



ECOBALTIC

BUSINESS PARK



Project  
presentation

# UROLOGICAL FOLEY CATHETER MANUFACTURING

ECOBALTIC industrial business park  
Bagrationovsky city district  
Kaliningrad Region

2018



## INVESTMENT IDEA

**Creation of urological Foley catheter (100% silicone) manufacturing.**

Foley catheters are used for the prolonged catheterization of the bladder. The silicon surface allows long-term use without change which is a painful procedure for the patient. This kind of catheters is more durable and “humane” for patients.



## IMPORTANCE

The project has a significant import substitution impact. Today, 100% of Foley catheters are imported in Russia. The production can be classified as high-technology and is included in the action plan on import substitution in the medical industry. Another important goal targeted by the project is the Russian export growth, as stated in the development strategy for the medical industry (“Pharma-2020”).



## 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. Increase of the share of the domestically produced medical products in the total consumption of medical products in both physical and monetary terms.
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 (Russia)  
nepes corporation (South Korea)



## LOCATION

ECOBALTIC industrial business park,  
Bagrationovsky city district,  
Kaliningrad Region

IMPLEMENTATION  
PERIOD

IV quarter 2019

Amount of investment

\$14M

Projected production output

2,9 mln un./year

Projected revenue

\$17,6M/year

Payback period

approx. 5 years

Tax liabilities

\$1,5M/year

New jobs

100

Sales market

Russia and EU 70%  
South Korea 30%

Potential market share

12%





## INFAMED K LLC.

The INFAMED K pharmaceutical plant, functioning since **2014**, is the first pharmaceutical enterprise in the Kaliningrad Region that produces the innovative popular antiseptic product **Miramistin®** 0,01% solution and **Okomistin®** eye drops, with the production output of up to **32** m units a year. Countries of presence: Russia, Ukraine, Belarus, Kazakhstan, Kyrgyzstan, Armenia, Turkmenistan, Georgia, Uzbekistan.

Currently, the company is preparing for registration in China and the EU countries. The company's revenue comprised **1,8** bn rubles in **2016**.

The company regularly carries out pre-clinical trials and clinical tests in order to develop new pharmaceutical product forms and broaden medical indications of the products' use in new areas of medicine (physiotherapy, phthisiology, phthalmology, proctology and others).

## nepes corporation

The co-investor of the project, an innovative South Korean company, the main focus of which is semiconductor technologies (integrated circuit manufacturing, wafer-level packaging). Other activity areas of the company include: functional chemistry and nanotechnologies, "green" construction, LED, displays and innovative medical devices. nepes was listed on KOSDAQ (the Korean electronic stock market, mostly for high-technology companies) in 1999.

nepes has affiliated companies and plants in 5 countries. Among the clients of the company, there are such giants as Samsung, LG, Toshiba, Hitachi, Sony etc.

### Experience of joint venture creation:

**2009** – iridos Ltd., together with the Solvay company, in Korea, specialization – color paste and pigments for LCD color filters

**2011** – nepesrus, in Mordovia, LED production

**2014** – Jiangsu nepes Semiconductor co. Ltd., in China, semiconductor technologies, backend-industry

## Insung Medical Co. Ltd.

An author of the patent for the production technology, a South Korean company, founded in 1984, specializing on single-use medical product manufacturing (catheters, intravenous systems, wound drainage and others). The main products are Foley catheters, chemo ports etc.). The company has a few plants in the Republic of Korea, including the one on silicon production, and a large R&D center in Daegu. The thinnest catheters in Korea (1-2FR) have been developed by the specialists of the company, as well as the unique flat balloon Foley catheters that were patented in 2016.

### Production of the company is certified with EN ISO 13485:2012, EN46001, CE.

Insung Medical collaborates with nepes in the field of application of IT in medicine, in particular, smart sensor catheters are being developed now. In the future, the transfer of IT to the joint venture in the Kaliningrad Region is possible.

