NANOLEK - RUSSIAN PHARMACEUTICAL COMPANY - OVERVIEW

November, 2014
NANOLEK aimed to become one of the leading Russian pharmaceutical companies by 2018

NANOLEK is a biopharmaceutical company that sets up a state-of-the-art manufacturing facilities with portfolio focus on prescription drugs for high disease burden and priority therapeutic areas: **vaccines**, **oncology**, **rheumatology**, **orphan drugs**, **antiretroviral** products

**Portfolio structure**

Sales pattern, 2018, forecast 2014

Well-balanced portfolio:
- Vaccines;
- Biosimilars;
- Orphan drugs;
- ARV and others;

**Manufacturing facility**

- Full compliance with best industry practice in respect to labour and environmental standards
- Full **EU GMP** compliance

**Ownership structure**

The company is 51% owned by Russian private shareholders and 49% - by state investment fund JSC Rusnano.
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<th>Russian market overview</th>
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<td>Portfolio Strategy</td>
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<td>Manufacturing</td>
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<tr>
<td>Sales &amp; Distribution</td>
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<tr>
<td>Team</td>
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<td>Value proposition</td>
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</table>
In 2014 Russian pharmaceutical market is about to reach USD18 bln. level. Key market drivers: new categories expansion, demand for modern treatment, governmental programs.
MARKET TRENDS: LOCALIZATION AND R&D

Government wants to grow local manufacturers …

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

LOCAL MANUFACTURING
• Reduce share of import
• Develop exports based on perception of high quality and effectiveness

LOCAL R&D
• Establish innovative local pharmaceutical industry
• Support competitiveness of domestic companies

15% margin preference + blocking governmental purchases for international products with domestic competition / 30% in terms of full-cycle production

SOURCE: Russia Ministry of Trade and Finance "Strategy for development of pharmaceutical sector to 2020"
MARKET OVERVIEW: SUMMARY

- Government will continue investing into healthcare, despite the financial turbulence
- “PHARMA 2020” localization push will create new Russian pharmaceutical manufacturing infrastructure
- Federal and private investment into R&D will keep growing
- Government investment in healthcare will go along with cost control measures
- Standards of production and quality of drugs tend to rise constantly
- Industry consolidation (production, distribution, retail): future belongs to large companies.
Russian market overview

Portfolio Strategy
  Manufacturing
  Sales & Distribution
  Team
  Value proposition
MARKET OPPORTUNITIES

GOVERNMENT SUPPORT

WIN-WIN SITUATION FOR NANOLEK

**NANOLEK STRATEGY**

- Low share of Russian products: imported drugs sales deliver 70% of the market value in 2012
- Government purchasing sector to grow by 2017 up to 40% of market
- Low share of innovative drugs
  - Branded generics – 50%
  - Generics - 25%
  - Originals – 25%

**PHARMA 2020:**

- Increase share of Russian products: 50% in 2020
- Oblige GMP compliance starting Jan 1, 2014
- Increase financing of healthcare programs
- Increase the share of innovative drugs: 50% in 2020

**Focus on government sector.**

NANOLEK Revenue 2017:
- government purchase 45%
- hospital segment - 43%
- retail – 12%

**Unique GMP manufacturing facility in Russia**

Less than 10% manufacturing facilities are fully or partially GMP compliant

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RUSSIAN VACCINE MARKET OVERVIEW

Substantial growth

• Annual vaccine market is Russia is about 100-110 ml doses or 400 USD mln

• Spectacular growth rate: 10-15% per year versus 5-7 % for pharmaceuticals (WHO, Worldwide)

• The Russian vaccine market is expected to grow 10-12% annually and reach the volume of 600-700 USD mln by 2017

• Russia has a large number of locally produced vaccines, but most of it are being manufactured not according to GMP standards

Vaccination Calendar

Russia

- Tuberculosis
- Diphteritis
- Pertussis
- Tetanus
- Measles
- Parotiditis

- Flue
- Hepatitis B
- Poliomyelitis
- Haemophilus influenzae

Germany

- Pneumococcus
- Meningococcal
- Varicella
- HPV

USA

- Hepatitis A
- Rotavirus

VACCINES
RUSSIAN BIOLOGICALS MARKET

Substantial growth

- Russia is at par with rest of Europe in terms of evolution of Specialty medicine, but still is 8%-10% behind by structure;

- In 2008 the introduction of the “Seven nosologies” program further increased access of the most expensive specialist treatment like hemophilia, cystic fibrosis, Gaucher disease, myeloid leukemia and multiple sclerosis;

- The introduction of DLO in 2005 has resulted in the higher access of expensive specialist medicine like those for Oncology;

- Very limited number of producers are trying to play on the Russian biosimilars market leaving wide scale of opportunities.

