

# Selecta Biosciences

## Implementing the Innovation Goals of Pharma 2020 with Selecta Biosciences

**Werner Cautreels, Ph.D.**

*General Director Selecta (RUS), LLC  
President and CEO Selecta, Inc.*

May, 22, 2013

# Selecta Platform Pioneers Novel Vaccine Applications



## **Prophylactic vaccines**

- Prevent disease
- Examples: infectious disease, such as malaria

## **Therapeutic vaccines**

- Harness the power of the immune system to treat disease
- Examples: cancer, smoking cessation, HIV, HBV, TB

## **Tolerogenic vaccines**

- Treat autoimmune diseases
- Examples: diabetes, allergies, protein replacement therapy

**Selecta's novel  
platform covers  
all three types  
of products**

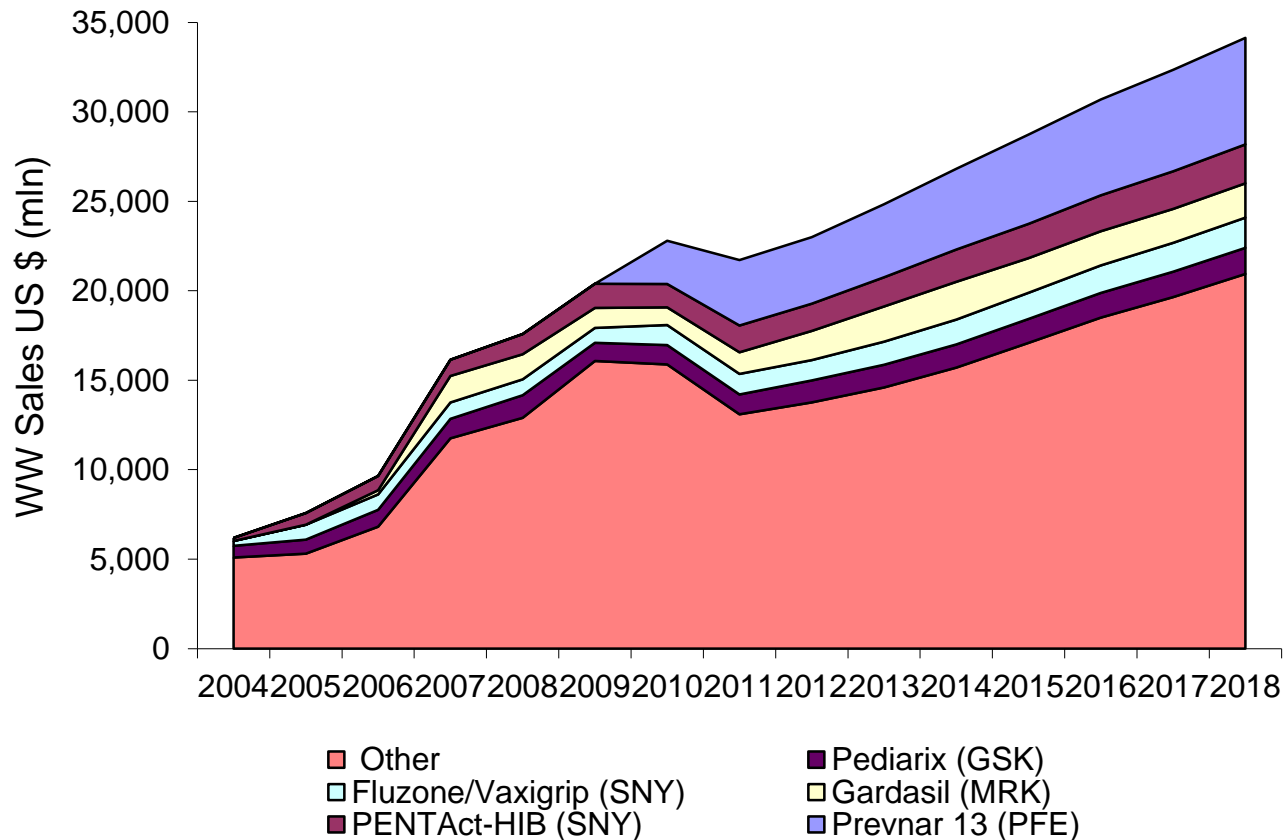
“The two public health interventions that have had the greatest impact on the world's health are clean water and vaccines”

*World Health Organization*

# Strong Growth Expectation for Vaccines



Total WW Market Value: Top 5 Products in 2018 + Other



- Vaccine market grew from \$17B in 2008 to \$22B in 2011 (9% annual growth)
- Expected growth to \$34B by 2018 (7% annual growth)

Source: Evaluate Pharma

# Selecta Combines State of the Art Immunology and Nanotechnology



## Founders



### **Robert Langer, ScD, MIT**

Institute Professor, National Medal of Science, National Medal of Technology and Innovation, Priestly Medal  
Founder of more than 20 companies

