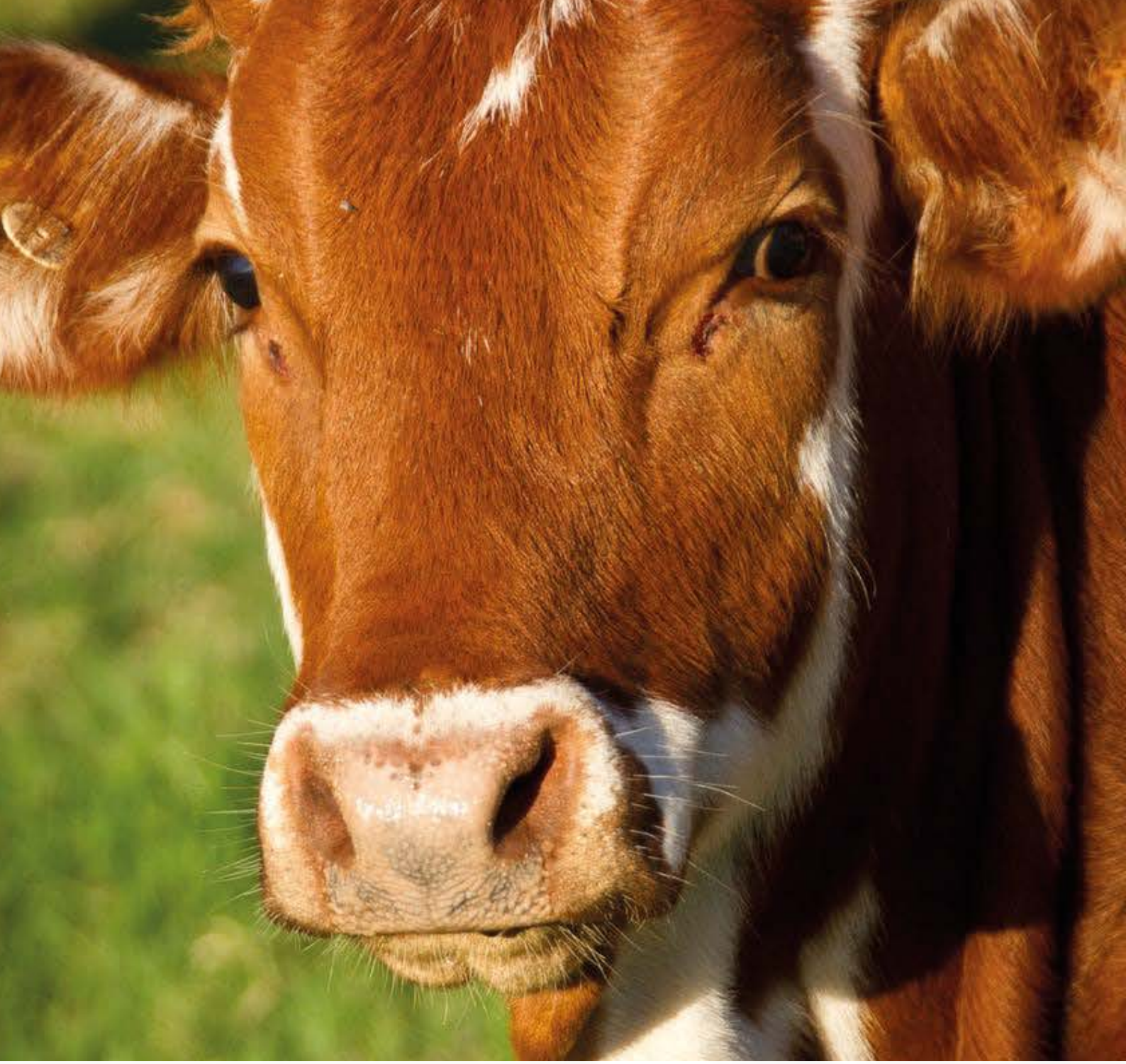
