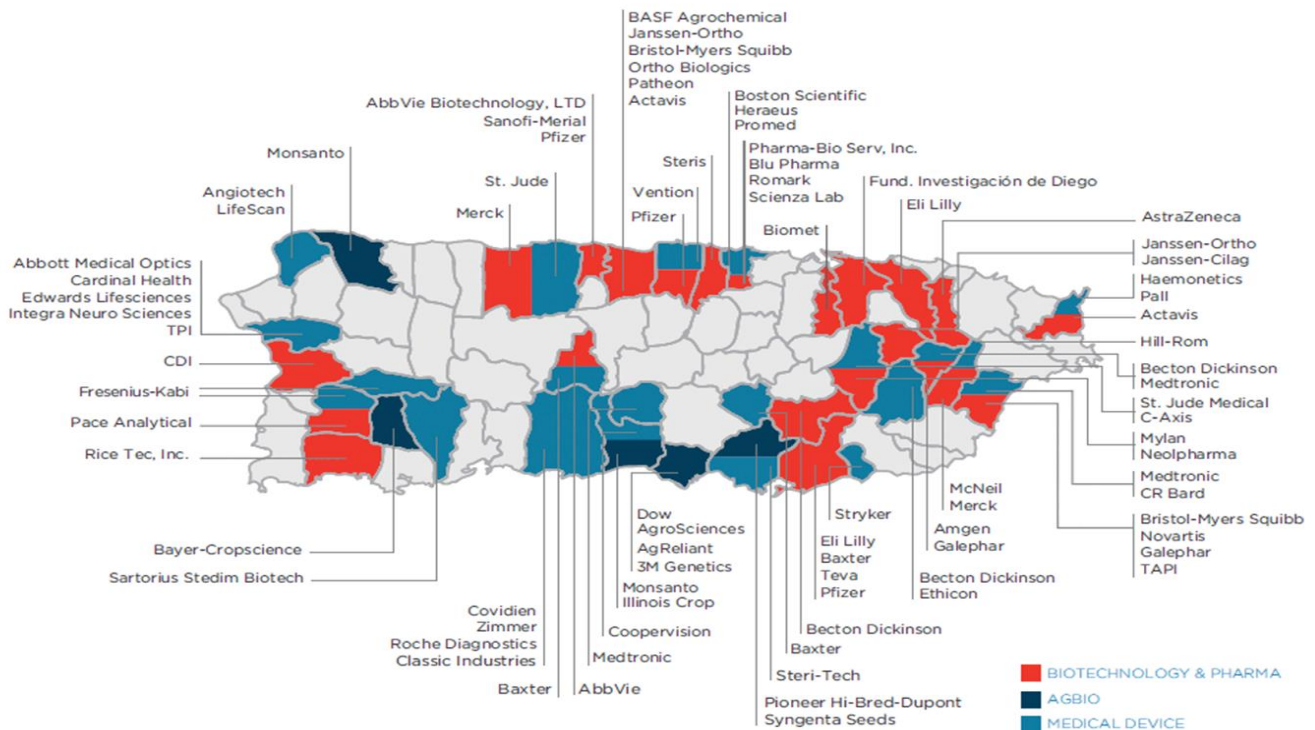
G. Example of current Biopharma industry installed based:

- (a) Amgen has its largest manufacturing facility located in Juncos, PR. More than 90% of its products are either formulated, finished or packaged here. Amgen assets in Puerto Rico have a valuation of over \$3 billion
- (b) Eli Lilly & Co., the company that invented insulin, has been in Puerto Rico for over 50 years with assets exceeding \$1 billion. It produces in Carolina, Puerto Rico almost all of the Humalog insulin sold in the world, among other products.
- (c) Abbvie produces in Barceloneta, Puerto Rico almost all of the Humira sold in the world, among other products.

H. In addition, Puerto Rico is a leading location for the manufacturing of medical devices and bio agricultural companies:

- A large number of the crops of the future are being developed here by companies such as Sygenta Seeds, Dow Agrosiences and Monsanto
- 11 out of the top 20 medical devices companies have manufacturing facilities in Puerto Rico
- Most of Microsoft software updates downloaded in the Americas is validated and distributed from Puerto Rico
- Honeywell has business support operations such as engineering design, supply chain, finance, and IT among other, for the Company's defense programs.

