



ECOBALTIC

BUSINESS PARK



Project  
presentation

# PHARMACEUTICAL SUBSTANCE MANUFACTURING

ECOBALTIC industrial business park  
Bagrationovsky city district  
Kaliningrad Region

2018



Sales revenue:  
3 bn rub. (2017)



32 mln  
pcs/year



350  
employees



### Miramistin® 50 ml with the urological applicator in set with the nozzle (travel/tourist form)

The compact bottle with the sprayer is easy to be taken when travelling. It is suitable for irrigation of mucous membranes and skin. Along with the sprayer, an urological applicator is present in the set. Miramistin® has a pronounced antiseptic action and meets the strict requirements of efficiency and safety.



### Miramistin® 50 ml with the urological applicator

The special nozzle is convenient to use in urology, for the purpose of prevention and other cases when the little amount of the product is needed. Miramistin® has a pronounced pharmacological activity against most of the infectants of the sexually transmitted diseases, such as syphilis, gonorrhea, trichomoniasis, chlamydia, genital herpes, HIV, genital candidiasis, and others.



### Miramistin® 50 ml with the gynecologic applicator

The special applicator is convenient to use in the gynecology for the prevention and treatment of infections, inflammatory gynecologic diseases, postnatal injuries, and others. The product has a pronounced hyperosmolar action resulting in the inflammation reduction, exudate absorption and overall healing. It does not damage granulation or suppress epithelialization.



### Miramistin® 150 ml in set with the nozzle

The sprayer is easy-to-use for irrigation of mucous membranes of the mouth cavity, nose and throat, as well as irrigation of wounds and skin. Miramistin® is used for treatment of wounds and inflammatory infections (as a topical therapy). It is used in surgery, combustingology, dentistry, otorhinolaryngology, pediatrics, obstetrics, gynecology, urology, dermatovenereology, and others.



### Okomistin®, in drops (eye, ear, nasal), 0,01%, 10 ml

The bottle of polymer material with the cap-dropper.

The original pharmaceutical product for treatment and prevention of inflammatory infections of eyes, as well as otitis and sinusitis.