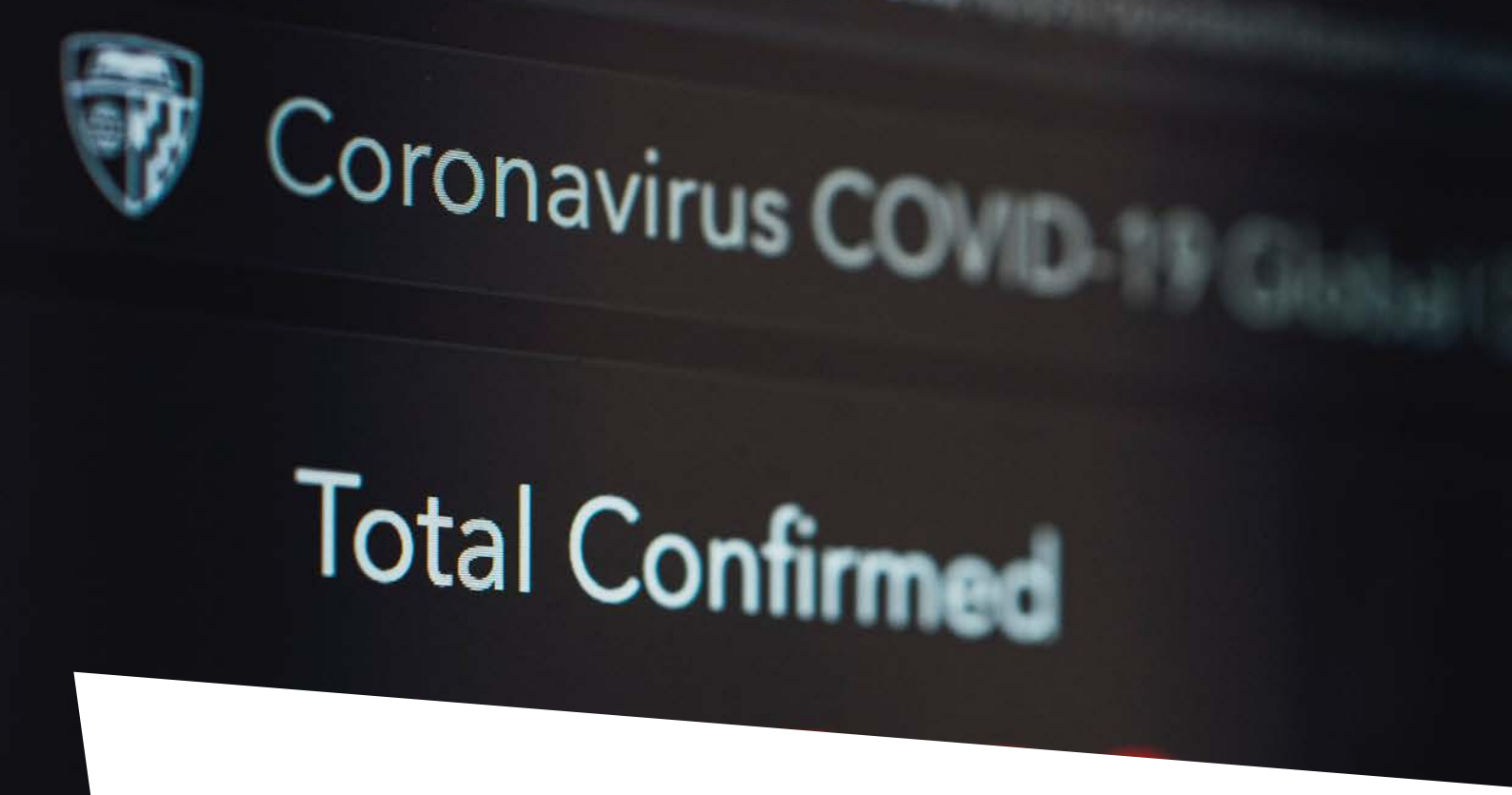


