



# Webinar Presentation

2nd Quarter 2017

September 11,  
2017

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# 2nd Quarter

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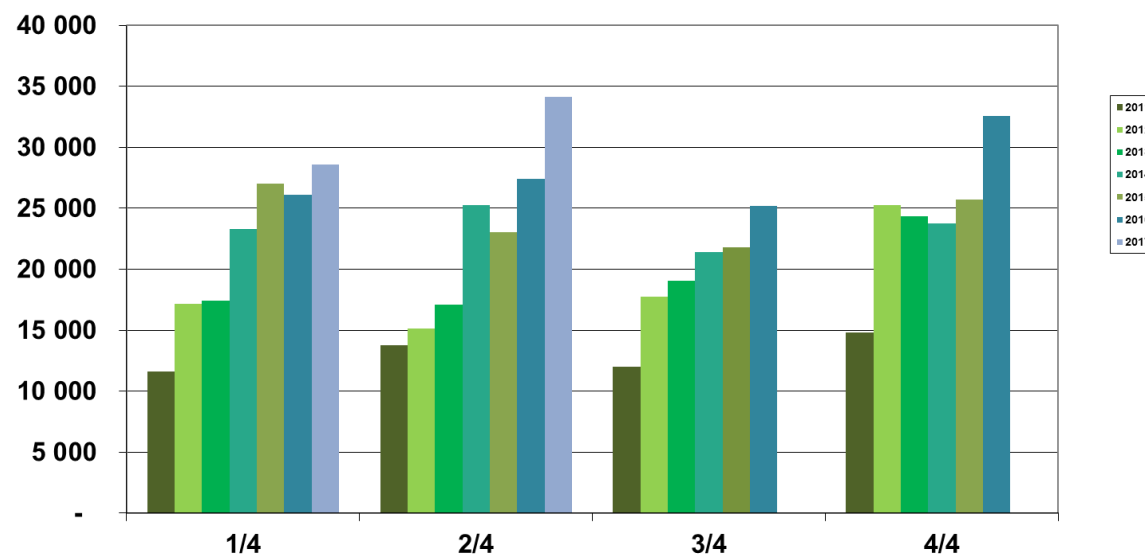


# Sales in 2nd Quarter

- Sales worth more than 34 million euros; clearly the best quarter in term of sales
- An increase by 25% compared to Q2 2016;
- Sales by pharmacies = 5.1 million gross, 2.6 million net;
- Sales by Silvanols = 1.1 million gross, 1 million net;
- Sales by Tonus Elast 2 million.

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Sales by Quarters, Thsnd. EUR

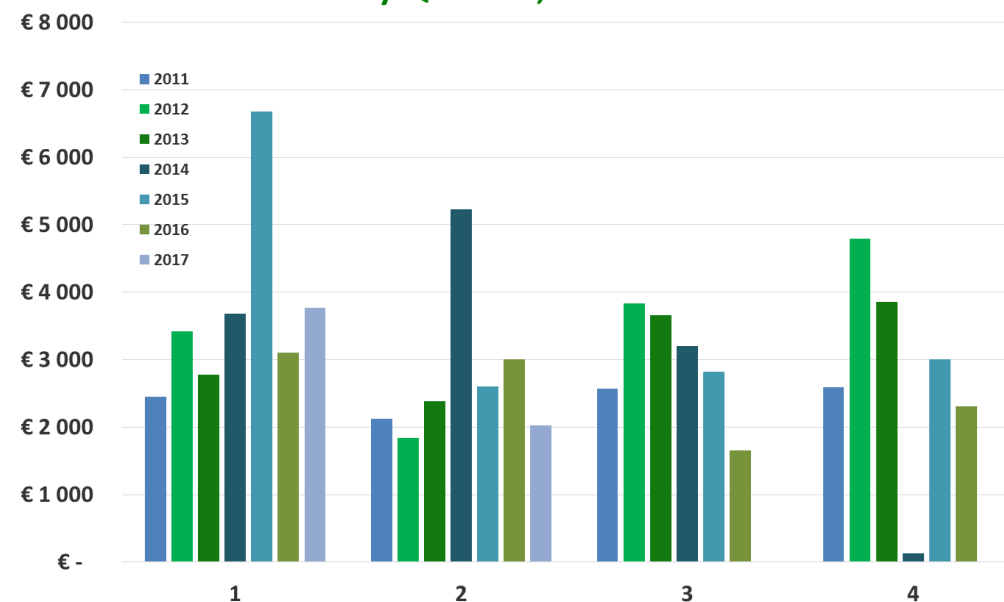


# Profit of 2nd Quarter

- Preliminary at 2 million euros, a reduction by a third compared to Q2 2016;
- Main operating factors influencing were increased sales costs (from 28.4% of sales to 31.1% of sales) and administrative costs (from 16.7% to 17.7%);
- Main one-off factors impacting adversely were forex loss of approx. 2 mln and provisions of 0.4 mln for recently acquired «Olaines Veselības centrs»;
- In terms of profit – one of the weakest quarters in recent history;

