



# INTERVACC

February 2023



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# Q4 update

|                                    | Oct - Dec |        | Jan - Dec |         |
|------------------------------------|-----------|--------|-----------|---------|
|                                    | 2022      | 2021   | 2022      | 2021    |
| Net sales                          | 3,884     | 1,068  | 9,684     | 5,241   |
| Operating result                   | -23,394   | -8,798 | -64,413   | -29,393 |
| Earnings per share before dilution | -0.46     | -0.17  | -1.28     | -0.59   |
| Earnings per share after dilution  | -0.46     | -0.17  | -1.28     | -0.59   |

- During the quarter Strangvac was launched in key European markets Germany, France, Austria, Belgium, the Netherlands, Luxemburg, Ireland, Poland and Italy
- Intervacc and the Swedish University of Agricultural Sciences, SLU, extended a multi-year contract for the development of innovative animal health vaccines
- Together with our distribution partner Dechra Pharmaceuticals Intervacc participated in several Veterinary and Equine events highlighting Strangvac®
- The number of sold doses of Strangvac in Sweden grew by approximately 150% between Q3 and Q4
- In connection with the year-end report 2022, the board decided to adopt the following long-term financial goals regarding Strangvac: Strangvac has the potential to reach annual global sales exceeding one billion SEK with a gross margin of approx. 65%

# Intervacc – A fully integrated animal health vaccine company



1 Developing and commercializing **modern, safe and effective vaccines for animals, focused on** infectious diseases caused by **streptococci and staphylococci**, based on a technology platform **using recombinant fusion proteins**. Potential to **reduce the use of antibiotics** and **fight antibiotic resistance**






2 **Sales of lead product Strangvac® in key European countries** after having received marketing approval in the EU and UK

3 Strangvac® **addresses a severe** (fatal), **common** and **highly contagious global disease**. A vaccine with **great coverage against all globally circulating strains** with the potential to be a **game changer** in the fight against equine strangles

4 **Demonstrated efficacy** against *Streptococcus suis* infection in piglets **by vaccinating sows**. **Successful safety and immunogenicity study** against *Staphylococcus aureus* infections to reduce mastitis **in dairy cows**

5 Innovative platform and vaccine pipeline based on partnerships with world leading expertise at the **Swedish University of Agricultural Sciences, SLU** and the **Karolinska Institute, KI**

# Strong current momentum based on key achievements

|   |   |  |
|---|---|--|
| ✓ | Strangvac® <b>granted marketing authorization</b> from EMA and VMD  |  |
| ✓ | Strangvac® European <b>distribution agreement signed</b> with Dechra for Europe excl. the Nordics & Baltics   |   |
| ✓ | <b>Sales start for Strangvac® in key European markets</b> (Sweden, Denmark, UK, Germany, France, Austria, The Netherlands, Belgium, Luxemburg, Ireland, Poland and Italy) | <br> |
| ✓ | <b>USDA approval process initiated</b> for US approval of Strangvac®  |   |
| ✓ | <b>Positive results in R&amp;D projects for vaccine against <i>S. suis</i></b> in pigs and <i>S. aureus</i> in cows based on the same technology platform                 |  |
| ✓ | <b><i>S. suis</i> patent approved</b> in US   |   |

## Our expertise and focus



### Developing modern, safe and effective vaccines for animals

- ✓ Technology platform based on recombinant fusion proteins
- ✓ We focus on Gram positive bacteria – and are a leading company in developing vaccines against staphylococcal and streptococcal infections