FarmPharma

ANTIBIOTICS-FREE LIVESTOCK RAISING



PANDEMICS MUST BE PREVENTED

LESSONS FROM COVID-19 PANDEMIC

Outbreaks of novel pandemics in the current century (SARS, MERS, COVID-19, avian and swine influenza) were zoonotic in nature and were caused by highly pathogenic viruses transmitted from various animals. With the potential for rapid viral replication, broad host range, cross-species transmission, person-to-person transmission, and lack of herd immunity in human populations, zoonotic pathogens can cause devastating pandemics. The offensive of towns in the habitats of wild animals, intensive industrial animal husbandry and globalization increase the risk of the development and spread of zoonotic infections. Therefore, the risk that novel highly morbific pathogen with increased cross-species transformation and / or elevated person-to-person spread may enter human populations with potentially disastrous consequences is rather high. “This time it was a virus, but next time it could be a bacterium and then antibiotics are the protection we have to avoid huge cases of illness and death”, according to the Swedish Minister of the Environment Per Bolund. The use of antibiotics in the beef production is discussed in the newspaper Näringslivet on May 24, 2021.

HOW TO STOP THE OVERUSE OF ANTIBIOTICS ?

PROBLEM

The infection management approaches in agriculture highly rely on antibiotics, causing antimicrobial resistance (AMR), whereas vaccines have limited effectiveness and don't provide universal protection. The emergence of AMR is recognized by the World Health Organization (WHO) as one of the greatest threats to global health leading to the inability to treat even the most common infections in humans. AMR is estimated to cause 700 000 human deaths annually and predicted to rise to 10 million deaths by 2050. Of all antibiotics consumed globally, more than 80% are sold for use in animal agriculture; with 70% of which being essential to human medicine. The pathogens are constantly developing resistance and even multiple resistance to the antibiotics used, making the AMR a growing global pandemic. The awareness that it is largely caused by the overuse of antibiotics in the livestock sector, resulted in several actions undertaken by different authorities to reduce the use of antimicrobials in animals. These actions have started to increasingly restrict farmers in the fight against infections, forcing them to change their way of working, creating a great unmet need for antibiotics alternatives to break the infection cascade in cattle.

SETTING NEW STANDARDS FOR LIVESTOCK RAISING

SOLUTION

This is why we want to introduce InterferOx, an interferon-based drug that has the potential to **not only treat bacterial and viral infections in cattle but also prevent them**. InterferOx has the potential to minimize the misuse and the over-use of antimicrobial drugs in cattle and therefore provide a solution for the highly destructive trend of rising AMR. InterferOx will improve animal health and therefore farm production and farmers' profit, while complying with official regulations without causing AMR and associated treatment difficulties. Our product was designed to improve the effective sustainability of treating humans and animals with infectious diseases. The vision of FarmPharma is to be a game changer in the development of sustainable, therapeutic and prophylactic veterinary products, by providing a solution to keep animals healthy without antibiotics. Our goal is to promote InterferOx to be the standard of care for infectious diseases in cattle in order to facilitate sustainable livestock production.

WE CREATE A SUSTAINABLE FUTURE: ONE PLANET, ONE HEALTH.

THE SOLUTION HAS BEEN PROVED

PROTOTYPE

InterferOx is a new type of anti-infective therapy based on bovine interferons, which trigger cellular immunity, leading to a broad and natural activation of immune defence to combat viral and bacterial infections. InterferOx was inspired by the Belarusian Proof-of-Concept study with a formulation consisting of two immune-stimulating proteins, interferons, which improved the recovery of cows in preventative (85%) and therapeutic use (88%) due to lower susceptibility to infections. This specific formulation is not in line with any regulatory requirements associated with marketing in the US or the EU, however, the Proof-of-Concept study highlights the strong potential for the development of InterferOx conforming to EU and USA standards. FarmPharma will expand this knowledge in producing a more advanced product with three carefully selected interferons to provide broader protection and higher efficacy, produced in accordance with global regulations.