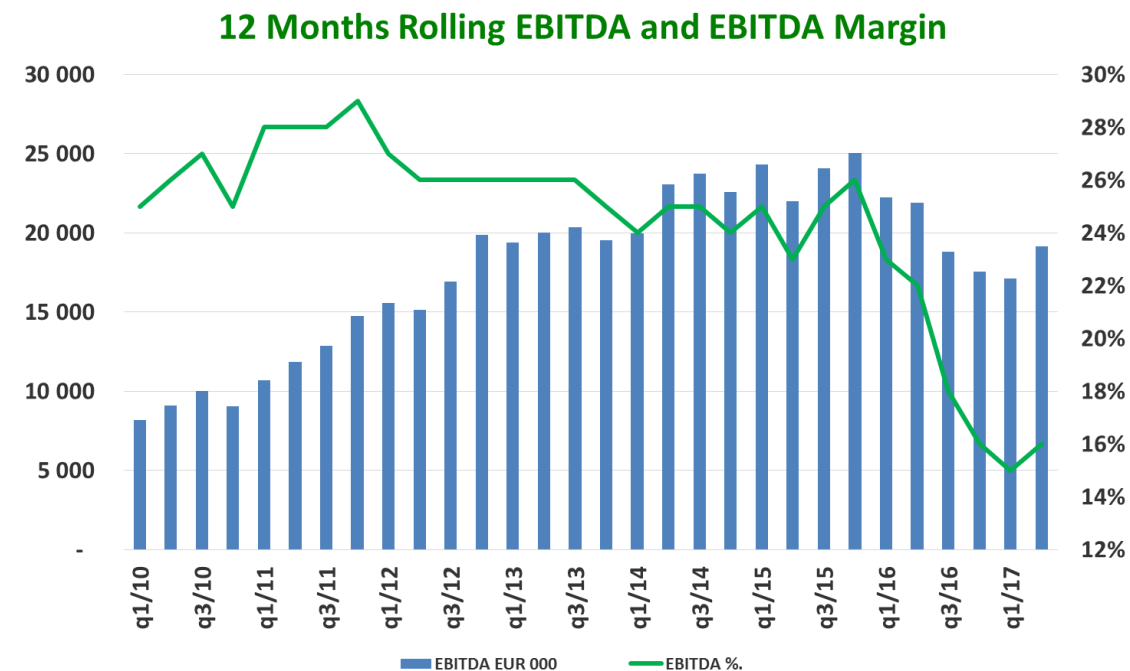
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Profit by Quarters, Thsnd. EUR