## Go to market strategy

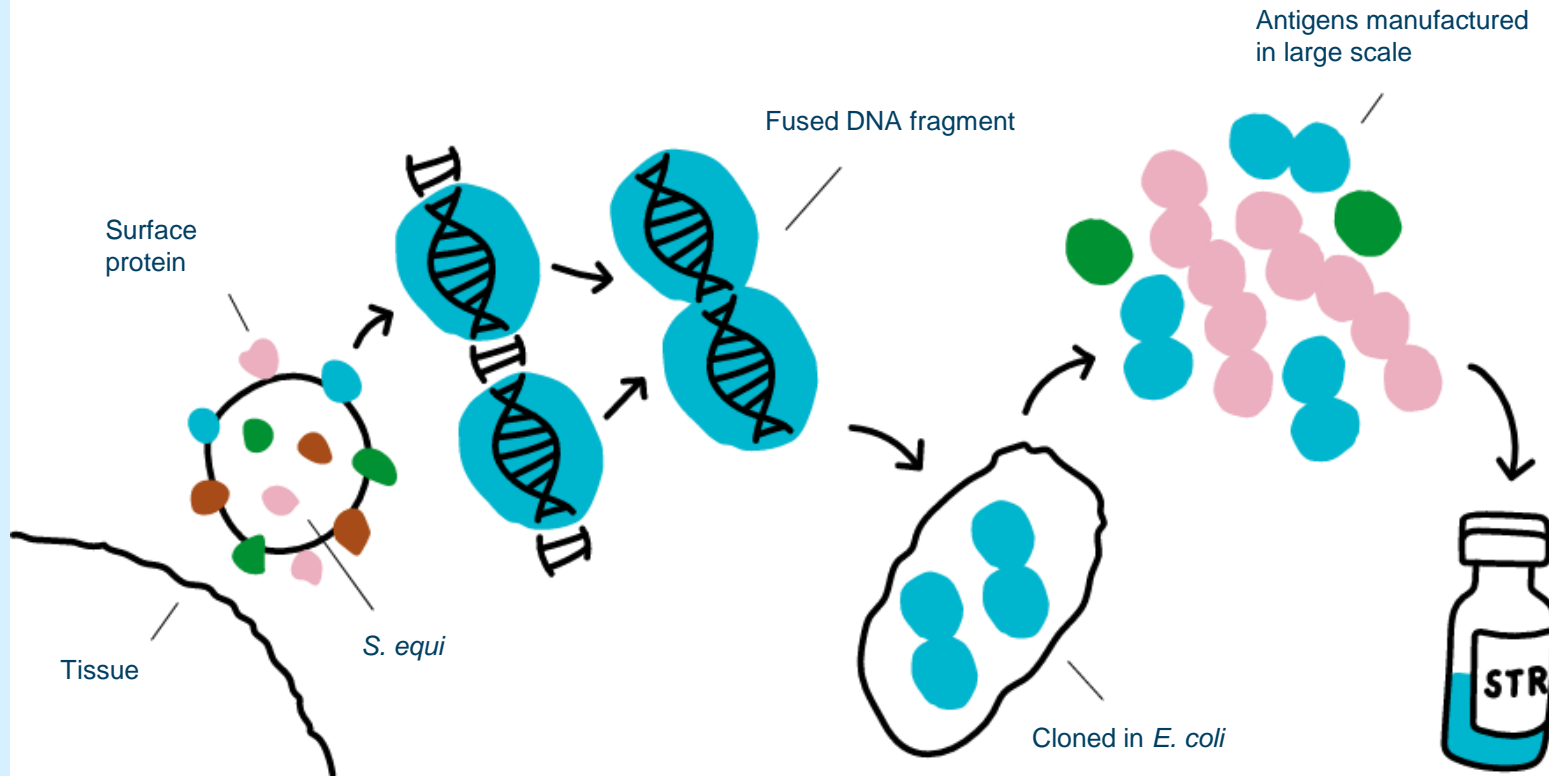


### Becoming a Marketing Authorization Holder enables Intervacc to generate greater economic returns

- ✓ Proven track-record of successfully managing the regulatory process
- ✓ Outsourcing manufacturing to CDMOs
- ✓ Reaching the global market via **Distribution Partner Agreements** with established global market leaders
- ✓ Direct sales in selected core regions



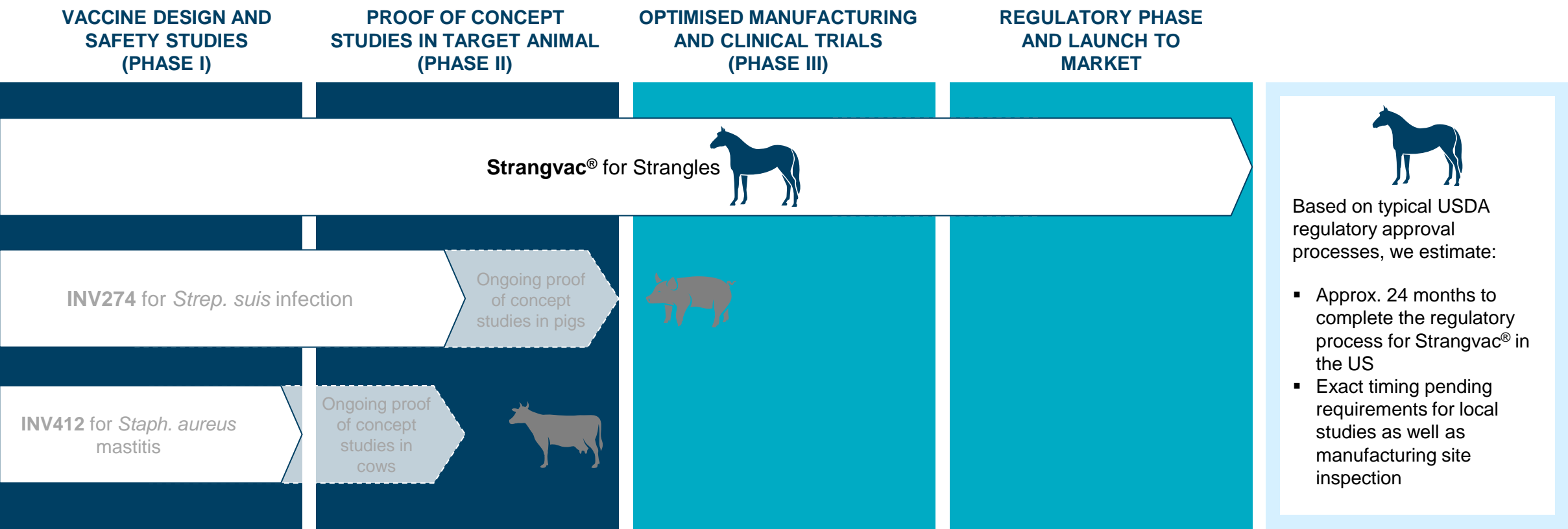
# Developing modern, safe and effective vaccines for animals, based on our technology platform with recombinant fusion proteins