# INFAMED





## Urological Foley catheters, class A

Material: 100% silicon

Type: 2-way

Sizes: 12-24



The product is designed for emptying the bladder of the patients who are not able to do self-urination (before and after surgeries, in the ICU etc.). It can also be used on a regular basis to guarantee the neo-urethra after operating hypospadias.

When put in the bladder, the balloon is placed closer to the end of the catheter by the entrance to the bladder, which allows to prevent the slip of catheter into the urinary tract.

The upper part of the catheter contains a valve through which the distilled water is infused into the balloon. The valve connects the tube with the urine bag.

Two types will be present in the product range:

Flat balloon catheters - 60%

Normal balloon catheters - 40%

Patent (flat balloon catheters): 10-1652236 (Korea).

The patent registration process in Russia is going on.

Flat balloon catheters do not have bonding parts on the balloon's border, hence the external part of the shaft is very flat and smooth.

Production processes are simplified, production expenses are lowered, antibacterial qualities are improved.

# JV Foley catheter

## 100% silicone

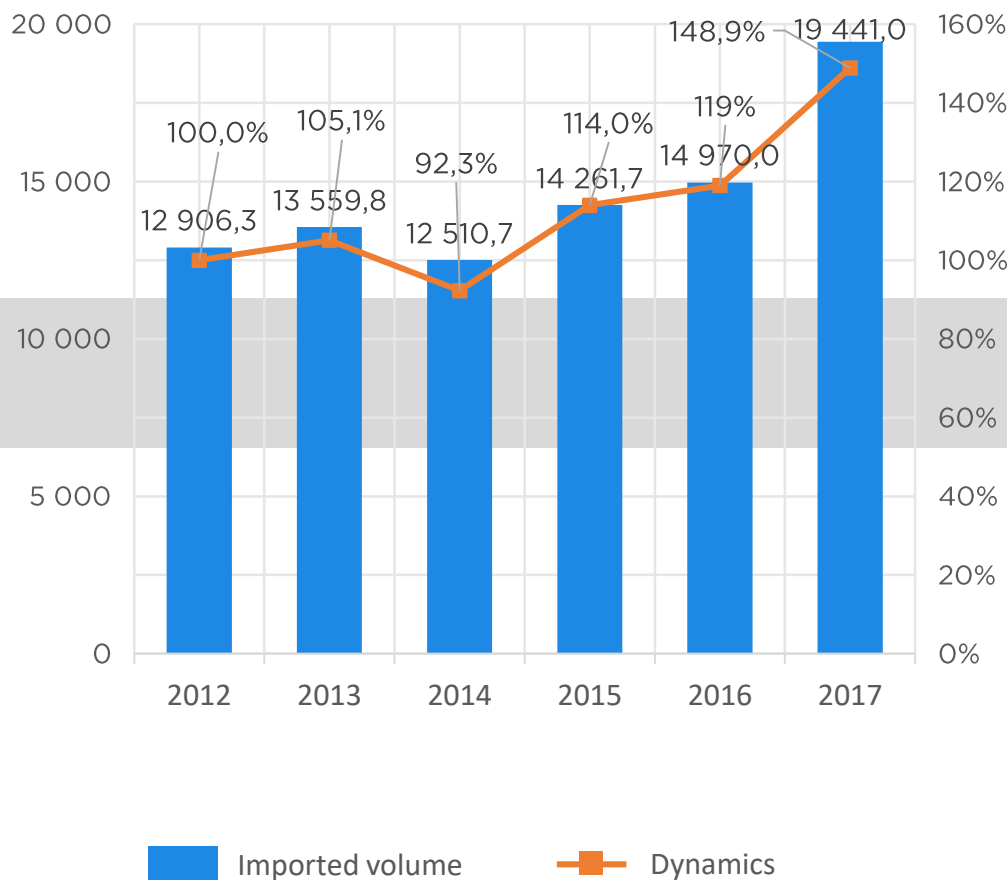
Import substitution  
of the high-quality  
products with the  
high degree  
of localization