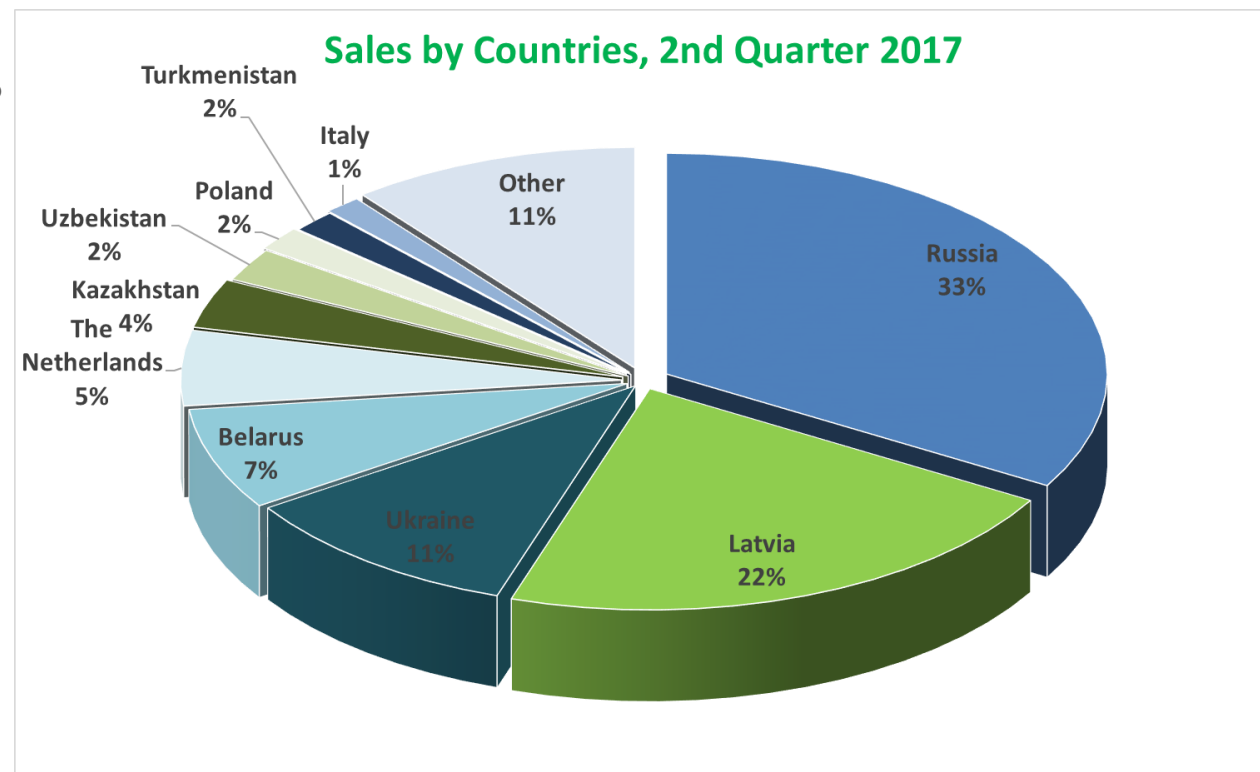
# EBITDA and Margin

- 12 months EBITDA at 19.2 million, some recovery after five quarters of decline;
- EBITDA margin at 16%, also a slight improvement;
- Neither forex loss nor gains are part influence EBITDA.



# Sales by Countries, 2nd Quarter

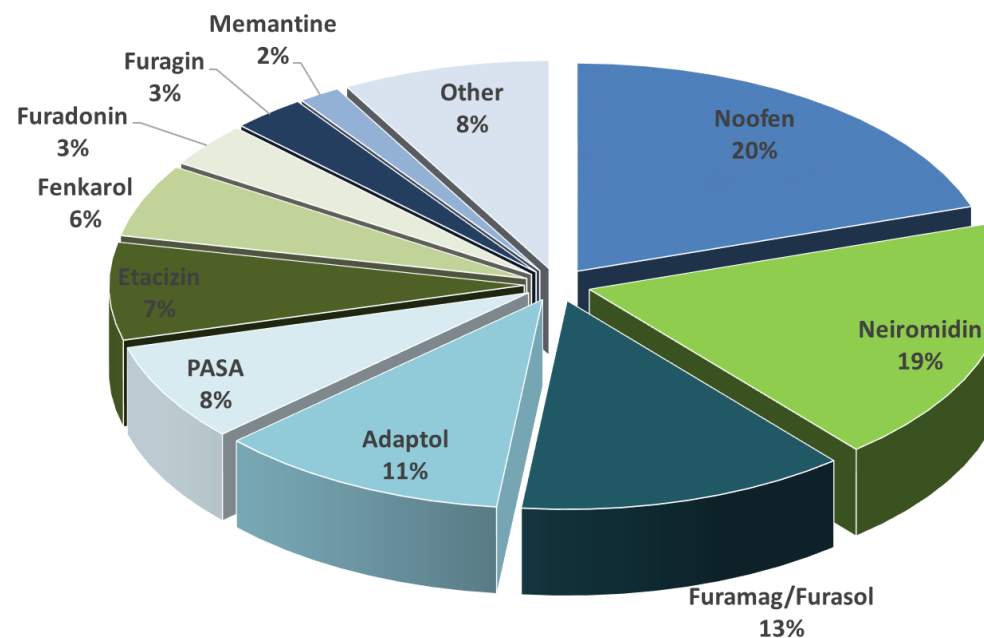
- ❖ Russia's share increases in Q2 to 33% from 28% in Q1, diluting Latvia's share to 22% from 28%;
- ❖ Ukraine recovering a little to 11% from 7%, as Belarus's share reduced from 12% to 7%;
- ❖ Kazakhstan, Uzbekistan, Turkmenistan and Poland improved significantly, as the last three replace Lithuania, Germany and Georgia.



# Sales by Products, 2nd Quarter

- Noofen has increased significantly from 10% to 20% and has become the best selling product;
- Neiromidin grew from 14% to 19%, and Furagin from 2% to 3%;
- Shares of all other products shrunk, Memantine first time among bestsellers, as it replaces Remantadine;
- In Q2 sales of Olainfarm products made up 68% of total consolidated sales.