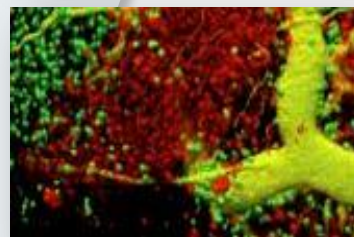
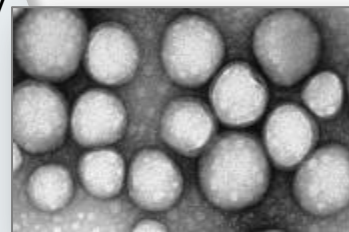


### **Omid Farokhzad, MD, Harvard Medical School**

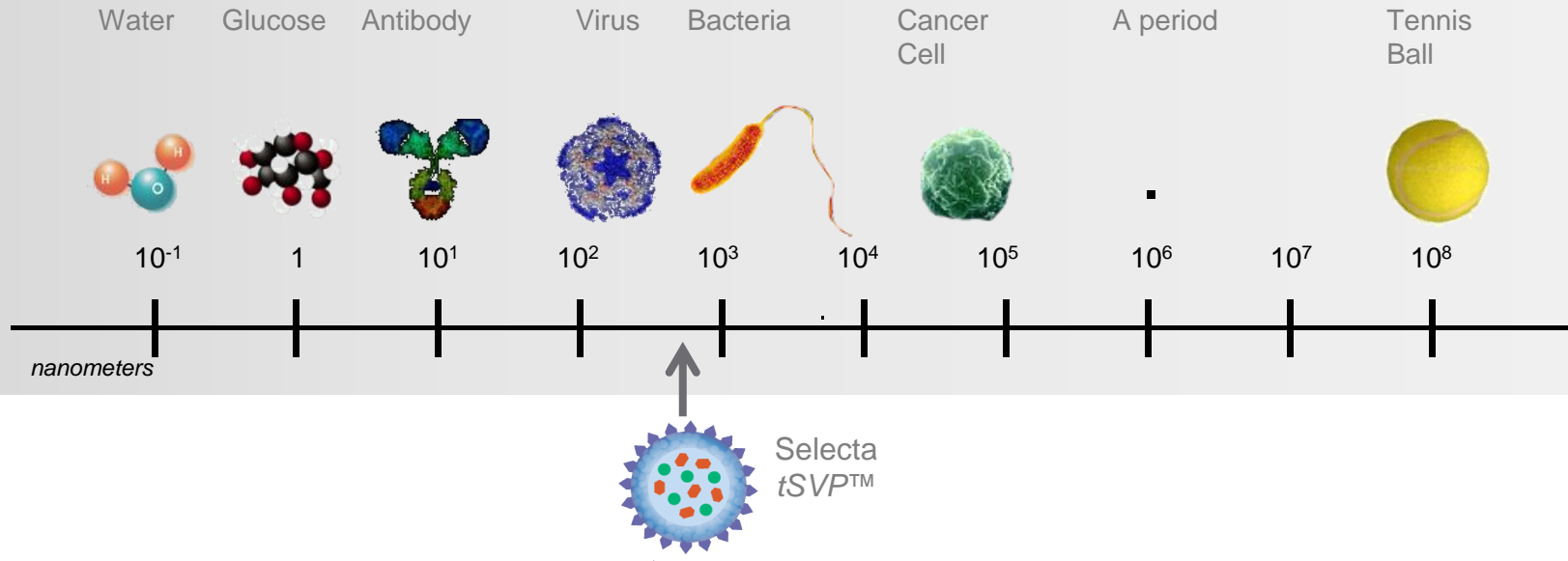
Associate Professor  
More than 70 issued patents,  
founder of 3 companies