- It does not cause any damage to a patient as it is made from 100% non-toxic silicone material
- It prevents leakages as its funnel is tightly connected to the connector of urine bag
- It is securely locked up in the bladder, due to the high elasticity and restoring force of the balloon
- No bonding parts on the balloon's border which helps to reduce the patients' pain and makes the process of insertion easier
- The tip part is designed to avoid the problems during insertion (round shape)
- The hardness between tip part and tube part is designed differently so that the tip part could be inserted more smoothly
- Doctor can find the location of the tip through X-ray after its insertion

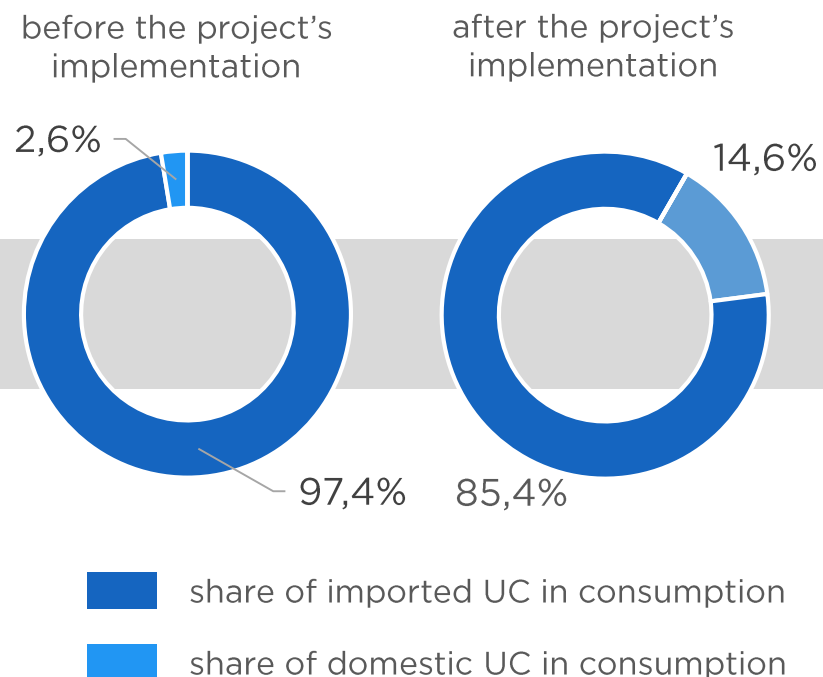
The unique production technology that allows to minimize painful sensations of the patients