Best-Selling Olainfarm Products, Q2 2017





# 6 Months of 2017

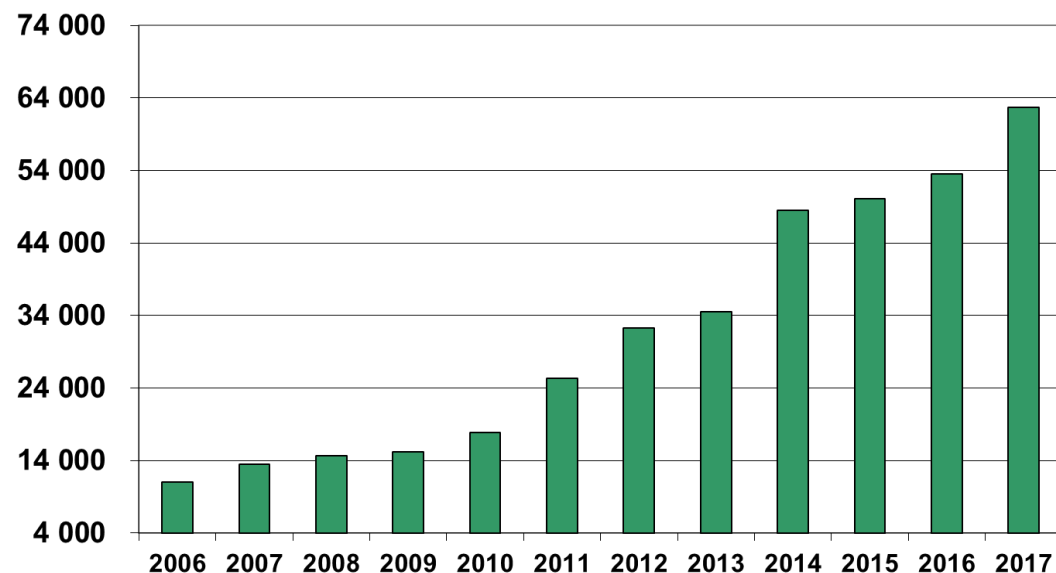
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# Sales in 6 months

- Sales at 62.7 mln, increase by 17% compared to H1 of 2016;
- Among others, Tonus Elast contributed 4 million and NPK Biotest 1 million to increase;
- Sales by pharmacies = 9.4 million gross, 4.4 million net;
- Sales by Silvanols = 2.4 million gross, 2.1 million net;

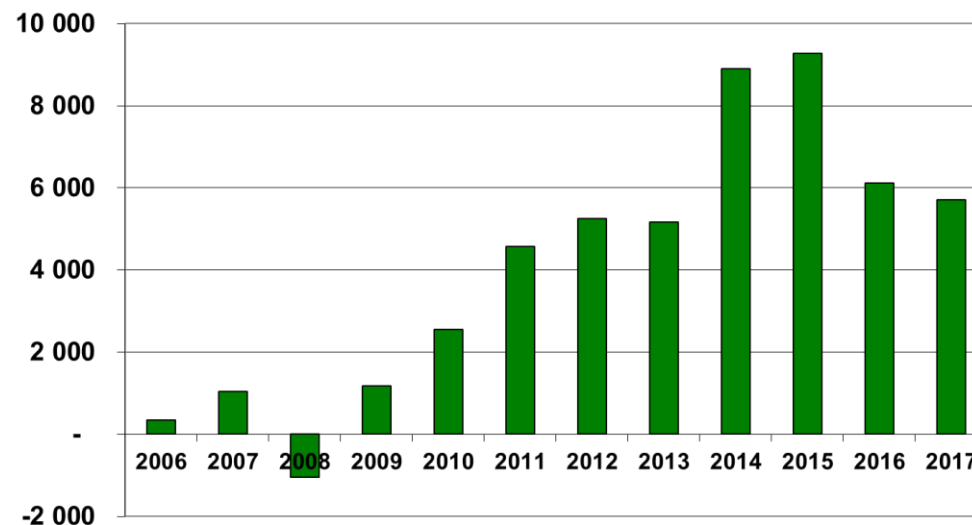
Six Months Sales, Thsnd. EUR



# Profit in 6 Months

- Preliminary at 5.7 million euros, a reduction by 7% a third compared to H1 2016;
- Main factors impacting adversely were forex loss of approx 2 mln and provisions of 0.4 mln for recently acquired «Olainfes Veselības centrs»;
- In terms of profit – one of the weakest quarters in recent history;