### **Ulrich von Andrian, MD, PhD, Harvard Medical School** Professor



# Nanoparticles Have the Optimal Size for Recognition by the Immune System



**The human immune system has evolved to recognize particles**

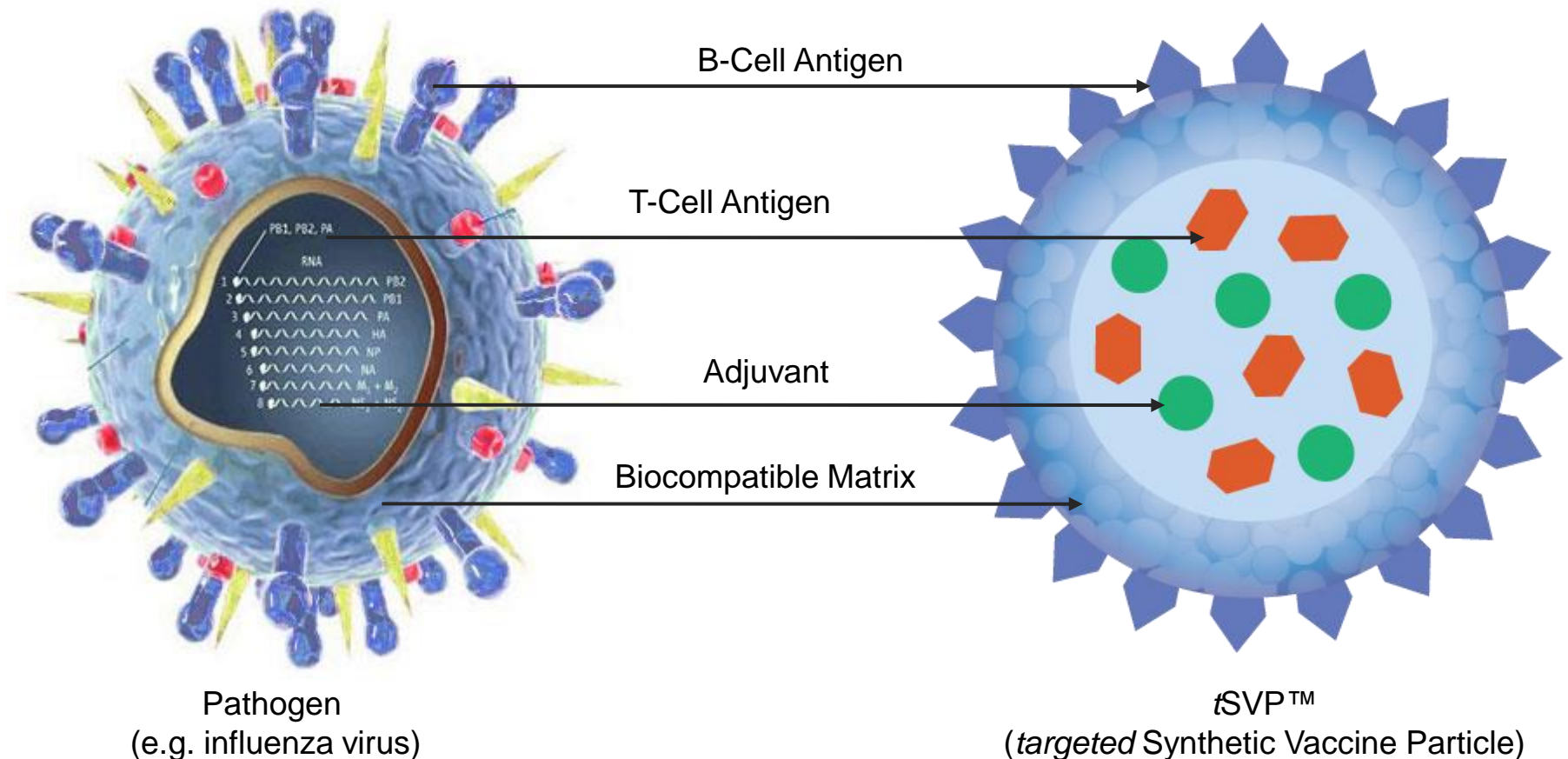
- Viruses are nanoparticles
- Bacteria are microparticles

**Selecta's immunotherapies freely flow through the lymphatic system to the lymph nodes**

- Delivery of required components to the targeted immune cells
- Controlled release of immunomodulators

# Synthetic Nanoparticles are Engineered to Mimic a Natural Immune Response

Example of Selecta Nanoparticle Activating Immune Responses to Protect Against Influenza Virus





# A Flexible and Modular Vaccine Platform

## Immunomodulator

e.g.

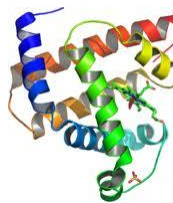
- TLR agonists
- Tolerogenic agents
- Checkpoint inhibitors

## T cell antigen

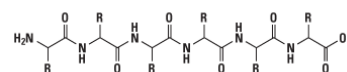
e.g.

- Disease-specific epitopes
- Protein antigens

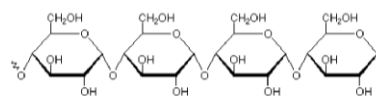
## B cell antigen



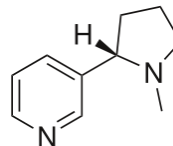
Protein



Peptide



Sugar



Small molecule

## Nanoparticle polymer

e.g.

- Particle size
- Surface properties
- Release rates

# Selecta's Nanoparticles are Self-Assembling and Synthetic



## Components

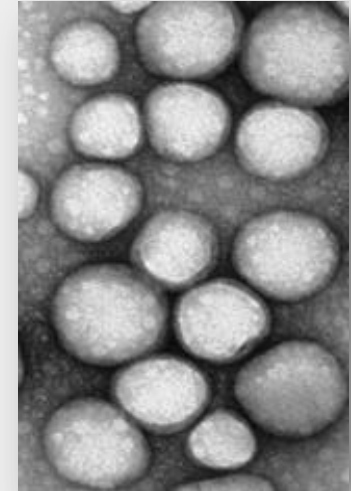


## Production



The table-top vessel shown here produces nanoparticles for 10,000 doses of vaccine within 15 to 20 hours. It has been used under GMP conditions.