COMBINING THE BEST INTERNATIONAL EXPERTISE

PROJECT PLAN

To achieve our aim, several interferons with known anti-viral and/or anti-bacterial effects have been selected and produced in lab-scale at the Karolinska Institutet for validation of complementary efficacy against different relevant bovine pathogens. The validation is currently performed at Federal State Budgetary Scientific Institution “Federal Scientific Centre – All-Russian Scientific Research Institute of Experimental Veterinary Medicine named after K.I. Skryabin and Y.R. Kovalenko of the Russian Academy of Sciences. The combination(s) of interferons will then be selected based on the demonstrated activity against bovine pathogens. We are looking for a combination that has broad protection against various pathogens. The combination will be formulated by the Karolinska Institutet and tested in vivo in calves by the French clinical research organization (CRO) CEBIPHAR in 2023, while the Slovenian CMO Jafral will develop InterferOx production under good manufacturing practice (GMP) standards. This will allow FarmPharma to seek a licensing deal with or acquisition by a large pharmaceutical company with a strong presence in animal health. That will help FarmPharma to start pivotal cattle effectiveness and safety studies under good clinical practice (GCP) requirements and commercialize InterferOx.

THE UNIQUENESS OF FARMPHARMA'S APPROACH

COMPETITORS

Currently, antibiotics and vaccines are the main therapies for respectively the treatment and prevention of infections in cattle. Antibiotic drugs have been highly efficient against bacterial infections, but the overuse and misuse of antibiotics have been leading and remains to lead to AMR. Vaccines do not cause AMR, but their effectiveness is highly variable and often limited as pathogens develop resistance, vaccines are species-specific and relatively expensive, and they are only indicated for the prevention of particular infections, mostly viral. As such, complex infectious diseases remain a key challenge for animal health. The most promising alternatives that are commercially available are immune-stimulating drugs, which InterferOx is also categorized as. The immune-stimulating drugs induce activation or increase the activity of the animal's own immune system, thereby providing a rapid, potent and broad-protective response to infectious agents. These immune-stimulating drugs have many advantages over currently used antibiotics and vaccines, mainly due to their effectiveness against multiple infectious agents. However, as these immune-stimulating drugs are a relatively new class of therapies, there is currently only a very limited number of available therapies and many of them have varying efficacies in different conditions. InterferOx is a one-of-a-kind game-changing innovation due to its unique aspects:

- works for both viral and bacterial infections;
- used for both therapeutic and prophylactic purposes;
- a unique combination of cattle-specific interferons.

BENEFITING SUSTAINABLE GROWTH

CUSTOMERS

With InterferOx, we are responding to the strong demand for limited use of antibiotics, by developing an effective and sustainable anti-infective therapy. To stimulate rapid and wide market uptake of InterferOx, we will initially target veterinarians as primary customers to convince farmers of InterferOx's value, and thereafter directly target farmers as they have a high willingness to pay for alternative therapies like InterferOx. Among all farmers, those who have to use a large number of antibiotics but want or forced to change their way of working are the most attractive customers for FarmPharma. These are farmers with large industrial farms.

The customer segment for InterferOx:

- Veterinarians who are the experts on animal health, which could introduce the medicine to new customers without causing AMR and associated treatment difficulties;

- The farmers that are open to minimize broad-spectrum antibiotic overuse because of ethical reasons that are communicated from their governments or in the strive towards higher sustainability motivated by global activists and by long term lower cost of production due to less animal loss;

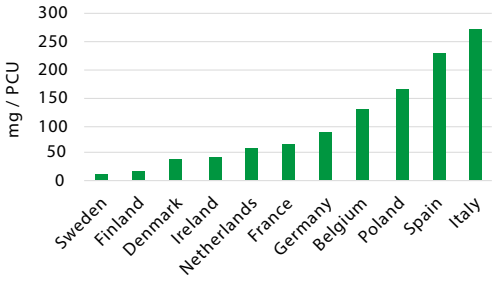
- The farmers that have tried vaccines without satisfying effect or that are skeptical to vaccines due to their price or other parameters (e.g. uncertainty of effect or lack of effect when the disease outbreak is a fact);

- Farmers that will be forced to minimize antibiotic use by the new governmental laws and regulations of their countries.