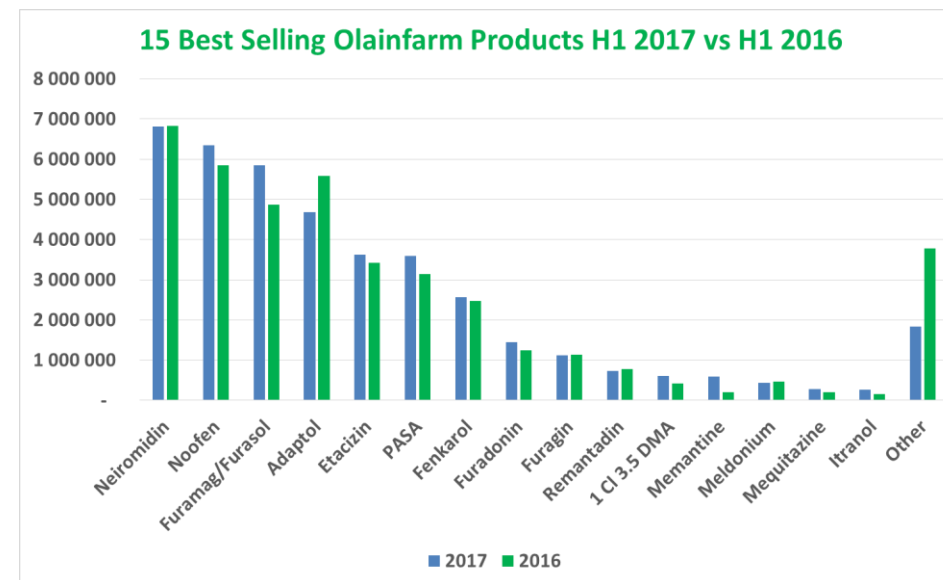
Net Profit of First Halves, Thsnd. EUR



# Growth Drivers: Products

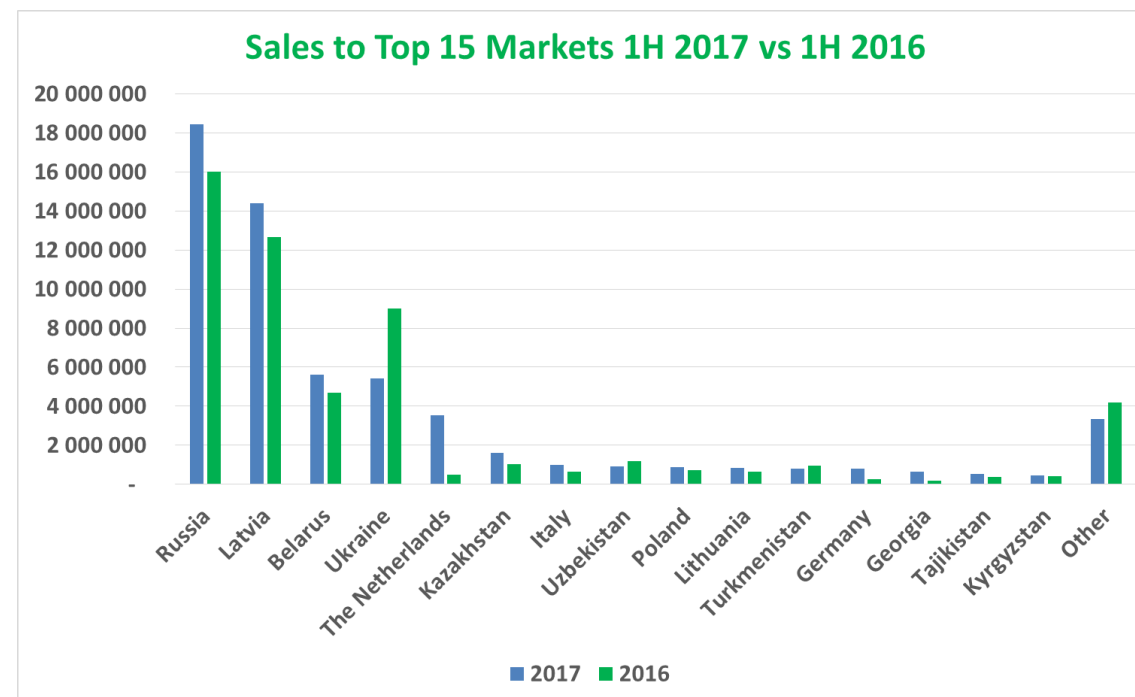
- 10 out of 15 growing;
- Most growth in monetary terms added by Furamag/Furasol (1m), Noofen (0.5m), and PASA (0.4m);
- Most growth in relative terms provided by Memantine (185%), Itranol (65%) and 1CI 3.5 DMA (45%);
- Most loss in monetary terms comes from all others (-2m), Adaptol (-0.9m) and Remantadine (-0.05m);
- Most loss in relative terms comes from all others (-51%), Adaptol (-16%) and Remantadine(-7%);
- Total sales of Olainfarm products were 40.7 million, an increase by 0,4%.

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# Growth Drivers: Countries

- 12 out of 15 growing;
- Most growth in monetary terms added by The Netherlands (WHO-3 m), Russia (2.4 m) and Latvia (1.7 m);
- Most growth in relative terms provided by The Netherlands (600%), Georgia (224%), and Germany (205%);
- Most loss in monetary terms comes from Ukraine (-3.6 m) all others (-0.9 m) and Uzbekistan (-0.3m);
- Most loss in relative terms comes from Ukraine(-40%), Uzbekistan(-21%) and all others (-20%);



# Performance of Key Daughter Companies



## Latvijas Aptieka

- Sales: 10.4 m
- Operating profit: 2.6 m ;
- Net profit: 0.4m



## Tonus Elast + Elast Medical

- Sales 6.3 m;
- Operating profit: 2.3 m;
- Net profit: 0.5 m.