## Self-assembly



## Advantages of Selecta's synthetic production vs. Biologicals:

- ✓ Flexibility
- ✓ Scalability
- ✓ Stable and Reproducible
- ✓ Lower cost
- ✓ Utilizes standard equipment



# Company Investors & Highlights



## Investors



\$1bln



\$3bln



\$7bln



n/a



\$10bln

## Selecta Biosciences Inc.

- Founded: 10/2008
- \$60 Million capital investments
- Laboratories in Boston, USA and Moscow, Russia
- 50 Scientists, ~150 scientist at collaborator sites
- Nicotine vaccine to start next clinical study in Russia
- Sanofi agreement in field of allergies (\$900M)
- More than 80 patent families, more than 3000 claims



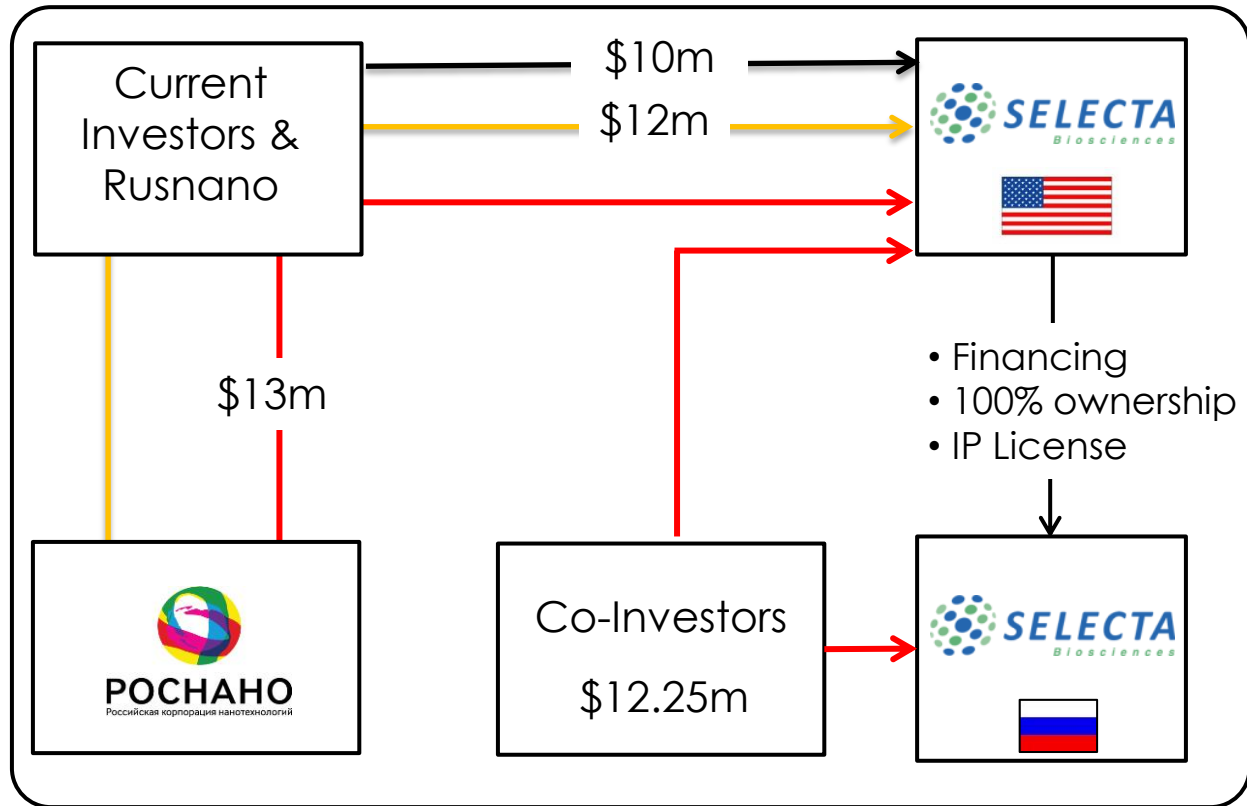
Approximate Assets under Management

# Selecta Inc. Funding



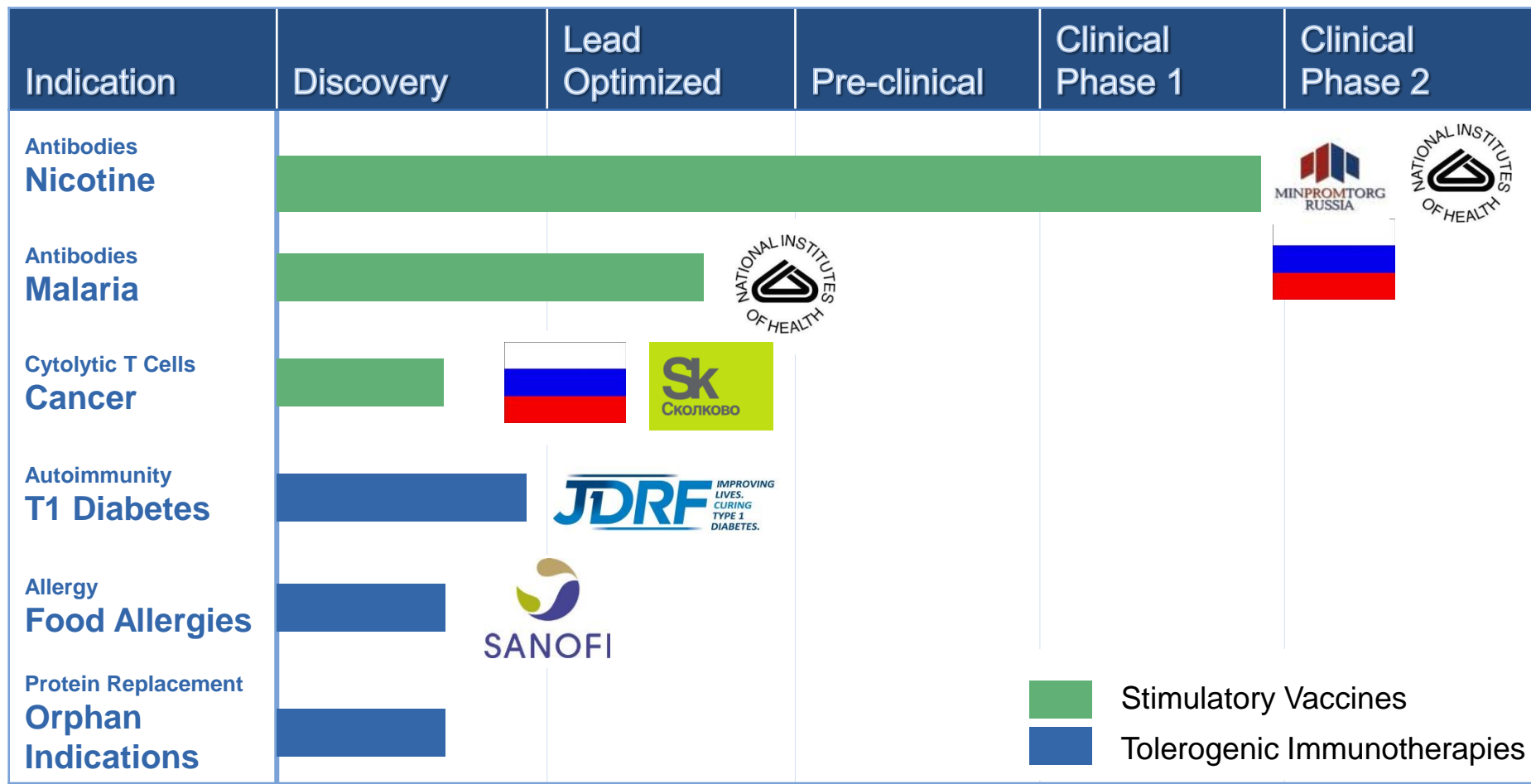
	<u>Date</u>	<u>Funding</u>	
Series A	May-08	\$ 2.5 Million	} <b>\$ 58.1 million</b>
Series B	Dec-08	\$15.1 Million	
Series C	Mar-10	\$15.0 Million	
Series D	Oct – 11	\$22.0 Million	
Series SRN Received	Oct – 11	\$ 3.5 Million	
Series SRN Committed	Over 4 years	\$ 9.5 Million	
Series SRN Open	Over 4 years	\$ 12.25 Million	
<b>Total Funding Received/committed</b>		<b>\$79.85 Million</b>	

# Selecta (RUS) Funding



- Traditional Preferred Existing Shareholders
- Traditional Preferred Rusnano
- Strategic Shares