## Urological catheter import dynamics in the Russian market, 2012-2017, in monetary terms (thousand USD)



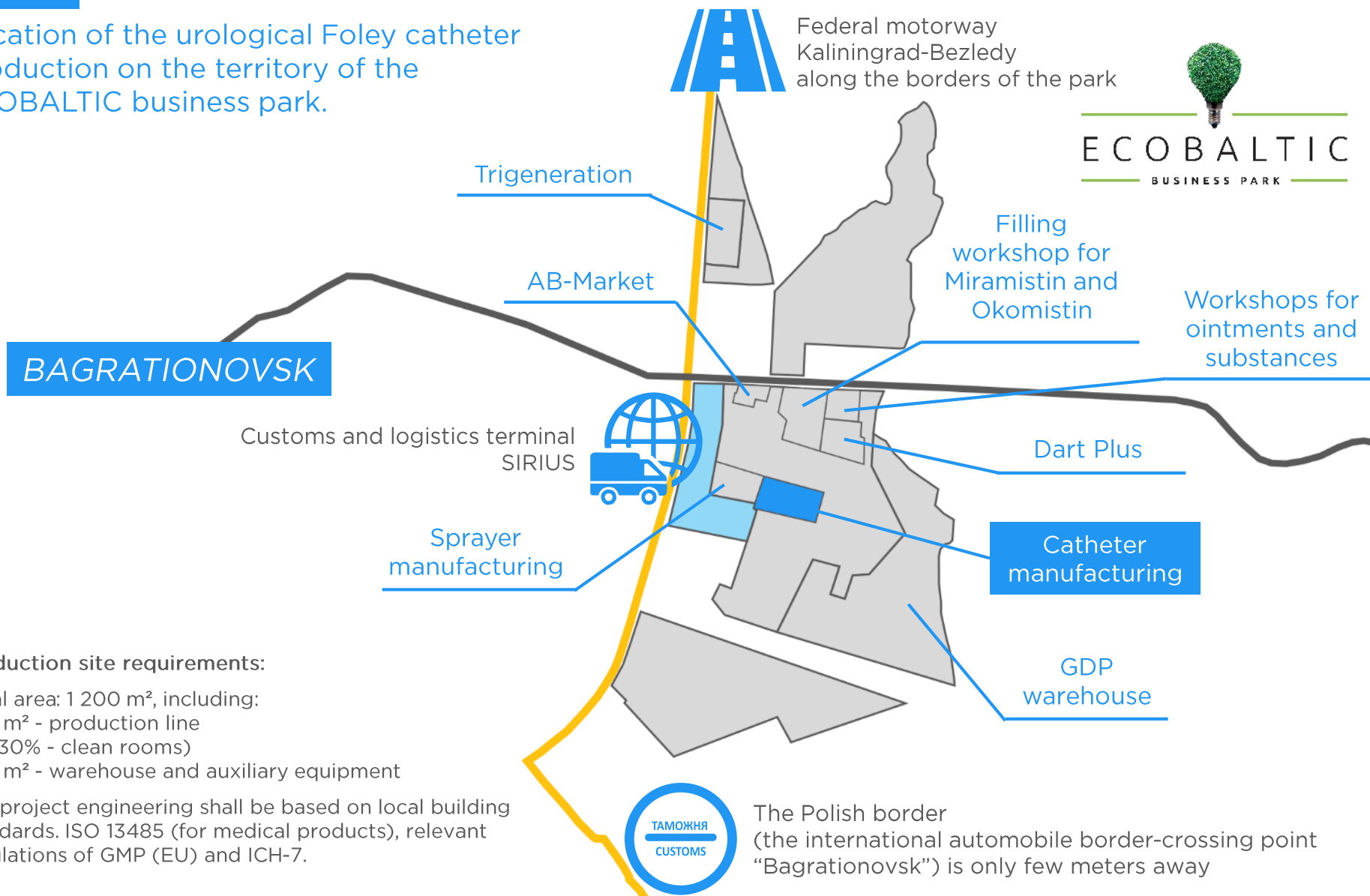
## Share of domestic and imported products in total consumption of urological catheters in 2017 and after the project's implementation



Source: Federal Customs Service of the RF, Federal Service for National Statistics of the RF, data collected from manufacturers, expert opinions



Location of the urological Foley catheter production on the territory of the ECOBALTIC business park.



#### Production site requirements:

Total area: 1 200 m<sup>2</sup>, including:  
 700 m<sup>2</sup> - production line  
 (25-30% - clean rooms)  
 500 m<sup>2</sup> - warehouse and auxiliary equipment

The project engineering shall be based on local building standards. ISO 13485 (for medical products), relevant regulations of GMP (EU) and ICH-7.





Component  
purchase and  
incoming  
inspection

1



Assembling

3



Packaging

5



Inspection (check for  
conformance to  
sterilization standards by  
using chemical indicators)

7



2

Washing by  
ultrasound or with  
pure water, placing in  
the drying oven



4

Quality control



6

Sterilization with  
ethylene oxide



8

Transferring  
for storage



#### Sterilization conditions:

- |   |   |
|---|---|
| (1) Gas: mixture of ethylene oxide (20%) and carbon dioxide (80%) | (5) Relative humidity: $60 \pm 10\%$                      |
| (2) Gas density: 940 mg/l   | (6) Sterilization time: 20 hours                          |
| (3) Pressure: 1.0 ~ 1.2 kg/cm <sup>2</sup>                        | (7) Air cleaning: more than 2 times (each time 15~20 min) |
| (4) Temperature 30 ~ 60 °C  |   |

After sterilization store more than 3 days under the following conditions:  
temperature 5°C(in winter) ~ 35°C(in summer), humidity 50 ~ 80 %.