## Silvanols

- Sales: 2.4 m;
- Operating profit: 1.3 m;
- Net profit: 0.1 m

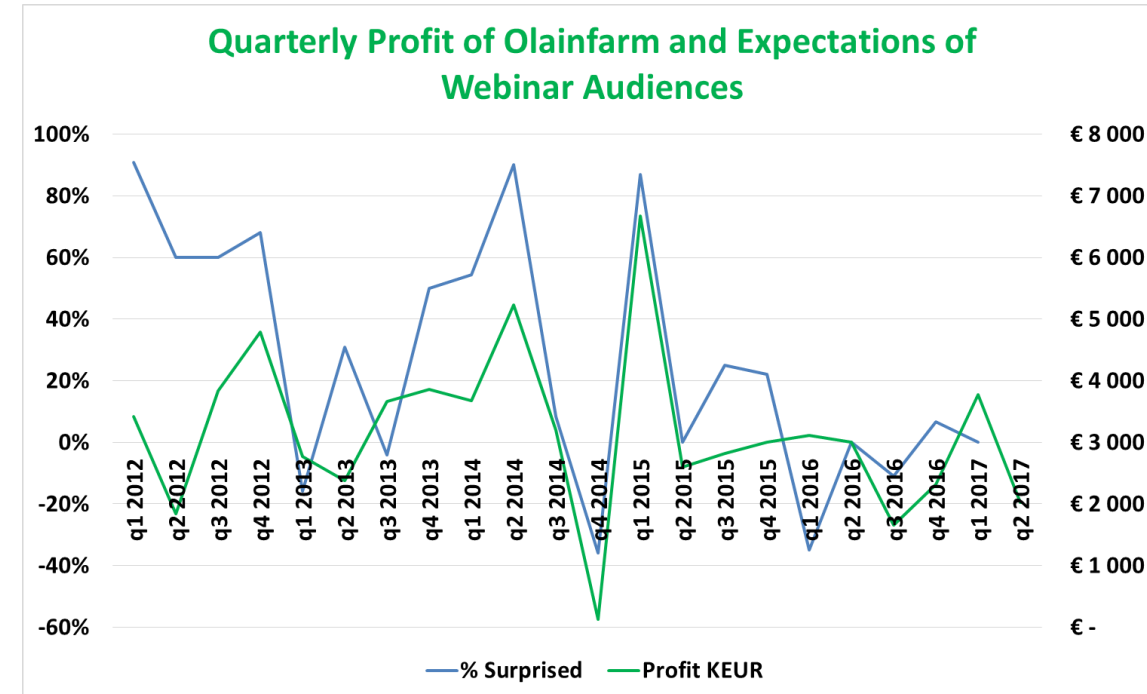
# Poll Question

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# Historic Expectations vs Fact

- Question asked in 22 webinars;
- In vast majority of cases both lines have similar movement;
- «Zero surprise» seems to be at approx. 3 mnl level per quarter;





# Update on Recent Events

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# Targets Changed

- Profitability numbers of H1, behind schedule due to several factors, not least:
  - Higher than expected sales costs;
  - Higher than expected administrative costs;
  - Forex loss, primarily Russian ruble.
- New projections for the remainder of the year produced, providing:
  - Standalone net profit of 11 million EUR (previously 12.7 million);
  - Consolidated net profit of 13.5 million EUR (previously 15.5 million);
  - All estimates are forex neutral
  - Sales projections remain unchanged.

# Poll Question

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# In Focus: Development of New Drugs