# Selecta's Pipeline: Diversified & Externalized



# Sanofi-Selecta Allergy Collaboration was the 8<sup>th</sup> Biggest Licensing Deal in 2012



Licensor	Partner	Product / Technology	Headline \$M
Molecular Partners	Allergan	MP0260 preclinical dual anti VEGF-A/PDGF-B DARPin for wet AMD; discovery alliance/options against selected targets in serious eye disease	1,463
Galapagos	Abbott	Collaboration for oral JAK1 inhibitor (GLPG0634) in RA and other autoimmune diseases (phase 2)	1,350
Five Prime Therapeutics	GSK	Discovery collaboration with options for asthma and COPD targets	1,191
Genmab	J&J	License to daratumumab, oncology (phase 1/2)	1,100
MacroGenics	Servier	Discovery alliance with options for Dual-Affinity Re-Targeting (DART™) platform technology for 3 cancer targets	1,100
Endocyte	Merck	License to vintafolide (EC 145) for ovarian cancer, NSCLC and other solid tumors (phase 3)	1,000
Astellas	J&J	Exclusive rights outside Japan to ASP015K, an oral JAK inhibitor for RA and psoriasis (phase 2)	945
Selecta	Sanofi	Discovery collaboration for antigen-specific immuno-therapies for life threatening allergies based on Synthetic Vaccine Particle (SVP™) platform	900
Forma Therapeutics	Boehringer Ingelheim	Discovery of small molecule therapeutics against oncology-relevant protein-protein interactions	815
Evotec	Bayer	5-year multi-target collaboration to develop 3 candidates for endometriosis	765