- ✓ Technology platform enables strong **safety profile**
- ✓ Suitable for **large scale manufacturing** (high antigen yield per fermentation)
- ✓ Enables **vaccines to simultaneously target multiple important proteins** that are used by bacteria to cause disease
- ✓ **Stable vaccines that are easy to handle and ready to use** (normal cold chain, liquid form, intramuscular administration)

Source: Company information.

# Promising pipeline targets significant unmet needs in several animal species



Source: Company information.

# Strangvac® targets the severe, common and highly contagious disease Strangles

## DESCRIPTION OF STRANGLES

- ➔ A **severe** and **fatal** disease. Up to 100% morbidity and 10% mortality
- ➔ The most **common** vaccine preventable infectious equine disease and the **most frequently** diagnosed infectious equine disease in the world
- ➔ **Highly contagious** and globally transmitted disease
- ➔ Outbreaks are **very costly** to control (quarantine, transportation restrictions, sanitation and veterinary costs)
- ➔ There are **60 million horses** in the world

## ANATOMY OF A HEALTHY HORSE AND INFECTED HORSES WITH NASAL DISCHARGE AND RUPTURED ABSCESSES



Source: (clockwise from left) [horsetalk.co.nz](http://horsetalk.co.nz); [horseandcountry.tv](http://horseandcountry.tv); [horsevet.co.uk](http://horsevet.co.uk); [thearabianmagazineonline.com](http://thearabianmagazineonline.com); [eurodressage.com](http://eurodressage.com)

**Strangles outbreaks are much more common in comparison to equine influenza outbreaks in countries like Sweden**



# Our lead product Strangvac<sup>®</sup> – a vaccine against equine strangles, is approved in Europe (EMA & VMD)

STRANGVAC<sup>®</sup> IS A MULTICOMPONENT FUSION PROTEIN SUBUNIT VACCINE

→ No live agent

→ Intramuscular administration

→ Strangvac conferred significant levels of protection after two doses. Up to **94% efficacy** in clinical trials after third dose \*

→ Large global market



**A game changer in the fight against strangles**

Source: \* Robinson et al., 2020; Vaccine

# Strangvac® targets a global market

STRANGVAC® ADDRESSES A GLOBAL POPULATION OF 60 MILLION HORSES

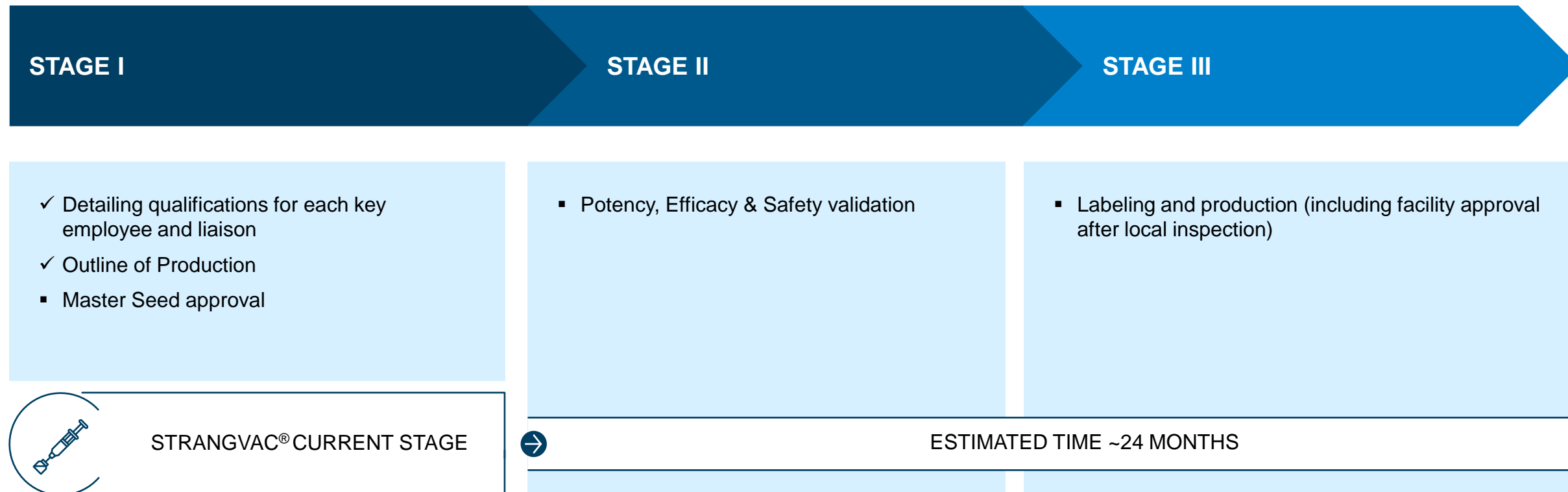


We have now launched in the most important European markets where the vaccination rate against other diseases affecting horses is high

