Disclaimer

All or part of the information contained in this document should be treated as the confidential property of Preclinical Study Centre. It cannot be published or divulged for whatever purpose to unauthorized persons, or third parties, in any form without the prior written consent of Preclinical Study Centre.

Pushchino, 2017

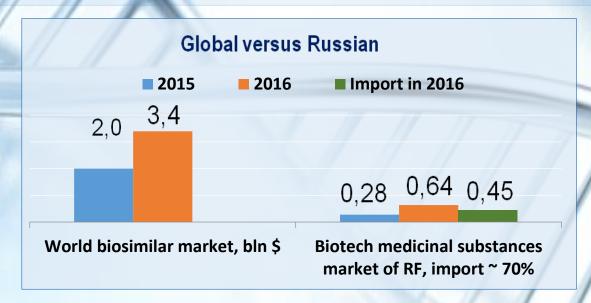
Contract Development Manufacturing Organization «Pushchino»



Production of more than 20 names of drugs, including

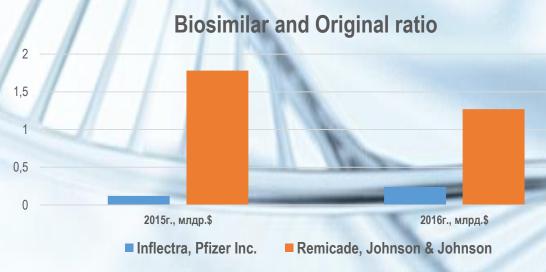
- monoclonal Ab Ekulizumab, Natalizumab, Adalimumab, etanercept, Tocilizumab, Bevacizumab, Cetuximab, Ranibizumab, Palivizumab, Trastuzumab, Ustekinumab and others.
- Recombinant and fusion proteins and enzymes— Alteplase, Dornase alpha,
 Darbepoetin alfa, Imatinib, Sunitinib, Interferons, etc..