Source: *Medius Annual Deal Watch 2012*

# Selecta (RUS) Highlights



- Selecta (RUS) was established in Oct 2011
- Wholly owned subsidiary of Selecta Biosciences Inc.
- License of entire Selecta IP portfolio for Russia and CIS markets
- The R&D center opened in Nov 2012 in Chemrar scientific park, Khimki, Moscow region.
- Initial technology transfer was completed in Feb 2013. The facility has successfully produced nicotine nanoparticle vaccine at the research scale ([Press Release](#)).

Nicotine Vaccine	Clinical Trials	Minpromtorg contract obtained (\$4.5 M)
Oncology	Pre-clinical	Skolkovo grant application (\$1 M)
Contract Manufacturing	Ongoing	Funding open and active termsheet negotiations

**Selecta RUS is establishing new facilities with full Research (from Discovery to clinical Proof of Concept) and GMP manufacturing capabilities**



# Advantages of a Russian Presence for Selecta



- **Momentum generated by Pharma 2020**
  - Committed investors in nanotechnology and biotechnology
  - Access to grants
  - New business opportunities
- **Access to a market with growing importance**
  - Growing economy
  - Positive demographics
  - Large unmet medical needs
- **Selecta company value creation**
  - Increased interest from big pharmaceutical players in local Russian business opportunities
  - Opportunities for investments from Russian pharmaceutical companies and private investors

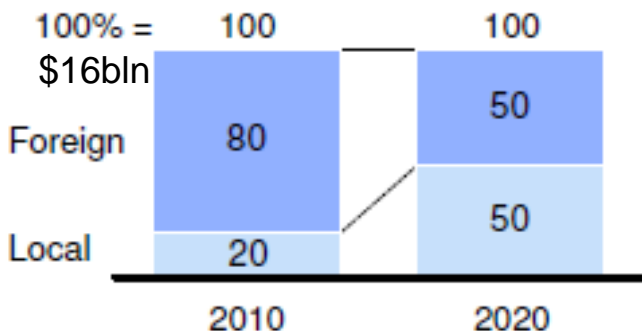
# Pharma 2020



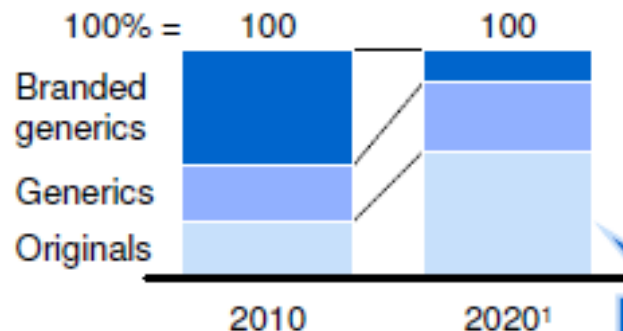
www.pharma2020.ru

Value  
distribu-  
tion,  
Percent

Government wants to push local manufacturers ...



... as well as increase the share of innovative drugs



## Local manufacturing

- Reduce share of foreign imports
- Develop exports based on perception of high quality, effectiveness

## Local R&D

- Establish highly innovative local pharmaceutical industry
- Support competitiveness of domestic Pharmacos

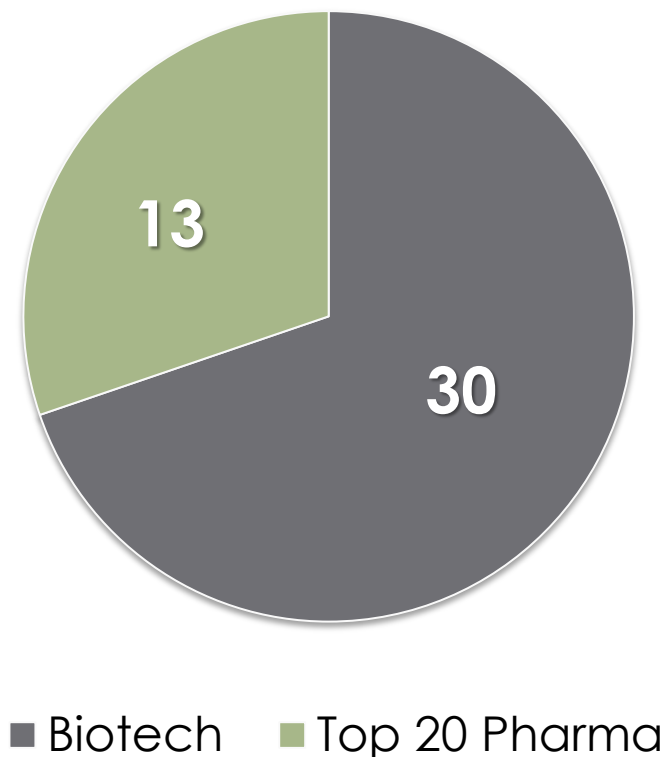
Gov't push  
**STRONGLY**  
favors  
localized  
players like  
Selecta