# 13 FEATURES

## of MIRAMISTIN®

making it one of the most efficient antiseptics

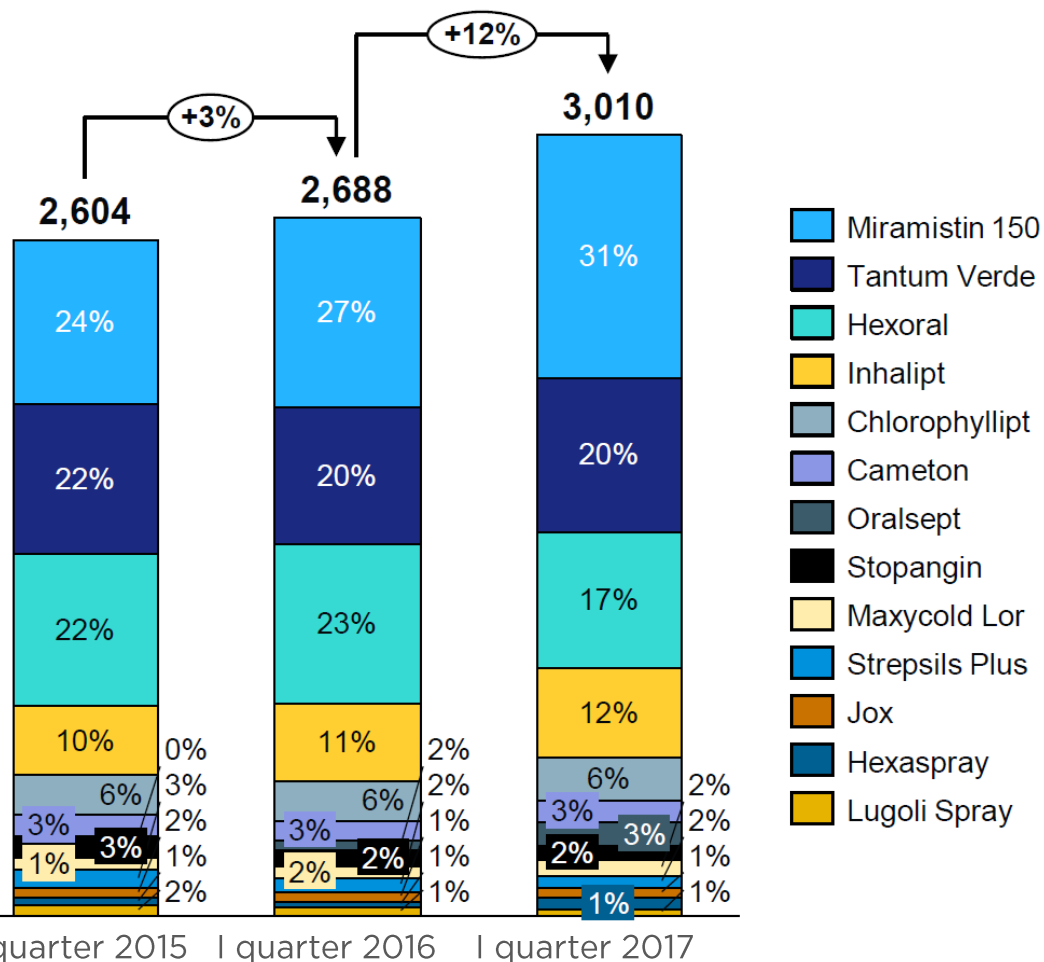
1. Miramistin® is an antiseptic product of a broad antimicrobial spectrum that has the following effects:
  - bactericide (Staphylococcus, Pseudomonas, Klebsiella, Proteus, Escherichia coli, etc.);
  - antiviral (varicella-zoster virus, influenza virus, adenovirus, labial and genital herpes virus type 1 and type 2, measles virus);
  - antifungal (yeast and yeast-like fungi (Candida, Penicillium, Aspergillus), dermatophytes);
  - active against sexually transmitted infections: gonorrhea, chlamydia, syphilis, trichomonas
2. Not penetrating through the skin, nor absorbing into the blood even when applied to mucous membranes or in case of accidental swallowing
3. Without mutagenic, embryotoxic or carcinogenic effects
4. Not affecting the developing fetus or exuding with milk and therefore can be prescribed to pregnant women
5. During manufacturing, only water is used as an auxiliary substance. Such monopartite compound of the product allows exclusion of side-effects and minimizing the allergy risk
6. Enhancing the effect of antibiotics, active only against pathogens and not influencing the composition of a normal human microflora
7. Immunomodulatory and anti-inflammatory action
8. Normalizing operation of the ciliary epithelium of the upper respiratory tract
9. Accelerating regeneration of the damaged skin and mucous membranes
10. Prolonging the duration of remission and reducing the frequency of recurrences of chronic processes
11. Efficient both in monotherapy and complex treatment
12. Ready-to-use and not requiring dilution. When frozen or heated, fully maintains its qualities
13. Original product, no generics, protected with the patents



The unique qualities of Miramistin® allow to use it in the therapy of various organ systems diseases, minimizing the risk of side-effects



## MIRAMISTIN® 150 ml market share (sales in rubles in retail prices, bn)



- The growth of the market size for MIRAMISTIN 150 (Q1 2017 MAT period against Q1 2016 MAT) in monetary terms comprised +23%; in physical terms - +14%.
- Top sellers by the end of Q1 MAT 2017 in the monetary terms (share in monetary terms): **MIRAMISTIN 150 (31%)** TANTUM VERDE (20%) HEXORAL (19%).
- The share of Miramistin 150 increased both in monetary and physical terms compared to MAT Q1 2016 and comprised **31%** in monetary terms and **19%** in physical terms (MAT Q1 2017).
- The distribution of Miramistin 150 (single-factor index) comprised **85%**, weighted index - **94%**, whereas the product is mostly present in the pharmacies of class A and B (March 2017).
- Miramistin 150 is positioned in the premium-segment (with the price of **387** rub. In March 2017), outpaced only by Strepsils Plus.