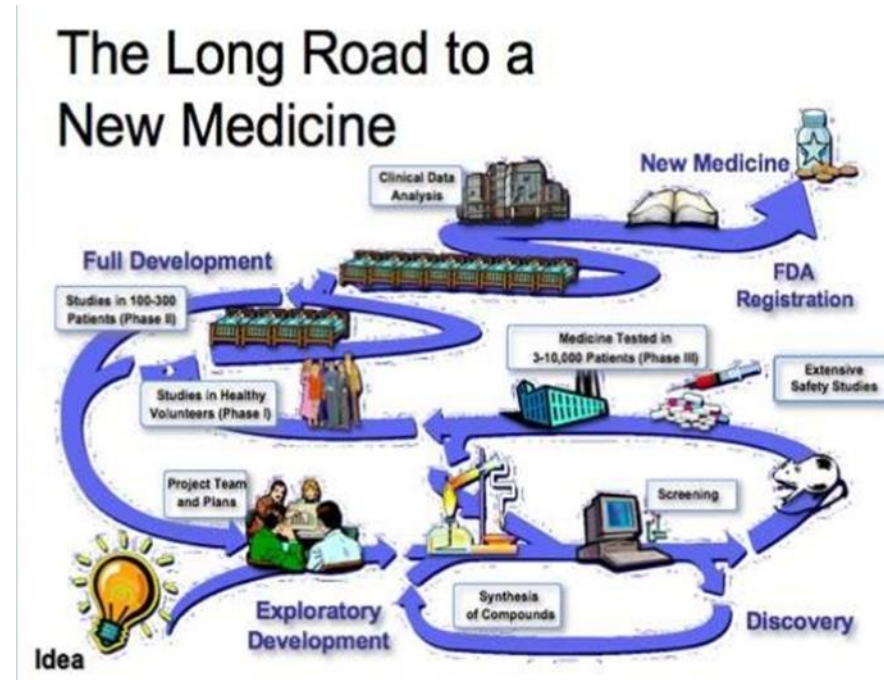
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# New Medicines

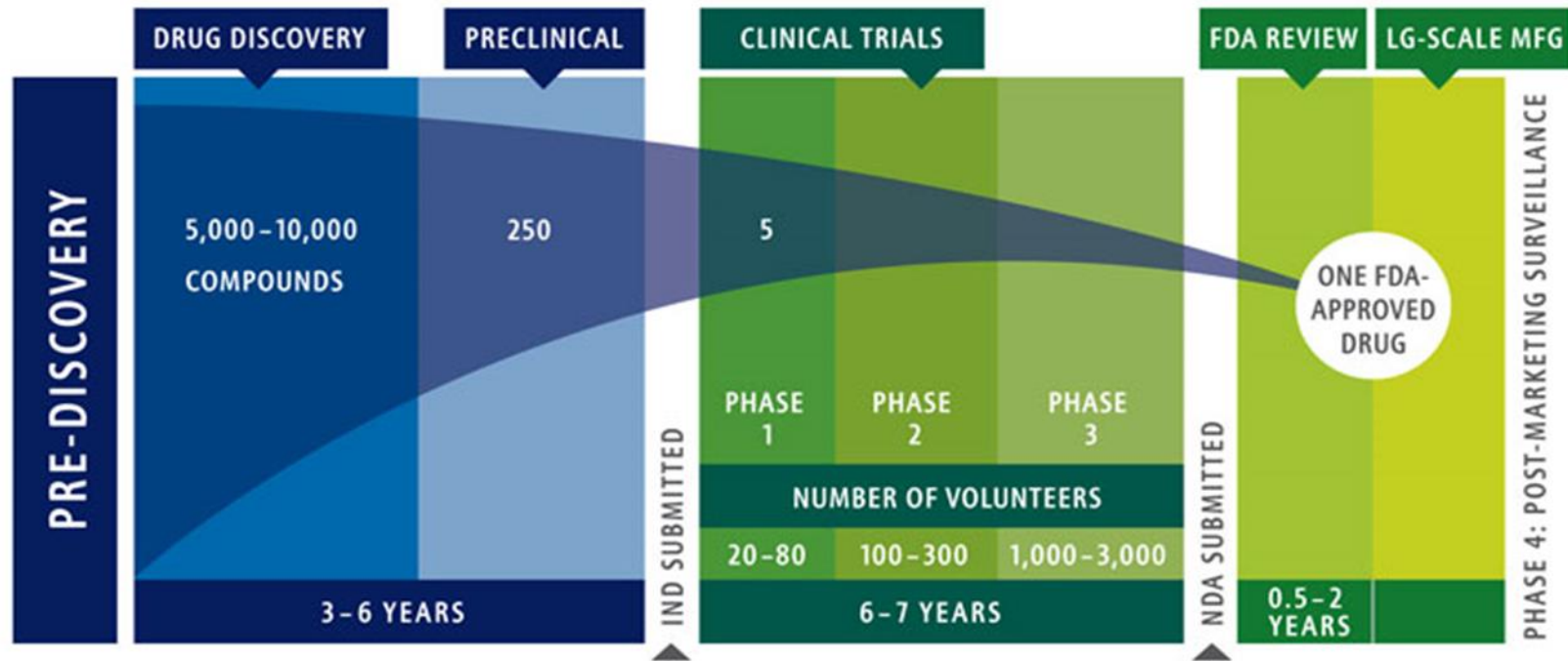
- For patients, new medicines offer fewer side effects, fewer hospitalizations, improved quality of life, increased productivity and, importantly, extended lives...
- ...but drug development process must proceed through several stages in order to produce a product that is safe, efficacious, and has passed all regulatory requirements.