<sup>1</sup> No exact numbers provided, approximation of illustration provided in the "Pharma 2020" strategy document

# Biotechnology is the Innovation Motor Behind Top Pharmaceutical Companies



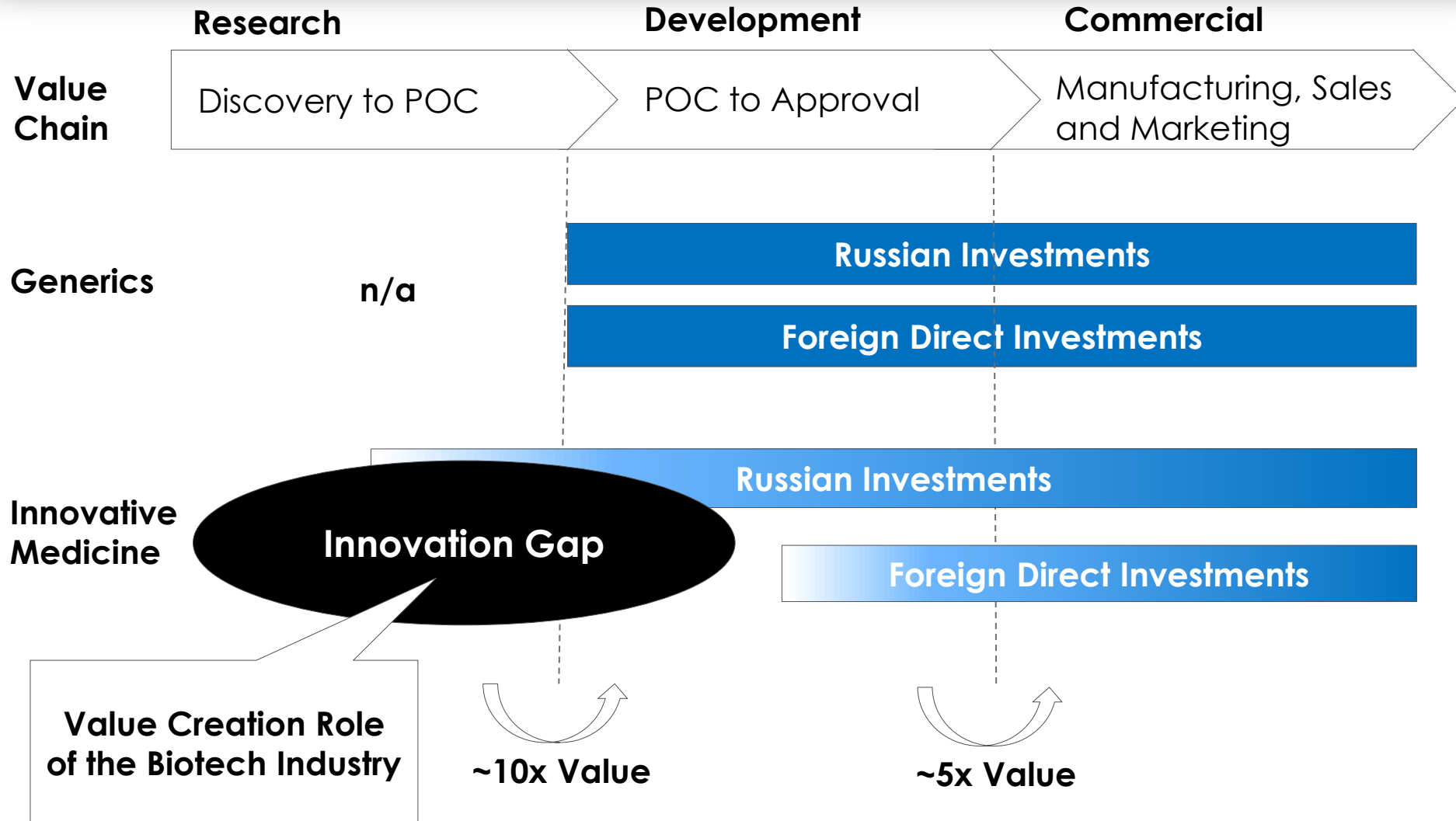
## New Molecular Entities USA, 2012



- 43 New Molecular Entities (NME) approved in the US in 2012
- 30 NMEs (70%) originate from Biotechnology companies who were acquired or licensed their products to a large cap pharmaceutical company
- Only 13 NMEs (30%) were discovered in the laboratories of the top 20 global pharma companies controlling more than 60% of global pharmaceutical sales