# Status update on Strangvac® US regulatory process



THE USDA PROCESS CAN BE ILLUSTRATED AS THREE STAGES<sup>1)</sup>

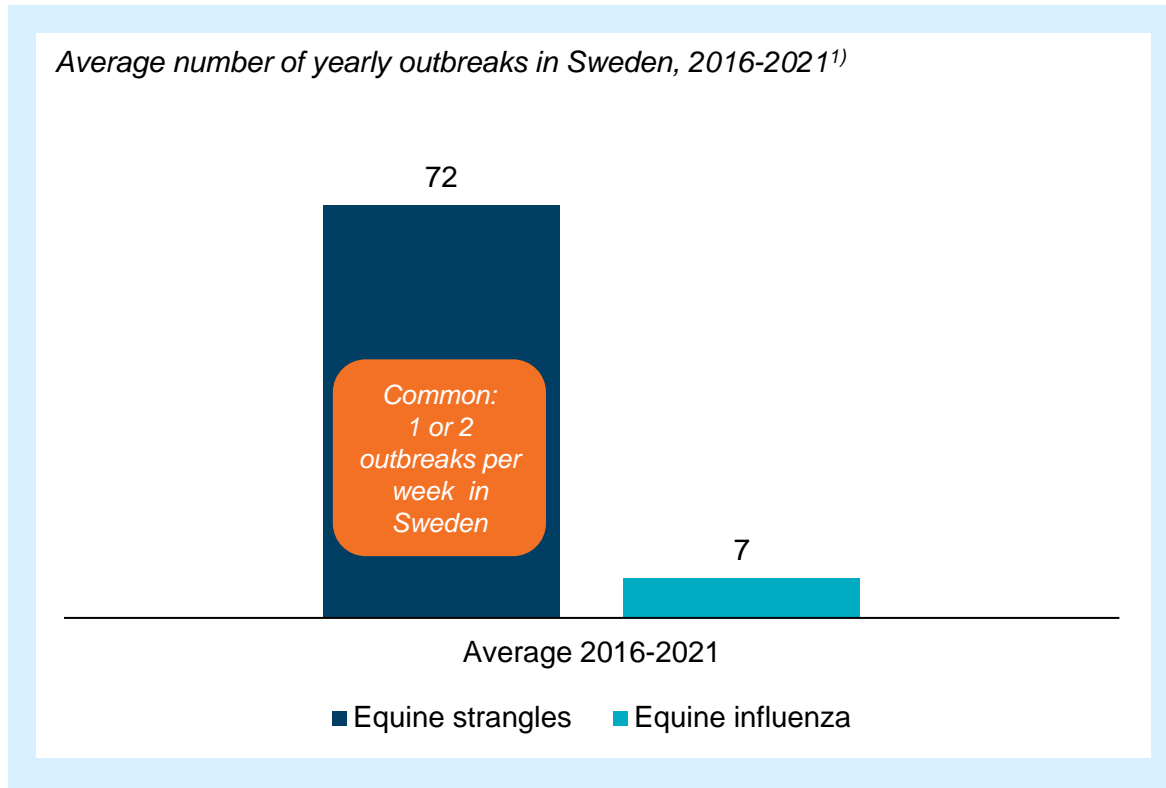


**Approx. 24 months to complete the regulatory process for Strangvac® in the US, with exact timing pending requirements for local studies as well as manufacturing site inspection**