Life Sciences Industry in Puerto Rico



BioPharma Companies with Manufacturing Operations in Puerto Rico

abbvie

AMGEN

AstraZeneca

Baxter



Johnson & Johnson

Lilly



Contribution of BioPharma Manufacturing in Puerto Rico

GDP



JOBS

78,000



TAXES



SALARY



PAYROLL



ASSETS BASE

\$10 Billion



Academia

- I. University of Puerto Rico's Mayaguez Campus (Engineering/Science University) Puerto Rico's Universities in Science & Technology:
 - Ranked 1st, among all U.S. institutions, in graduating Chemical Engineers
 - Ranked 2nd in women engineers
 - Ranked 11th in undergraduate enrollment among engineering schools in the U.S
 - UPR has had over a twenty years a special bachelor's program in Industrial Biotechnology
- J. 40% of the 25,700 bachelor's awarded annually are in Science & Engineering, 2,040 post-graduate degrees in Science & Engineer
- K. UPR (Mayaguez Campus) and Polytechnic University of PR are in the top 20 of undergraduate engineering enrollment

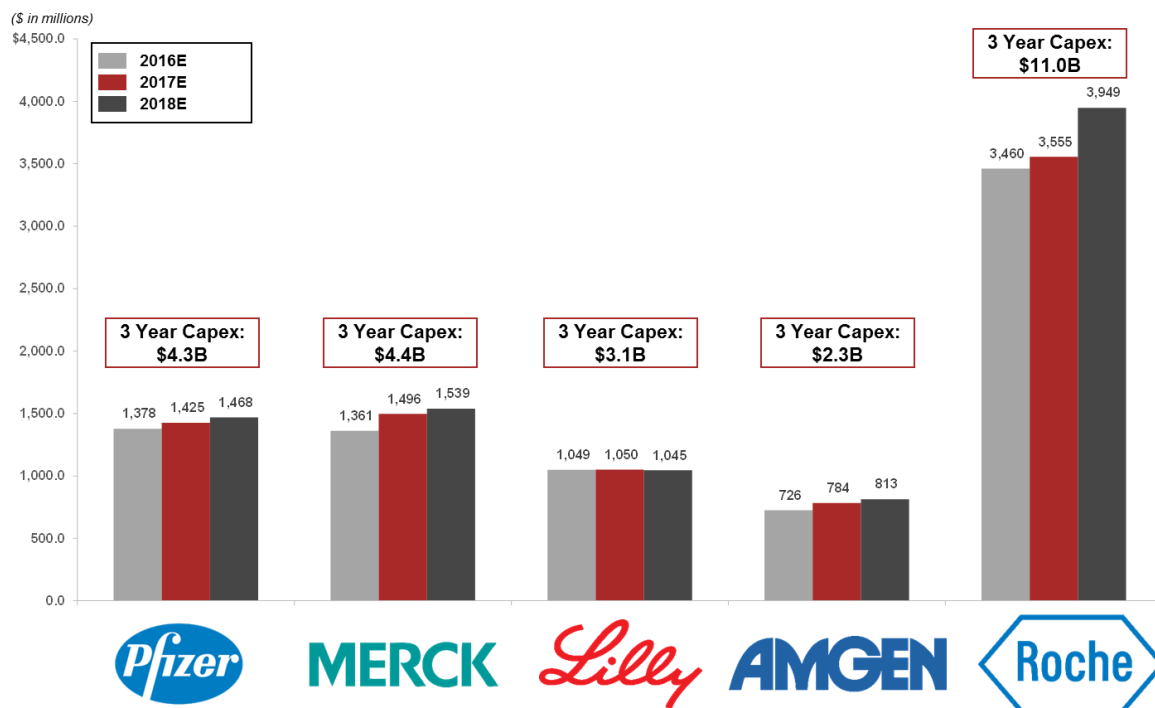
Competitive Environment

- L. Maybe the most important element of Puerto Rico's strength regarding the Life Sciences' industry is its competitiveness, resources and ecosystem:
 - PR is one of the most competitive regions, world-wide, in regards to Life Sciences manufacturing
 - PR has one of the strongest life sciences manufacturing ecosystems in the world (industry, academia, suppliers, judicial systems)
 - PR has one of the highest "productivity yields" (companies' effectiveness in converting input to outputs) in the world regarding Life Sciences manufacturing.
 - PR is known in the Life Sciences industry for its process development and quality processes
 - Examples:
 - (a) From 2003-2007, \$6.2 billion, four (4) green field sites where built by 4 of the top 10 biopharmaceuticals in world in Puerto Rico. ALL OF THEM PASS APPROVAL TO SELL THE PRODUCT ON THE FIRST FDA INSPECTION.
 - (b) In May of 2016, Janssen Gurabo – made history in the BioPharma world becoming the 1st ever, Continuous Mfg. approved by FDA worldwide.