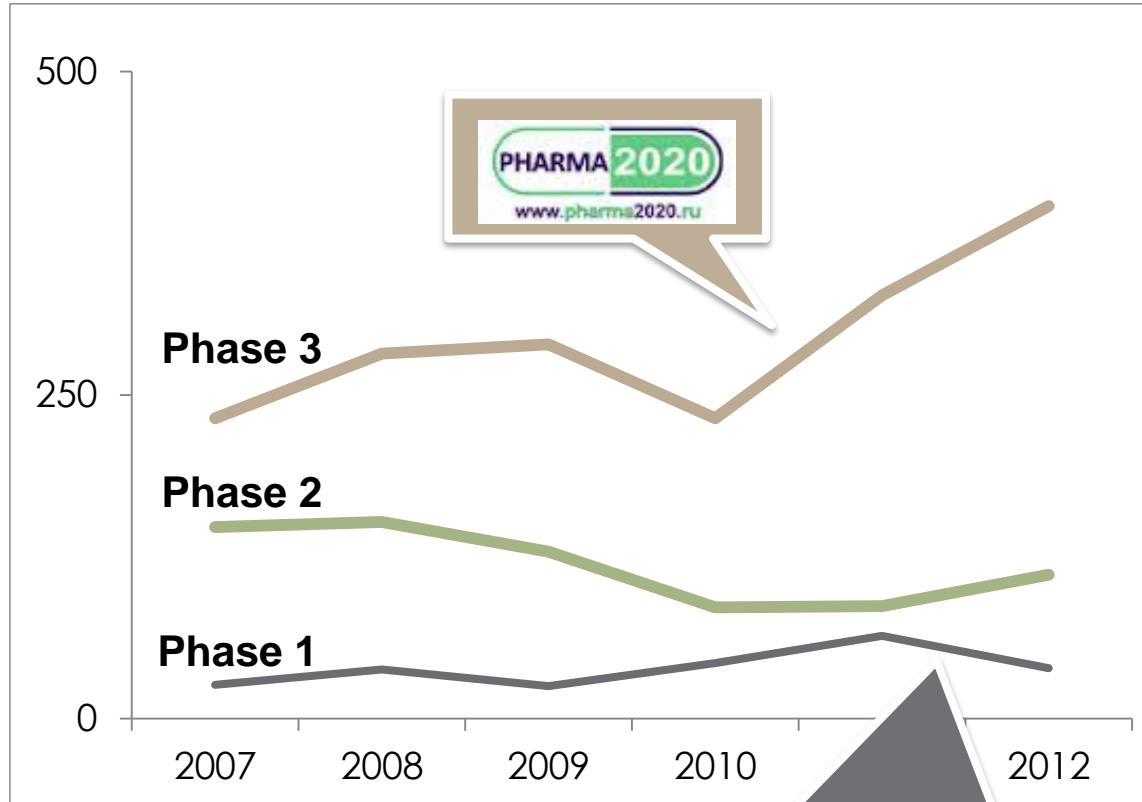
Source: Evaluate Pharma

# Russia's Pharmaceutical Market Outside-In Perspective



# Russia has a Relatively Low Level of Phase 1 Clinical Studies

Number of Clinical Studies in Russia by Phase



- Pharma 2020 has attracted many international companies conducting parts of their pivotal studies in Russia
- Lack of early development studies indicative of missing Biotechnology infrastructure for international companies (e.g. GMP production)



Requirement of Russian Ministry of Health to produce Phase 1 clinical supply in Russia under GMP conditions?

# Selecta's Plan Builds on Existing Success and Accelerates Russia's Biotech Sector



## Selecta Initiative

## Selecta Value Proposition

### Early Pipeline

- Build a robust pipeline of early stage clinical assets (Phase 1 and 2) in Russia from Selecta technology and partners

### Facility

- Construct a flexible GLP and GMP type laboratory and manufacturing space to facilitate the development of a diverse early clinical pipeline

### Manufacturing Services

- Close GMP manufacturing gap for the Russian Biotech sector
- Support localization of foreign biotechnology companies

**Attract Direct Investments in Pharmaceutical and Biotech Industry**



# Conclusions



- Attracting additional foreign biotech companies and early stage clinical projects should be an additional priority for Pharma 2020
- Selecta (RUS) LLC can be instrumental in filling two major gaps in the Russian Biotech Industry to attract early clinical asset required to build a robust Biotech industry:
  - Contract GMP manufacturing of clinical supplies
  - Attracting additional foreign companies and projects
- Selecta Biosciences Inc. has the international network and expertise to facilitate this process

**Selecta will create high value exit opportunities through its own and licensed pipeline.**

**Significant value inflection events can be reached in short to mid term by bringing diversified assets to clinical proof of concept.**



<http://www.selectabio.com/Selecta-Russia.cfm>