Biosimilar market behavior



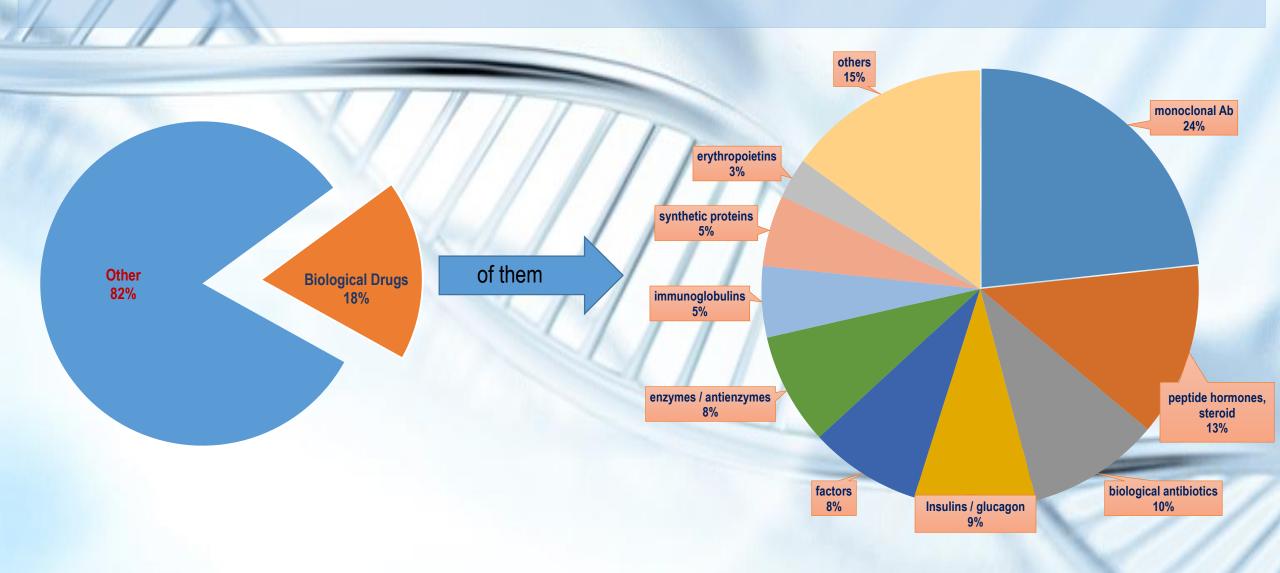




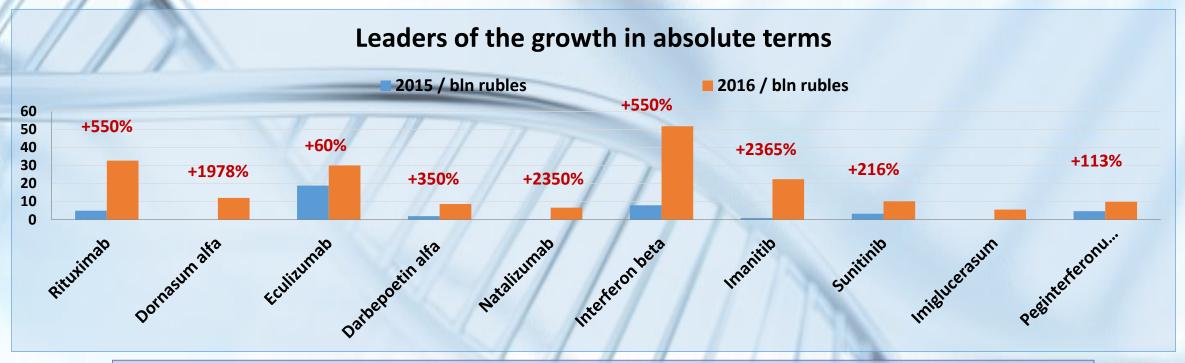


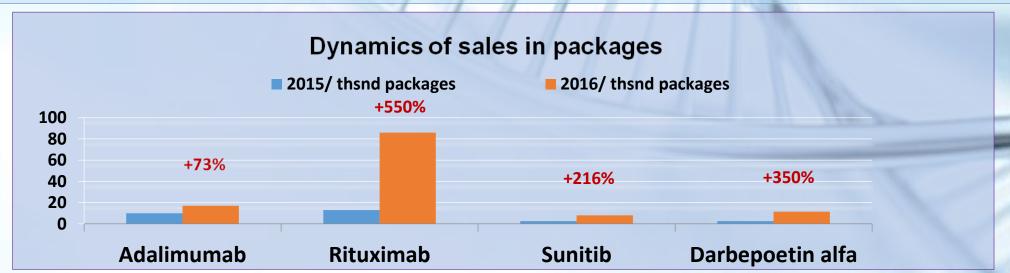
> Biosimilars are able to actively generate incomes on markets occupied with existing blockbusters

State import substitution programme analysis according to Ministry of Industry and Trade of the Russian Federation Federal Law #656 as of 31 Mar 2015



Dynamics of Government Biological Drugs Procurement Market - Target product line





Distinctiveness, Novelty and Attributes

International Accreditation







Full GxP testings







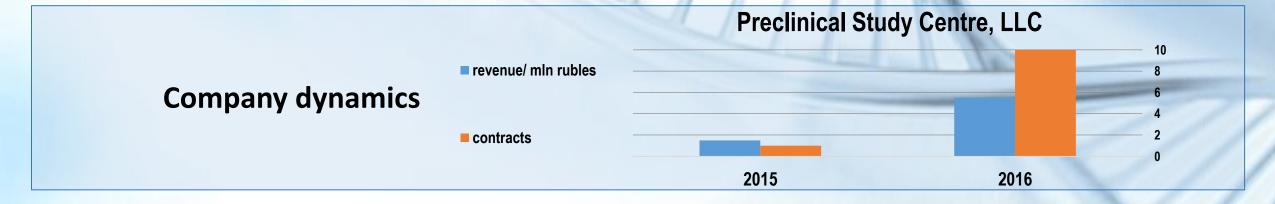


Prospects for the development







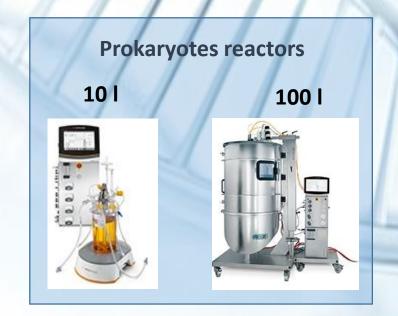


Value Proposition

Biotechnological GMP grade industry zone 2000 m² 3 fermentation plants 6 pharmaceutical substances production lines