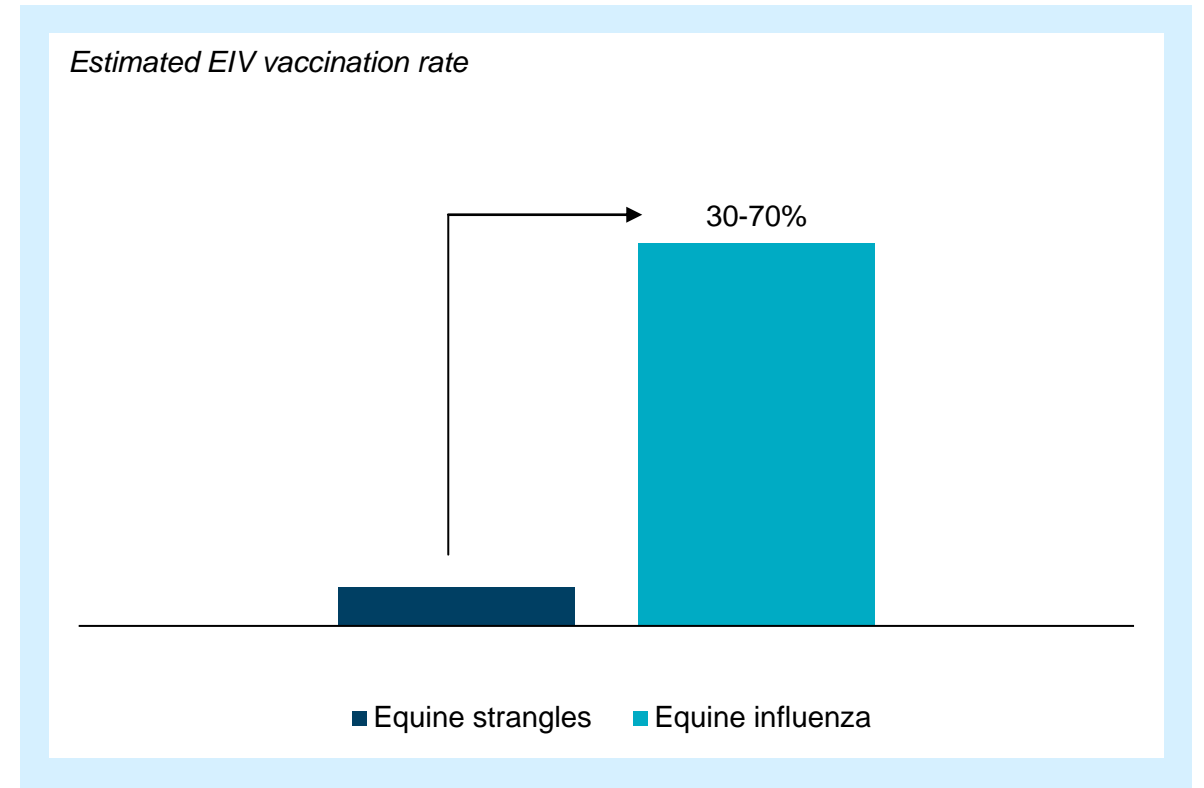
Notes: 1) Application for Sale and Distribution in Canada can be made largely in parallel and have the same requirements.

# Clear potential for increased adoption of Strangvac®

STRANGLES OUTBREAKS ARE MUCH MORE COMMON THAN EQUINE INFLUENZA...



... DUE TO HIGHER RATES OF VACCINATION



High market acceptance for vaccines against equine influenza, a milder disease, showcases the large potential for increased adoption of vaccines against the more severe equine disease strangles

1) Svensk travsport

# Manufacturing for global demand with world class CDMOs

## Production of Strangvac



**Antigens are produced** in a process with sufficient yield for millions of vaccine doses



Vaccine doses are formulated by **mixing the antigens with adjuvant**



The vaccine doses are filled into vials that are **labelled, packaged and released for sale**



Together with world class CDMO<sup>1)</sup> partners, the **manufacturing process is scalable** to meet global demand, enabling us to **reduce cost of goods as volumes increase**

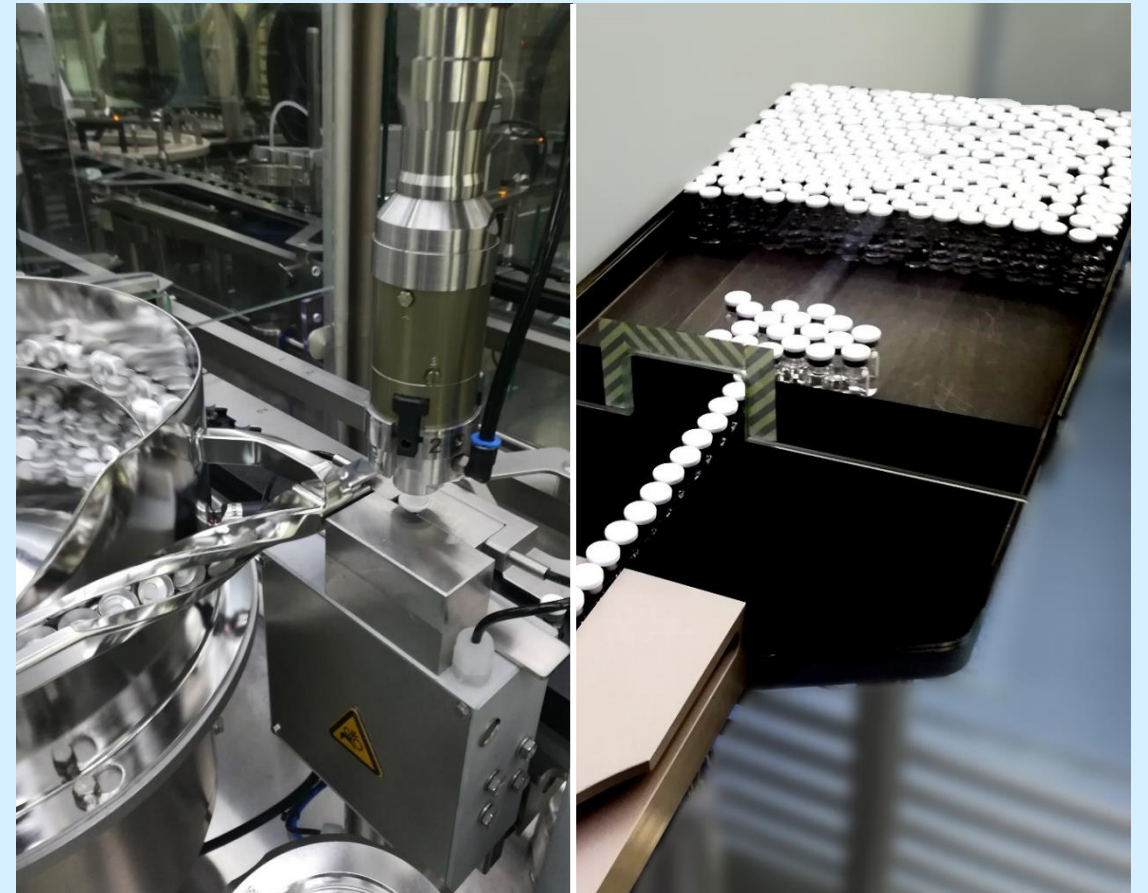
Since EMA and VMD approval...