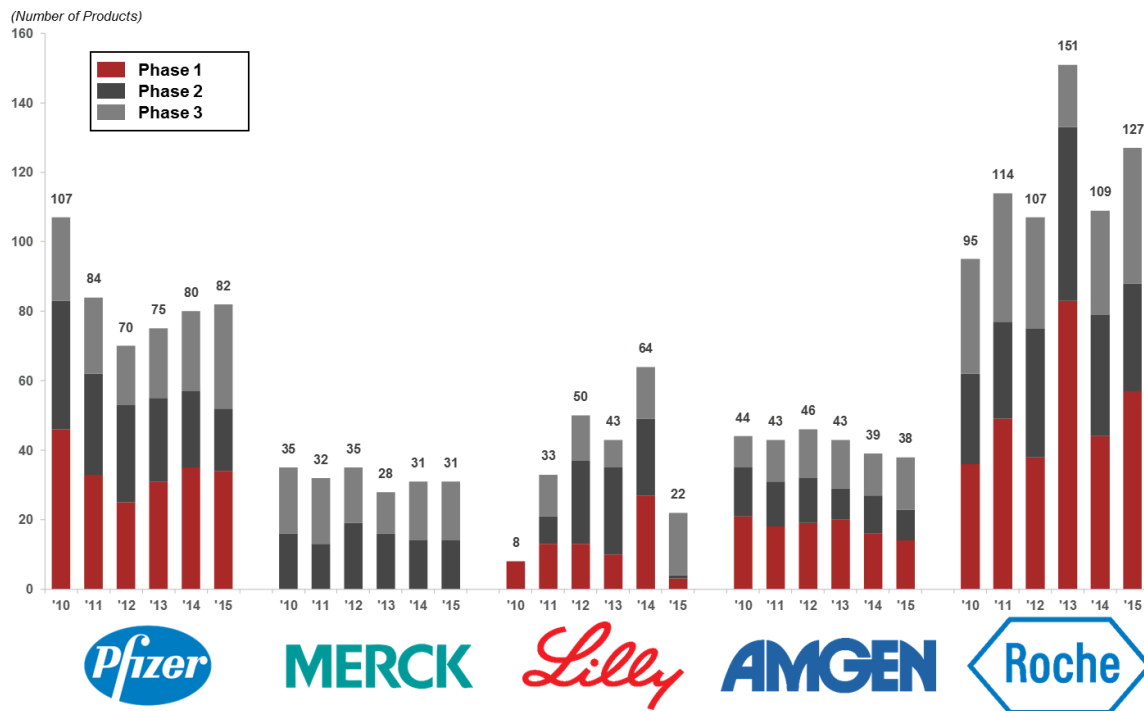
II. Current Situation - Biotech Industry (Worldwide)

THE U.S.A NEED

- A.** SIGNIFICANT NEED in the U.S. Life Science industry.
- B.** Ireland alone has, since 2015, received in Biopharma manufacturing investment approximately \$3.8 billion (incl. Alexion \$750 m, BMS \$1 billion, BioMarin \$1 billion, Regeneron \$1 billion).
- C.** \$28 Billion - the expected capital expenditure for the next three years (2016, 2017, 2018) of the following five (5) Life Science companies (just a sample), all with significant presence in Puerto Rico:
- Pfizer: \$1,378 m (2016), \$1,425 m (2017), \$1,468 m (2018). Total: \$4.3 Billions
 - Merck: \$1,361 m (2016), \$1,416 m (2017), \$1,539 m (2018). Total \$4.4 Billions
 - Lilly: \$1,049 m (2016), \$1,050 m (2017), \$1,045 m (2018). Total: \$3.1 Billions
 - Amgen: \$726 m (2016), \$784 m (2017), \$813 m (2018). Total: \$2.3 Billions
 - Roche: \$3,460 m (2016), \$3,555 m (2017), \$3,949 m (2018). Total: \$11 Billion.