SOURCE: IMS Health MIDAS Jun 2014, Rx bound
Highly potential drugs in several therapeutic categories

<table>
<thead>
<tr>
<th>Therapeutical category</th>
<th>Key drugs in the category</th>
<th>Launch year</th>
<th>Total number of products</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccines</td>
<td>- HEP B</td>
<td>Y2015 (MA obtained)</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>- IPV</td>
<td>4Q2015 (Clinical trials)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Cell-based FLUE</td>
<td>Y2018 (Pre-clinical trials)</td>
<td></td>
</tr>
<tr>
<td>Biosimilars</td>
<td>- Filgrastim</td>
<td>Y2015 (MA obtained)</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>- Rituximab</td>
<td>Y2018 (Clinical trials)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Interferon beta 1A</td>
<td>Y2018 (Clinical trials)</td>
<td></td>
</tr>
<tr>
<td>Orphan drugs</td>
<td>- Idursulphase</td>
<td>Y2016 (Clinical trials)</td>
<td>3</td>
</tr>
<tr>
<td>ARV</td>
<td>- Tenofovir</td>
<td>Y2016 (Clinical trials)</td>
<td>5</td>
</tr>
<tr>
<td>CNS &amp; CVS</td>
<td>- Leviteracetam</td>
<td>Y2015 (MA obtained)</td>
<td>17</td>
</tr>
<tr>
<td></td>
<td>- Clopidogrel</td>
<td>Y2015 (MA obtained)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Nebivolol</td>
<td>Y2015 (MA obtained)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Rosuvastatin</td>
<td>Y2015 (MA obtained)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Pregabalin</td>
<td>Y2015 (MA obtained)</td>
<td></td>
</tr>
</tbody>
</table>
Combining R&D and manufacturing potential of Kirov region

**Science «core» of cluster**
- Biological faculty of Vyatskiy state university
- R&D Institute of Microbiology of Defense Ministry
- Kirovskaya medical academy
- Vyatskaya state agricultural academy

**Production «core» of cluster**
- Biopharmaceutical complex NANOLEK
- Biopharmaceutical veterinary complex «AGROVED»
- Production of immuno biology drugs «PHARM Defense»

**Potential members**
- ALSI Pharma
- ABBA RUS
- Kirovskiy Bio-Chemical factory
- Omutinskaya science-industrial factory
- Kirovsky R&D Institute of hematology and blood transfusion
- ROSPLAZMA
Main parameters:
• Location: Russia, Kirov Region (1000 km East of Moscow)
• Total investment: USD 100 MM
• Total land area: 14 hectares
• Total facility area: 28,000 sq.m.
• Number of employees in 2015: 250

Annual output:
• 1 bln. tablets/capsules
• 35 mln. vials;
• 42 mln. prefilled syringe;

Localization options:
• Primary & Secondary packaging
• Fill & Finish
• Fermentation synthesis of biopharmaceutical products
• Design was made by leading European engineering company GMproject
• All production buildings are already constructed; inner engineering systems are being installed
• Solid dosage forms manufacturing license – 4Q 2014.
• Biologicals manufacturing license – 2Q 2015
SCHEDULE OF INSTALLMENTS

Facilities installment is synchronized with schedule of portfolio registration, sales growth and state requirements to localization.

Stage 0: Construction

- Site Preparation:
  - Purchase of ground plot and its formation
  - Engineering site preparation, incl internal and external networks (canalization, energy)
  - Construction of production workshops
  - Construction of none-production workshops
  - Construction and start of energy generating unit


Stage 1: Set up of production

- Full cycle production line №1
  - Granulation
  - Tabletizing and capsule filling
  - Labelling, pre-packing, packaging


- Full cycle production – line №2 and №3
  - Granulation
  - Tabletizing and capsule filling
  - Labelling, pre-packing, packaging


Stage 2: Full cycle of solid forms

- Full cycle of solid forms:
  - Granulation
  - Tabletizing and capsule filling
  - Labelling, pre-packing, packaging

2016 - 2017

Stage 3: Full cycle of biologicals

- Full cycle of injection dosage forms

2018 - 2020

- Full cycle – line № 1
  - manufacturing of cell-based vaccines

2020 - 2022

- Full cycle – line № 2
  - manufacturing of recombinant proteins
  - protein purification

Secondary packaging of solid and injection forms

- Fill finish
  - Spray freeze drying
  - Filling in flasks
  - Filling in prefilled syringes
  - Inspection
  - Labelling, filling, packaging
CONSTRUCTION: PHOTO UPDATE

3Q2012

1Q2014

3Q2014
### M A N U F A C T U R I N G  
### F A C I L I T Y  F O R  S O L I D  
### F O R M S

A few days before operations. Licence acquisition - *December 2014*; mass production Q2 2015