DS Shelf-life extended to 28 months

Increasing precision of analytical methods

Reducing lead times and improving COGS



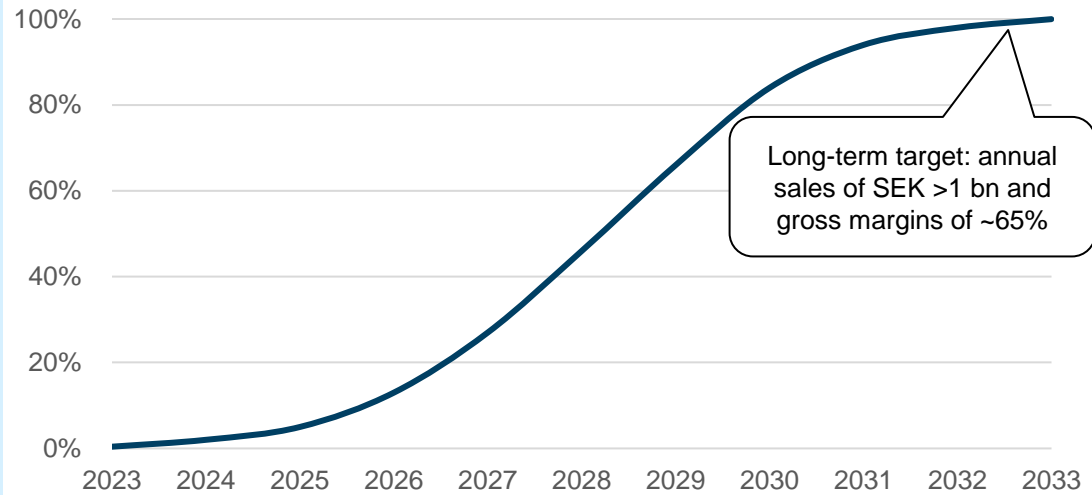
Notes: 1) Contract Development Manufacturing Organizations



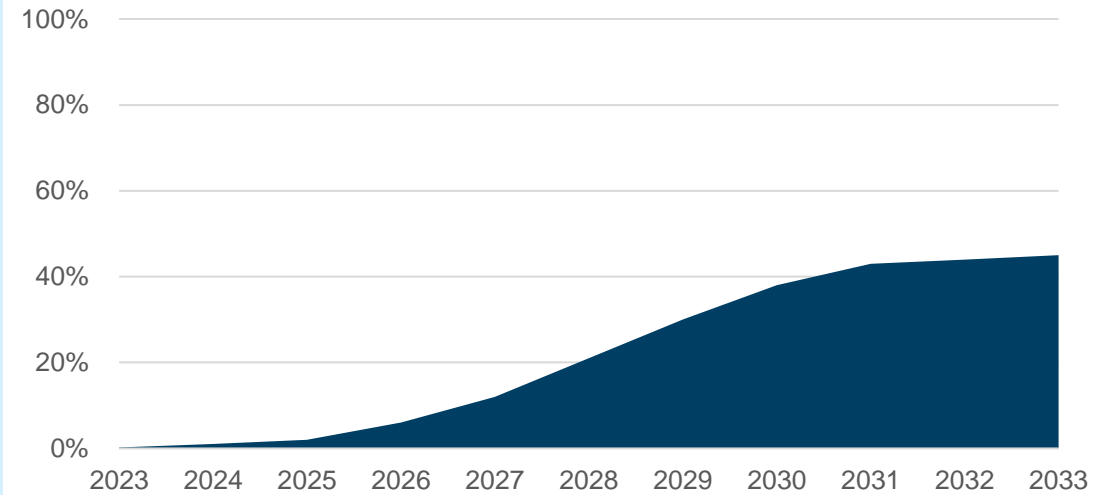
# Strangvac® anticipated global growth path