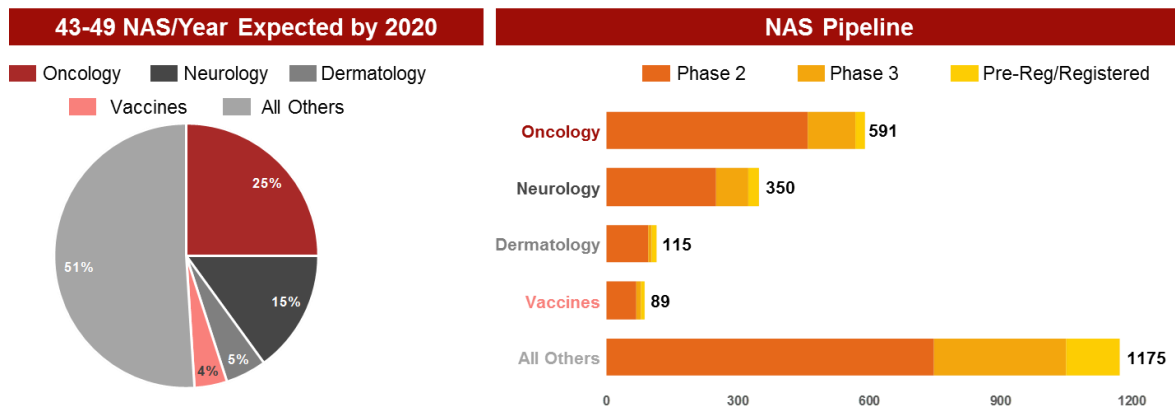


D. Strength in Phase 1-3 drug pipelines of leading biopharma companies contributing to continued sector growth over the next 5 years



E. Strong pipeline of late phase R&D creating need for automation expertise over the next 5-10 years

- Continued push by biopharma companies to expand drug offerings
 - Large, late phase R&D pipeline – nearly 50 annual New Active Substances (NAS) expected by 2020
 - 25% and 15% of which are in Oncology and Neurology, respectively
- Significant volume of NAS in pipeline – from Phase 2 to Pre-Registration/Registered
 - Biopharma companies will require best-in-class sourcing, suppliers and context to help them succeed



III. Short & Medium/Long Term Sustainable Economic Development Ideas

THE OPPORTUNITY – CREATE AMERICAN JOBS

Immediate Short-term Sustainable Economic Development

A true win-win situation. The U.S. Life Sciences' industry needs the BIGGEST ASSET Puerto Rico has, its world-class competitive environment in Life Sciences manufacturing, as much as Puerto Rico needs the FDI from the Life Sciences industry.

- A. Step #1:** Certainty (A MUST)– Law 154, which imposes the current 4% tax and which 95% is paid by these 9 Biopharma companies, must not be altered. It expires in 2017, any alternative to be considered must be less or equal to 4%.
- Non U.S. based life sciences companies cannot claim the tax credit to the US' therefore, a measure should be identified for those companies.
- B. Step #2:** Credibility (A MUST) – Significant (to say the least) lack of credibility on Puerto Rico Government. Law 154 was implemented abruptly on a Saturday night in 2010 by local Government without any prior notification to these companies.
- In addition, it was supposed to tapered down yearly but then, in 2012, a new Government increased it from 2.75% to 4% again. Law 154 violated existing bilateral contracts between PR's government and these companies – the conditions under which an investor decides to invest in a country must not change after the investment is made, specifically for capital intensive business which are also highly regulated such as Life Sciences.
- Any incentive to the industrial sector, in particular to the BioPharma companies, who got hit with an additional \$1.2 billion tax annually needs to come with significant credibility, clarity and guarantees by U.S. government.
- Current agreements among PR Government and existing FDI companies (existing or prospective) must be honored by the Fiscal Control Board or any other entity assigned to handle this as to promote an environment of certainty and credibility.
- C. Step #3:** Energy – significant concern by the Life Sciences industry about the sustainability of PREPA and its capacity to supply energy with the required quality and in a consistent manner. Areas to focus are:
- Maintenance and/or replacement of infrastructure to generate and transmit energy
 - Build up required operational knowledge due to retirement of existing personnel
 - Integration of renewable energy and alternative fuels
- D. Step #4:** Activate a “temporary” incentive to this industry, like AIPR and Coalition “Growth Proposal” 245A – duration 5-10 years' maximum.
- E. Step#5** – Significant overhaul of existing laws in Puerto Rico that hampered economic growth such as:
- Labor law (replicate labor laws in the state “at will”
 - Christmas Bonus Law
 - Act 75 – Protectionary law that limits competitiveness in the distribution/supply chain of goods including food and beverages, increasing prices due to protectionism and preventing ompetition