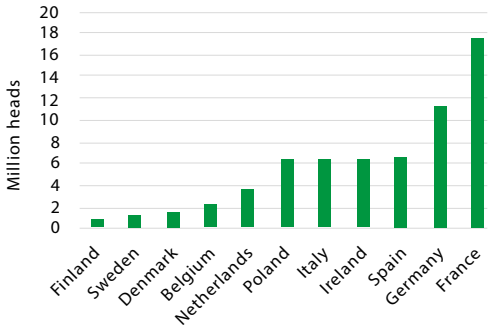
HUGE

UNMET NEEDS

Antimicrobials for food-producing animals 2017:



Bovine population in 11 European countries 2020:



MARKET

Globally there are 1.5 billion cattle held, with 121 million of them held in Europe and 94 million held in the United States who are number one and two in the dairy industry and the meat industry in the world. InterferOx specifically targets the cattle antimicrobials market segment, which is currently worth of €1.7 billion and expected to further grow in the coming years with a compound annual growth rate (CAGR) of 4.6%. This is thus the size of the total target market of InterferOx.

As the initial market introduction segment, we strategically chose France, Germany, Italy, Spain and Poland. They are the most attractive go-to markets for FarmPharma with InterferOx. All these countries have the highest cattle population in the EU. One group of countries have the most intensive and most developed cattle industries (France, Germany and Italy), the moderate to high antibiotic consumption for livestock farming and in general, also have the strictest rules regarding the use of antimicrobials, and therefore will also be the first ones (early adopters) to buy new veterinary products, especially if these have the potential to displace antibiotics like InterferOx. On the other side, the need for a drug like InterferOx might be higher in countries with the highest use of antimicrobials – and higher infection rates, such as Italy, Spain and Poland.

The global markets will be penetrated after product launch in the EU using data from clinical trials and effects reported in the first launch country. The US is the most attractive expansion opportunity beyond Europe due to its large volume of cattle. Other non-EU countries with well-developed cattle industries, and thus interesting market opportunities for InterferOx, are Canada, New Zealand, UK and Australia. Another attractive country for commercialization of InterferOx is China where the cattle population is now slightly larger than that in the USA and the usage of antibiotics in the cattle industry recently began to be regulated by the government.

InterferOx will be a first showcase of FarmPharma's approach to infection management. The mode of action, making use of the animal's own immune system creates great spin-off potential for the development of similar, interferon-based products for other farm animals.

JOINING FORCES

BUSINESS MODEL

To capitalize on the market opportunity, we prefer to commercialize InterferOx by establishing a licensing deal with a large pharmaceutical company. This will enable FarmPharma to perform large-scale safety and efficacy trials on cattle, register and commercialize InterferOx. Besides the licensing deal, we are open to an exit via a trade sale of our company, including our product portfolio.

WE ARE

FarmPharma

OUR COMPANY

FarmPharma AB is a Swedish start-up, founded in April 2018 as a subsidiary of Double Bond Pharmaceutical. From April 2020 FarmPharma is led by our CEO Dr. Irina Zaitseva, who has significant experience in preclinical studies and profound knowledge of interferon signal transduction. The company is supported by an experienced Board with strong expertise in drug development, chaired by the successful Life Sciences entrepreneur Igor Lokot, the co-founder of FarmPharma and Double Bond Pharmaceutical. We have also set-up an initial value chain with key partners, including Karolinska Institutet, All-Russian Scientific Research Institute of Experimental Veterinary Medicine, CEBIPHAR and Jafral.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