## INVESTMENT IDEA

**Construction of the workshop for pharmaceutical substance manufacturing.**

The workshop is designed in compliance with the international GMP standards and has been qualified in the EU. The production is equipped with the state-of-the-art high-technology machinery made by BÜCHI (Switzerland), which is all-purpose and allows to produce other pharmaceutical substances by contract.



## IMPORTANCE

The pharmaceutical substance production and manufacturing of highly efficient antiseptic products on its basis is considered by INFAMED K as the import substitution process and the national pharmaceutical security factor. In the future, it is planned to validate the plant according to the GMP standards, which will allow to fulfill orders for the customers both in Russia and Europe.



## OBJECTIVE

Creation of the domestic manufacturing of the high-quality products for the national market that will be able to replace the foreign counterparts partially, with the perspective of further export to the international markets.



## GOALS

1. Organization of the full process flow for Miramistin® production within the borders of the Ecobaltic industrial park;
2. Achievement of a positive socio-economic effect by means of creation of new high-performance jobs in the region;
3. Increase in the amount of tax liabilities assigned to the budgets of all levels.



INITIATOR  
OF THE  
PROJECT

INFAMED K LLC



LOCATION

ECOBALTIC industrial business park,  
Bagrationovsky city district,  
Kaliningrad Region



IMPLEMENTATION  
PERIOD

I quarter 2019



Amount of investment

\$6,4M

Production output

6 tons/year

New jobs

50

Production area

1000 m<sup>2</sup>

Sales market

Russia, EU

General contractor

Santechmontazh-Service LLC

Availability of planning permission

Yes

Project engineering

GxP Engineering LLC



Fermentation

1



Purification

3



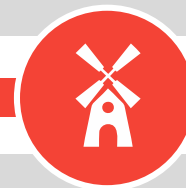
Recrystallization

5



Milling

7



2



Extraction

4



Isolation

6



Drying

CHEMICAL  
COMPOUND

Benzyldimethyl[3-  
myristoylamino)propyl]  
ammonium chloride, monohydrate



STRUCTURAL CLASS

Quaternary ammonium  
compounds



PHARMACOLOGICAL CLASS

Antiseptic product



Marketing authorization number of Miramistin®:  
P N001926/01





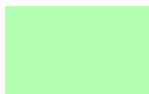
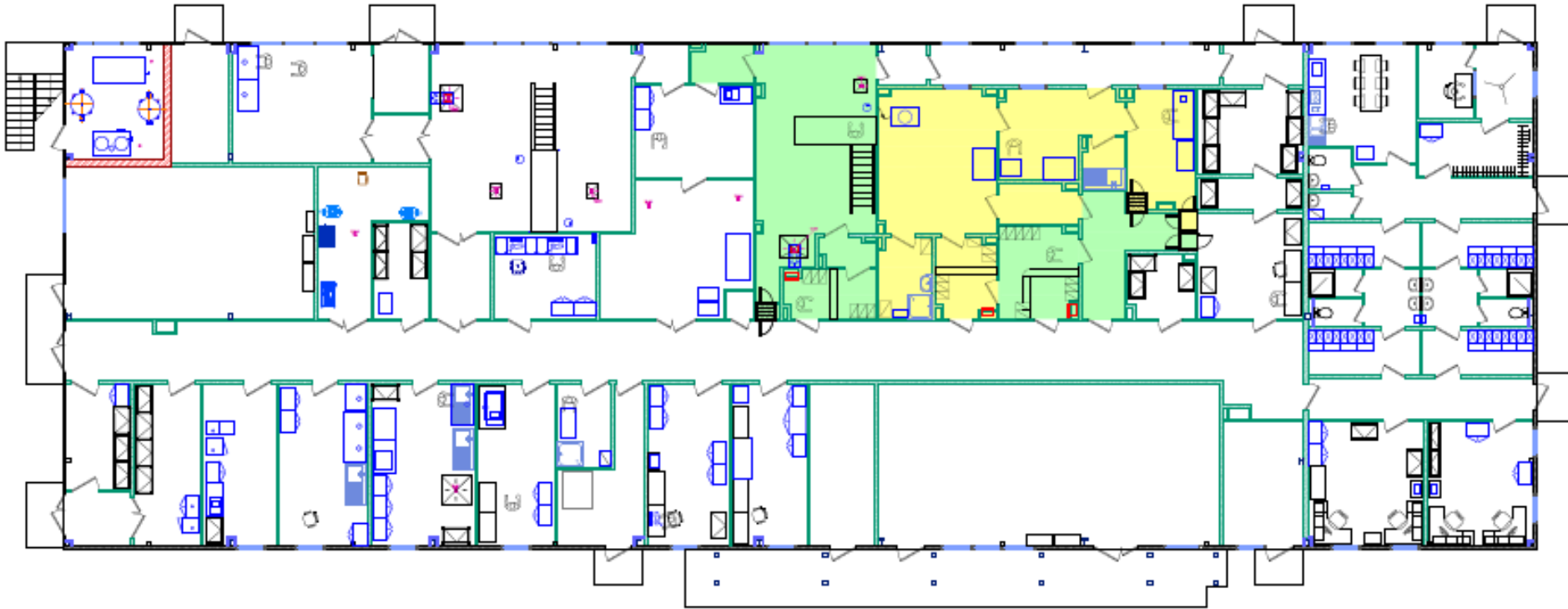
### The general list of equipment:

- Reactor system for the intermediate product's synthesis – 2 lines
- Reactor system assembled for obtaining the substance – 1 line
- Nutch filter assembled in-frame and (or) centrifuge
- Vacuum ovens
- Vacuum traps, chillers for reactor systems
- Rotary evaporator with a chiller
- Ventilation hood
- Local water conditioning
- Nitrogen generator
- Laminar flow units

Chemical reactors in the pharmaceutical execution Büchi - ChemReactor GR30-K-C (3 independent production lines with the CIP-stations, washers and peripheral equipment).  
Manufacturer: Buchi AG Switzerland.



## Plan of the ground floor of the pharmaceutical substance workshop



Class D (ISO 8)