- F. **Step#6** – Commence in parallel initiatives described in next section “*Medium/Long Term Sustainable Economic Development*”

Medium/Long Term Sustainable Economic Development

- A. **Vision:** Our locally based companies, with no contracts with the local government, generate over 30% of Puerto Rico’s GDP’s through value creation around the world. Many of these, publicly traded companies.

Note: In the history of Puerto Rico, it has never had a publicly traded company that creates over 10% of its overall value outside Puerto Rico!

- B. **Mission:** A stream of export-oriented, innovative, ambitious new entrepreneurial ventures as an essential- element in Puerto Rico’s growth strategy (currently missing).
- C. **Goal:** In Puerto Rico a tipping point will be achieved when at least 30 new high potential ventures* enter the “system” each year. To achieve this, we will need to annually double the number of high potential ventures in Puerto Rico in the coming 3-5 years by cultivating a self-sustaining entrepreneurship ecosystem, fed with appropriate types and amounts of capital

* High Potential Ventures:

- Has strong leadership
- Has significant potential market, export oriented
- Has passed initial market test (at least initial sales)
- Has growth ambition

Step #1: Ensure the Life Sciences FDI procures products and services locally and as such provokes the needed overspill and shared value for local suppliers of this industry to internationalize and establish operations worldwide.

Step#2: Create a “CEO” (Chief Entrepreneurship Office) position to, under one strategic initiative, combined all existing e-ship initiatives within Puerto Rico

Step#3: Create an Endeavor chapter in Puerto Rico, to collaborate with all existing initiatives who enable e-ship (e.g. Grupo Guayacan, YEES, Parallel18, Foundation for Puerto Rico, etc.) to provoke a significant ecosystem of locally based companies that create value around the world

Step#5: Refer to Babson’s “Puerto Rico Entrepreneurship Ecosystem Project” (PREES) Phase 1 results and proposed Phase 1.5 and Phase 2 roadmap and execute accordingly. Here a summary of Babson’s PREES Phase 2 steps:

- Provoke sound and sustainable “Access to Capital” – “Prime the Pump”, incentives for private equity and venture capital to be accessible. Address low deal flow by matching management fees.
- Focus on “Scale-up” on existing proven business to export and establish presence internationally
- Recognized our “weak” Eco-system Pillars
 - Government leadership ignorant of entrepreneurship, confused in policies, FDI-oriented
 - Large enterprises perceived as protective, even predatory
 - Risk capital unavailable, government overinvolved
 - Culture anti-wealth, insular, low ambition
 - NGO’s poorly coordinated, FDI focused
 - Little entrepreneurship training, work ethic poor, brain drain to US
 - Good News:
 - Puerto Rico has excellent human resources, including Diaspora resources, to start ventures

- Puerto Rico has numerous other assets: science, multinationals, US access, management talent
- Babson estimates that there are 300-500 actual or potential entrepreneurs who have the skill and mindset to fuel sufficient numbers of high potential ventures, and more will be created when they see some initial success
- Establish a coordinated effort to address the following for “Start-ups” and “Scale-ups” in the next 1-3 years:
 - **Policy:** High priority for export-oriented entrepreneurship, Fast tracking of high potential ventures
 - **Finance:** \$200 million new capital for “pump-priming
 - **Culture:** Island-wide PR and media campaigns
 - **Supports:** Create linkages and common platform for NGOs
 - **Human Capital:** Entrepreneurship training from K-12-BA-MA
 - **Markets:** “Buy small” campaigns supported by training and coaching
 - A temporary entrepreneurship independent, non-government agency (PREES) to stimulate, coordinate, synergize, and disband

The End -