BASE OF S-CURVE AND FINANCIAL INFORMATION FROM JAN 2023

*Horses in Strangvac vaccination program as percentage of “peak”*



*Horses in Strangvac vaccination program as percentage of total population*



- In the long-term, we anticipate that Strangvac® alone has the potential to generate in excess of SEK 1bn in annual revenue for Intervacc<sup>1)</sup>, and that gross margins could amount to approximately 65 percent
- Based on the long-term financial goals adopted by the Board, we believe that Strangvac®, in the medium-term, should be able to generate sales of SEK 150-300m, and increase gross margins through scale

Note: 1) In our primary markets Europe, North America and Oceania.

# Strangvac® – progressing up the S-curve

STRATEGY – IT TAKES TIME TO BUILD A MARKET AND CONVERT ACTIVITIES INTO SALES

## Building the market, creating demand

- Increase awareness of Strangles
  - A severe (fatal) and highly contagious global disease
  - The disease is underreported in most European countries
  - A special focus on creating awareness that Strangles is a common disease that can affect any horse

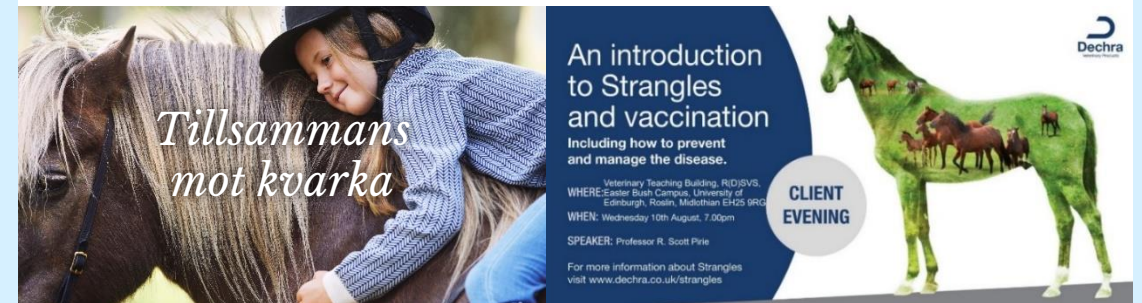
## Establish guidelines and recommendations, give confidence

- Make Strangvac® a Basic or Core vaccine, start with key decision makers
- Vaccine Ambassadors and Key Opinion Leaders
- Attract early adopters to use the vaccine to generate additional safety data and experience

OUR MARKETING AND SALES ACTIVITIES FIT INTO THE STRATEGY

## Building brand image, encouraging use

- A modern and easy to use vaccine with great coverage against all globally circulating strains
- Protect your loved ones
- Profitable vaccine for stable and other business owners – Include vaccination in the disease prevention program
- Financial benefits from insurance companies



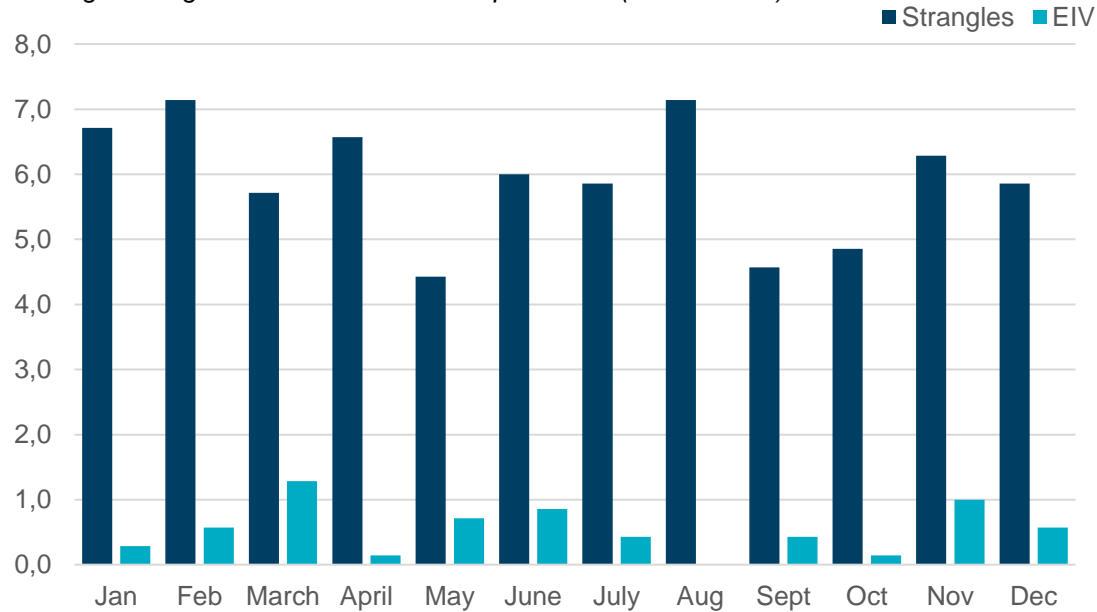
A game changer in the fight against strangles