# A Long Story Short...



# ...Still Short, but a Little More Professional

## Drug Discovery and Development: A LONG, RISKY ROAD



Source: Pharmaceutical Research and Manufacturers of America

# As Everything, It Starts With an Idea

- IDEA;
- Discovery process;
- Product characterization;
- Manufacturing;
- Pre-clinical research (in laboratory; on animals);
- Clinical research (on humans);
- Drug registration process (Only now *The new drug is on market*);
- Post marketing safety monitoring.



# Stage 1: Discovery

- Research for a new drug begins in the laboratory;
- The discovery process includes the early phases of research, which are designed
  - to understand the disease and condition;
  - to choose a molecule to target with a drug;  
(Up to 5,000 to 10,000 molecules for each potential drug candidate are subjected to a rigorous screening process);
  - to find a promising molecule (a «Lead compound») that could be a new medicine;
  - to perform initial tests in the lab on promising compounds

# Stage 1: Discovery (2)

- Early stage pharmacology studies help to characterize the underlying mechanism of action of the compound;
- Once scientists confirm interaction with the drug target, they typically validate that target by checking for activity versus the disease condition for which the drug is being developed;
- By the end, researchers hope to identify a promising drug candidate to further study in the lab and in animal models, and only then in people.

**This process takes approximately  
3-6 years**

## Stage 2: Manufacturing

- Drug developers must devise a formulation that ensures the proper drug delivery parameters;
- It is critical to begin looking ahead to clinical trials at this phase of the drug development process;
- Scientists determine the drug's stability:
  - in the formulation itself;
  - for all the parameters involved with storage and shipment, such as heat, light and time;
- The formulation must remain potent, sterile and safe (nontoxic);
- Drug formulation and delivery may be refined continuously until, and even after, the drug's final approval.

# Stage 3: Pre-Clinical Research

- Drugs undergo laboratory and animal testing to answer basic questions about bioactivity, safety and efficacy of the formulated drug product;
- Preclinical toxicology testing - the goal is to determine toxic dose levels and observe clinical indications of toxicity;
- Pharmacokinetic (PK) and ADME (Absorption/Distribution/Metabolism/Excretion - these studies provide useful feedback for formulation scientists);
- This testing is critical to a drug's eventual success and, as such, is scrutinized by many regulatory entities

# Stage 4: Clinical Research (1)

- While preclinical research answers basic questions about a drug's safety, it is not a substitute for studies of ways the drug will interact with the human body;
- "Clinical research" refers to studies, or trials, that are done in people;
- Before a clinical trial begins, researchers review prior information about the drug to develop research questions and objectives for each of the different Clinical Research Phases and begin the Investigational New Drug Process (IND), a process they must go through before clinical research begins.



# Stage 4: Clinical Research (2)

- Clinical studies are grouped according to their objective into three phases:

## **Phase I studies (Human Pharmacology)**

- Study Participants: 20 to 100 healthy volunteers or people with the disease/condition;
- Length of Study: Several months;
- Purpose: Safety and dosage;
- Approximately 70% of drugs move to the next phase.

# Stage 4: Clinical Research (3)

## Phase II studies

- Study Participants: Up to 100 to 300 patients with the disease/condition;
- Length of Study: Several months to 2 years;
- Purpose: Efficacy and side effects;
- Approximately 33% of drugs move to the next phase

# Stage 4: Clinical Research (4)

## Phase III studies

- Study Participants: 300 to 3,000 patients;
- Length of Study: 1 to 4 years;
- Purpose: Efficacy and monitoring of adverse reactions;
- Approximately 25-30% of drugs move to the next phase.



# Stage 5: Drug Registration Process

- A New Drug Application (NDA) tells the full story of a drug;
- Its purpose is to demonstrate that a drug is safe and effective for its intended use in the population studied;
- A drug developer must include everything about a drug—from preclinical data to Phase 3 trial data—in an NDA (must include reports on all studies, data, and analyses);
- Competent Authorities review teams thoroughly examine all of the submitted data related to the drug and make a decision to approve or not to approve it.

# Post Marketing Safety Monitoring

- Competent Authorities continue monitoring of all drug safety once products are available for use by the public;
- Even though clinical trials provide important information on a drug's efficacy and safety, it is impossible to have complete information about the safety of a drug at the time of approval.

## Phase IV studies

- Study Participants: Several thousand volunteers who have the disease/condition
- Purpose: Safety and efficacy

# Conclusion

- On average, it takes at least 10 years for a new medicine from initial discovery to the marketplace;
- Clinical trials alone are taking 6-7 years on average;
- The average cost to research and develop each successful drug is estimated to be at least around a billion Euro (this number incorporates the cost of failures);
- Only a few of compounds that may be screened and assessed early in the R&D process receives approval);
- The overall probability of clinical success (the likelihood that a drug entering clinical testing will eventually be approved) is estimated to be less than 12%.

# Poll Question

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# Q&A Session

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