<table>
<thead>
<tr>
<th>Stages</th>
<th></th>
</tr>
</thead>
</table>
| **Q2 2015**  
Full cycle production  
Line #1 | • Granulation  
• Tableting and Capsule filling  
• Labeling, Pre-packing, Packing  
**Capacity**: 500 mln tablets and 100 mln capsules |
| **Q3 2016**  
Full cycle production  
Line #2 & #3 | • Granulation  
• Tableting and Capsule filling  
• Labeling, Pre-packing, Packing  
**Full Capacity**: 1 bln tablets and 400 mln capsules |
## Manufacturing Facility for Biologicals

<table>
<thead>
<tr>
<th>Stages</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2Q2015</strong></td>
<td>• Filling line, 1 ml syringes, in pharmaceutical isolator</td>
</tr>
<tr>
<td>(Fill-Finish)</td>
<td>• Filling line, vials 2R, 6R, 8R, 15R and 30R</td>
</tr>
<tr>
<td></td>
<td>• Spray-freeze drying in pharmaceutical isolator</td>
</tr>
<tr>
<td></td>
<td><strong>Services</strong>: aseptic liquid filling, lyophilization, QC test, label &amp; packaging</td>
</tr>
<tr>
<td><strong>2018</strong></td>
<td>• 1st production site: manufacturing of cell-based vaccines</td>
</tr>
<tr>
<td>(Wall-to-wall, incl. API manufacturing)</td>
<td>• 2nd production site: manufacturing of recombinant proteins (produced in E. coli and mammalian cells)</td>
</tr>
<tr>
<td></td>
<td><strong>Full capacity</strong>: 42 mln prefilled syringes/ 35 mln vials per year</td>
</tr>
</tbody>
</table>
Focus on public purchases leads to a limited number of professional sales staff securing their presence in large cities.

**Nanolek Sales Forecast for 2015: USD 50 mln.**

**Development of sales department**

<table>
<thead>
<tr>
<th>Year</th>
<th>Regional manager</th>
<th>Key account manager</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y2014</td>
<td>15 employees</td>
<td>12 cities</td>
</tr>
<tr>
<td>Y2015</td>
<td>20 employees</td>
<td>17 cities</td>
</tr>
<tr>
<td>Y2016</td>
<td>40 employees</td>
<td>20 cities</td>
</tr>
</tbody>
</table>
Distribution is arranged via largest national and regional wholesalers who participate in public tenders, provide for with Sales Force team Nanolek’s portfolio presence in pharmacy chains and for marketing support.

### NANOLEK’s COMMERCIAL NETWORK

<table>
<thead>
<tr>
<th>National pharmacy chains</th>
<th>Distributors</th>
<th>Local</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>National</strong></td>
<td><strong>Regional</strong></td>
<td><strong>Local</strong></td>
</tr>
<tr>
<td><strong>F1-A</strong></td>
<td><strong>F2-A</strong></td>
<td><strong>F3-A</strong></td>
</tr>
<tr>
<td>- Protek</td>
<td>- Oriola</td>
<td>- Pharm-SKD</td>
</tr>
<tr>
<td>- Katren</td>
<td>- Pulse</td>
<td>- Zdravservice</td>
</tr>
<tr>
<td>- CIA International</td>
<td>- Imperia-Pharma</td>
<td>- Vitta Company</td>
</tr>
<tr>
<td><strong>F1-B</strong></td>
<td><strong>F2-B</strong></td>
<td><strong>F3-B</strong></td>
</tr>
<tr>
<td>- Rosta</td>
<td>- Irvine-2</td>
<td>- Volgopharm</td>
</tr>
<tr>
<td>- Alliance Healthcare</td>
<td>- Godovalov</td>
<td>- LipetskFormation</td>
</tr>
<tr>
<td><strong>F1-C</strong></td>
<td><strong>F2-C</strong></td>
<td><strong>F3-C</strong></td>
</tr>
<tr>
<td>- Biotek</td>
<td>- Medexport</td>
<td>- Avikon-Med</td>
</tr>
<tr>
<td></td>
<td>- Agroresources</td>
<td>- Medintorg</td>
</tr>
<tr>
<td></td>
<td>- Pharmazevt</td>
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<tr>
<td></td>
<td>- Nadezhda-Pharm</td>
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</tr>
</tbody>
</table>

- **Regional pharmacy chains**
- **Delivery to hospitals**
- **Delivery to regions**
Well-known and reliable member of Nanolek group

Well-established distribution company for immunobilologicals:

- 25 mln. USD annual turnover (100% regional tenders and hospitals)
- Fully equipped “cold chain” logistics system
- Experienced Import and Client Service team
- 250+ Loyal customers
- Long-terms relationship proved by agreements with leading manufacturing companies
- 150+ governmental contacts on purchases have been performed;
- Up to 35% of Pandemic Vaccines market;
- 15% of Local Flu Vaccines market

Portfolio Structure

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vaccines</td>
<td>33%</td>
</tr>
<tr>
<td>Immunoglobulins</td>
<td>14%</td>
</tr>
<tr>
<td>Serums</td>
<td>16%</td>
</tr>
<tr>
<td>Albumines</td>
<td>11%</td>
</tr>
<tr>
<td>Bacteriophage</td>
<td>8%</td>
</tr>
<tr>
<td>Chemical Formulations</td>
<td>6%</td>
</tr>
<tr>
<td>Other</td>
<td>8%</td>
</tr>
</tbody>
</table>
Russian market overview
Portfolio Strategy
Manufacturing
Sales & Distribution
Team
Value proposition
Nanolek has a professional team which has not only a significant industry experience, but also experience in solving similar problems facing the company in the leading Russian and foreign pharmaceutical companies.

### Mikhail Nekrasov
**General Manager**
- 1997 – founder and Head of «Makiz Pharma».
- 2002 - «Makiz Pharma» - Russia's first pharmaceutical factory, designed according to GMP standards.
- 2007 - During 5 years led «Makiz Pharma» to Top 5 Russian drugmakers by revenue and sold it to «STADA CIS» for € 125 million.
- 2007 - Founder and Head the group of companies «EPIDBIOMED» - a major distributor and immuno-diagnostic products and medical consumables.

### Svetlana Efimova
**Head of TT/ Procurement Department**
- 2004 - 2005 - Procurement manager at "Vedis-Steel".
- 2005 - 2007 - Procurement Manager at «New Line Fabrik».
- 2007 - 2010 - Head of procurement department at «Akrilinh».
- 2010 - 2014 - Head of procurement department at «R-Pharma».

### Vladimir Kutyrov
**Commercial Director**
- 1998 – 2003 – Regional sales manager at F.Hoffmann-La Roche
- 2003 - 2007 – Regional sales manager at «AstraZeneca».
- 2007 - 2009 – Business Unit Director (Oncology) at OJSC Verofarm - Russian production company.
- 2009 - 2014 – Commercial Director at Akrihin.

### Andrey Belov
**Head of Production Department**
- 1995 - 2007 - Electronics Engineer at «Immunopreparat».
- 2001- 2007 - Mechanic at «NPO” Microgen».
- 2007 - 2011 - Deputy of General Manager/ Head of production department at «Medical and industrial equipment Factory».
- 2011 – 2013 - Head of solution & lyophilizate production area (block) at «R-Pharm».
### Team Members

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Duration</th>
<th>Experience</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ilya Vyazovsky</strong></td>
<td>Medical Director</td>
<td>2004-2007 - Clinical operations manager at «Servier». 2007-2013 - Clinical operations manager at «Amgen».</td>
<td>14 years</td>
</tr>
<tr>
<td><strong>Alfia Gabidova</strong></td>
<td>Head of Regulatory Affairs Department</td>
<td>2001-2013 - Senior positions in the Ministry of Health of the Russian Federation: - Drugs certification State quality control; - Drugs production State quality control;</td>
<td>20 years</td>
</tr>
<tr>
<td><strong>Maria Pavlova</strong></td>
<td>Head of HR department</td>
<td>2003-2006 - HR manager C&amp;B department at «Rostelecom». 2006-2010 -Head of recruitment department at «Actavis». 2010-2012 -Head of HR department at «Actavis».</td>
<td>12 years</td>
</tr>
<tr>
<td><strong>Svetlana Gogoleva</strong></td>
<td>Head of Portfolio development</td>
<td>2006-2007 Project manager at «Nielsen». 2008-2012 rr. – Adviser at «IMS Consulting Group».</td>
<td>5 years</td>
</tr>
<tr>
<td><strong>Svetlana Shabalova</strong></td>
<td>Head of Quality department</td>
<td>2001-2008 rr. – Deputy Head of the Quality Control Laboratory «Farmaks». 2008-2011 -Head of Quality Assurance at «Rosplazma»; 2011-2013 rr. – Head of Quality department at «R-Pharm».</td>
<td>14 years</td>
</tr>
</tbody>
</table>
What are we looking for?

Collaboration with companies aimed to win on the Russian market

- Keen interest in the Russian market
- Ability to conduct clinical trials in Russia
- Ability to out-license product for Russia and CIS
- Past experience and accomplishments of the company
What are our value proposition?

Our company has people, facilities, experience and necessary resources to provide market access for the long term and efficient expansion of the product on the Russian market.
THANK YOU!

NANOLEK