2017

June – September

registration of relations between the project participants, registration of the joint venture

2017-2018

September – June

purchase and shipment of equipment (FAT)

2017-2018

November – February

project engineering

2018

April – December

plant construction, connection of utilities

2018

July – September

delivery of equipment and site acceptance test (SAT)

2018-2019

October – March

installation of equipment, commissioning

2018-2019

December – September

ISO certification (Russian standards)

2019

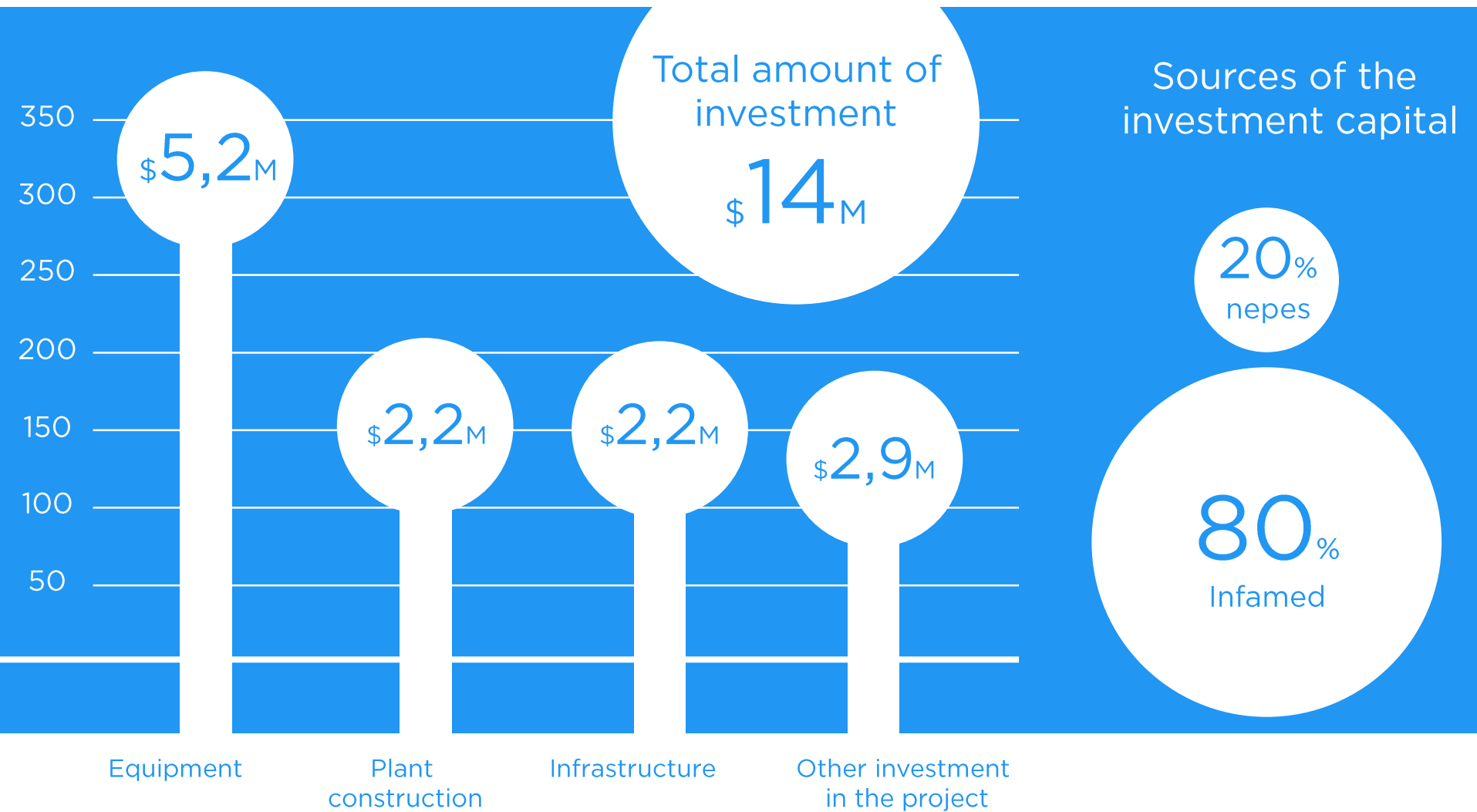
March

launch of mass production (for Russia and Korea)

2019-2020

September – April

European certification (CE)





WATER SUPPLY

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



ELECTRIC POWER

\$ **0,05** /kWh