Up to 5 kg API/ year



Up to 13 kg API/ year



Up to 23 kg API/ year

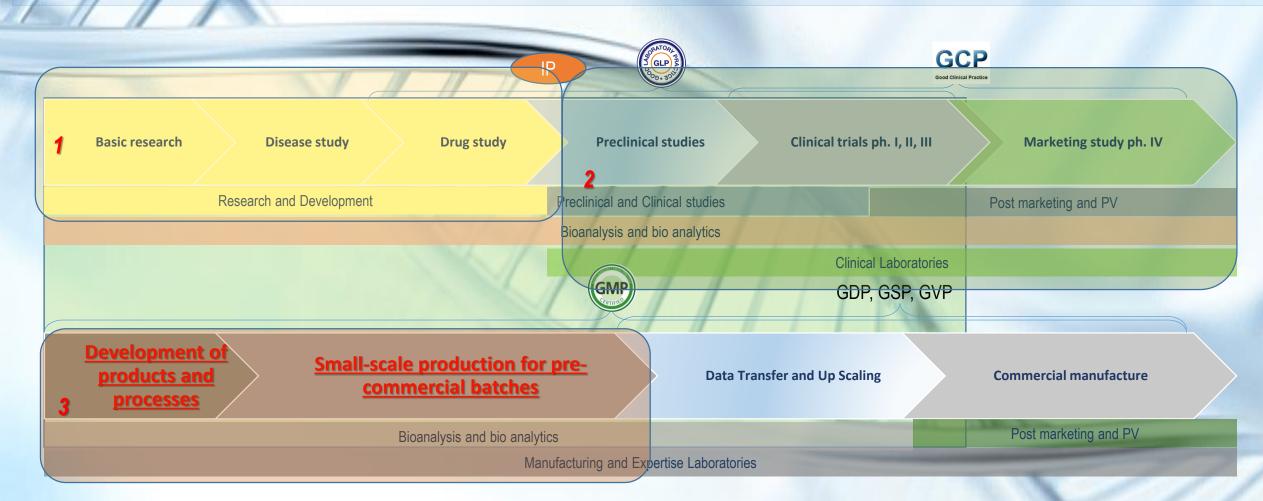
Thank you for kind attention!

Ilya N. Chistyakov, MD, PhD chistyakov@preclinical.ru +7 (916) 226 25 48

"Preclinical Study Centre" LLC.

of. 409, 3 Nauki av., Pushchino Moscow Region, 142290, Russia e-mail: request@preclinical.ru

Development of a new drug product progress



- 1 Pushchino Scientific Center RAS activities
- 2 Pharmaceutical Valley Cluster activities
- 3 Demanded CDMO activities

Project localization infrastructure

Laboratory of Biological Testing IBCh, RAS

In vivo rodent toxicology





Moscow Institute of Physics & Technology

Toxicocinetics bioanalytical and clinical chemistry

Pushchino Scientific Center Clinic

Bioeq and Phase I-III
Clinical trials



Pharmaceutical Valley Cluster



Moscow State University of
Fine Chemical Technologies
Moscow State University
Science Park I.M. Sechenov First
Moscow State Medical University
Pushchino State Naturally Institute of Science

Institute of Medical Primatology

In vivo non-HP toxicology





Institute of Biochemistry and Physiology of Microorganisms

In vitro microbiology

Stages and terms of project implementation

Year Year		2017			2018				2019			
quarter	I	II	Ш	IV	1	II	III	IV	I	II	III	IV
Pre-feasibility study												
Bankable Feasibility Study	10											
Tender for FEED												
Front-end engineering design, feasibility analysis, conceptual planning	/						1	- 100				
and design												
Detailed design, grid connection, equipment delivery, operation,												
installation, commissioning and start-up												
Staff training, validation of processes and equipment, handover to												
production		/										
		`- commencement of operations										
		` - completion of work										
		`- complete										

Conclusive statement

Of current concern

- > The market is growing rapidly.
- > The project is of high interest for the government, the investors and the producers.
- > The competitors contract 100% of their production capacity at the building phase.

«At the right time and place» (the fundamental grounding for successful implementation)

- > Historically established scientific and human capacities of Pushchino.
- ➤ Personnel training programs developed in Pushchino State Naturally Institute of Science in cooperation with Moscow State University of Fine Chemical Technologies, Moscow State University and the Science Park of I.M. Sechenov First Moscow State Medical University.
- > 70% of orders portfolio is already formed

Achieving the strategic objective

- Creating a powerful tool to provide the National biological security
- > Increasing the competitiveness of the domestic biopharmaceutical industry
- Import substitution of thigh-tech products
- Increasing federal and local tax payments and creating jobs