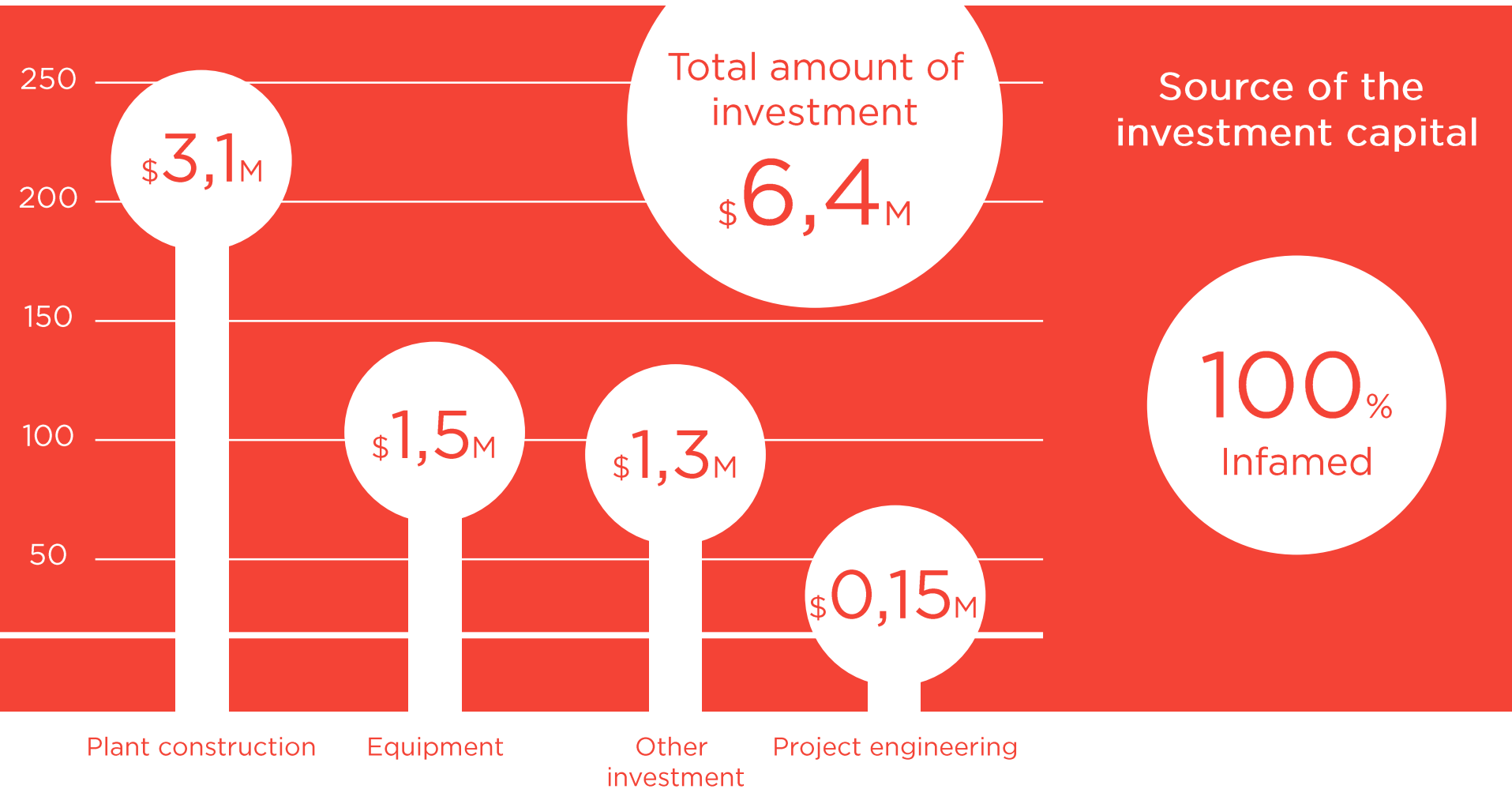


Class C (ISO 7)

# PLANT CONSTRUCTION

Pharmaceutical substance manufacturing







Location of the pharmaceutical substance production on the territory of the Ecobaltic business park.



Federal motorway  
Kaliningrad-Bezledy  
along the borders of the park

Trigeneration

AB-Market

Filling workshop  
for Miramistin and  
Okomistin

**BAGRATIONOVSK**

Customs and logistics terminal  
SIRIUS



Workshops for  
ointments and  
substances

Sprayer  
manufacturing

Dart Plus

Catheter  
manufacturing

GDP warehouse



The Polish border  
(the international automobile border-crossing point  
"Bagrationovsk") is only few meters away

Production site requirements:  
Total area: 1 000 m<sup>2</sup>



## ELECTRIC POWER

\$0,05/kWh

## WATER SUPPLY

\$0,27  
/m<sup>3</sup>



## WATER DISPOSAL

\$0,13  
/m<sup>3</sup>

## GAS SUPPLY

\$75  
/1 000 m<sup>3</sup>



## LAND PLOT

\$60 000  
/ha



## OFFICE RENT

The price is negotiable

## AVERAGE SALARY

\$6 360  
per year

## RENT OF PRODUCTION PREMISES

\$6/m<sup>2</sup>

The price for resources is calculated according to the state tariffs

The tariffs are changed 1-2 times a year

Calculation of variable expenses: monthly with metering devices

The prices do not include VAT



WE ARE READY TO SHARE  
WITH YOU MORE!



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