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



RENT OF PRODUCTION PREMISES

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

AVERAGE SALARY

\$ **6 360**  
per year

Calculation of variable expenses:  
monthly with metering devices

The prices do not include VAT

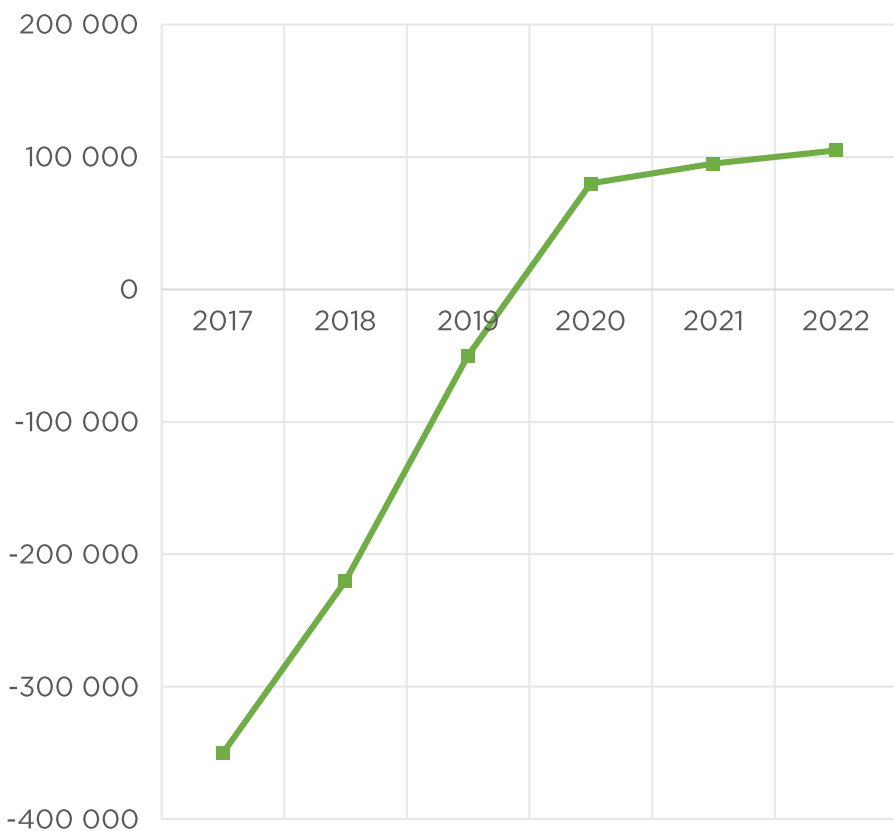
The price for resources is calculated  
according to the state tariffs

The tariffs are changed 1-2 times a year





### Net profit variance, thousand rub.



### Performance indicators of total investment costs

Net present value  
3,5  
bn rub.

Discounted payback  
period  
5  
years

Internal rate of return  
48,6  
%

Rate of return of the  
discounted expenses  
4,4



WE ARE READY TO SHARE  
WITH YOU MORE!



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