# Strangvac® getting horses into the vaccination program – tipping points

## STRANGLES OUTBREAKS DRIVE AWARENESS AND THE CALL TO ACTION

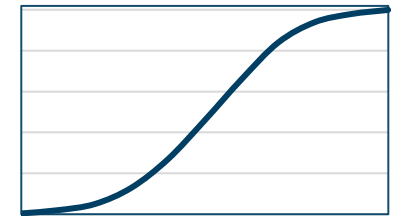
### Strangles outbreaks are common and occur throughout the year

Average Strangles outbreaks in Sweden per month (2016 – 2022)



## EXPERIENCE FROM THE FIELD – ADOPTION AND SUPPORT IS GROWING

- Stables requiring vaccination against strangles for all horses
- Veterinarians actively urging horse owners to vaccinate
- Key institutions and associations are positive
- Good experiences spread throughout the horse community
- Pre-import requirement for some countries



A game changer in the fight against strangles

# Great responses to awareness campaigns and positive KOL feedback

## POSITIVE MESSAGES FROM KEY OPINION LEADERS

“” *I believe a **strangles vaccine can make a big difference**. Instead of having one to two outbreaks per week in Sweden, maybe we could have one or two per year” – Gittan Gröndahl, Deputy state veterinary officer*

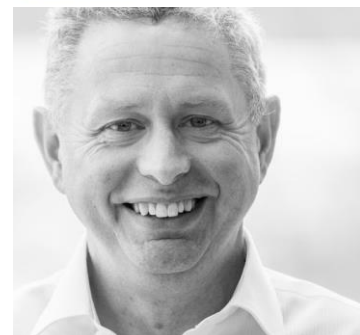
“” *“Strangles has proven to be one of the hardest diseases to get a vaccine for that is horse-friendly, user-friendly and effective. **I am pleased we now have access to a new tool in the fight against strangles.**” – Nic de Brauwere, Redwings’ Head of Welfare and Behaviour*

- “”
- *“**It is great to see Strangvac coming onto the veterinary vaccine market.**”*
  - *“Its availability for vets and horse owners represents an exciting and novel additional tool for the prevention and control of this highly significant and still prevalent equine infectious disease.”*
  - *“I am especially excited that Strangvac, being based on fusion protein technology rather than killed or modified live bacteria”*
- Richard Newton, director of epidemiology and disease surveillance at the University of Cambridge Department of Veterinary Medicine

## PROMISING RESPONSE FROM LAUNCH CAMPAIGNS



Our Chief Scientific Officer Dr Andrew Waller will speak about the prevention of *strangles* at the London Vet Show on Thursday the 17th of November at 12:30 pm and on Friday the 18th of November at 12:35pm. Join the CPD (Continuing Professional Development) sessions organised by Dechra. The CPD sessions are first come, first served, and are expected to be well attended, so please get there early. Further information can also be found at stand M25. <https://lnkd.in/d/vU0h55q>



# Distribution partner Dechra highlighting Strangvac®



## Pipeline Delivery

*Another year of consistent progress*

### Key product launches in FY22

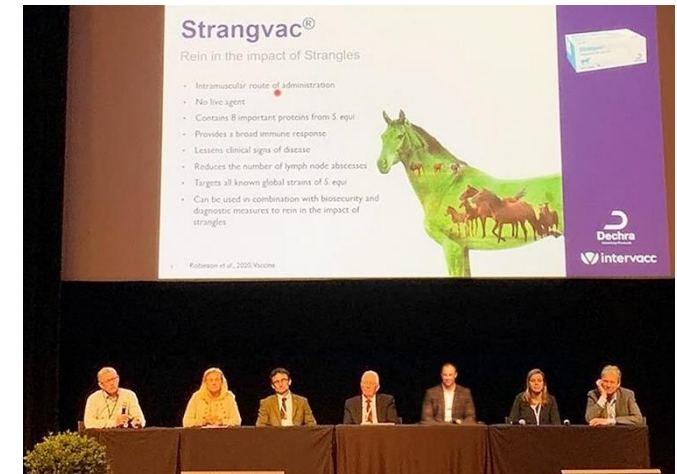
- Launch of Zenalpha, a novel therapeutic product
- Equine Strangles vaccine launched in EU



## Positive feedback from launch

### Recent Joint activates

- **Irish Equine Veterinary Association (IEVA) Conference in Ireland**
- **London Vet Show**
- **Dutch Equine Conference**
- **Jumping Amsterdam Vet. Congress and FEEVA core meeting**





# Feedback from the field since Strangvac® vaccinations commenced



- **Over 100 horses that were not vaccinated with Strangvac® developed strangles** at a large European facility
- So far, the **mortality rate is around 6%**, including cases of strangulation
- These are very well-kept horses in a high-class facility
- Clearance of *S. equi* will take **time and lead to significant disruption and expense**

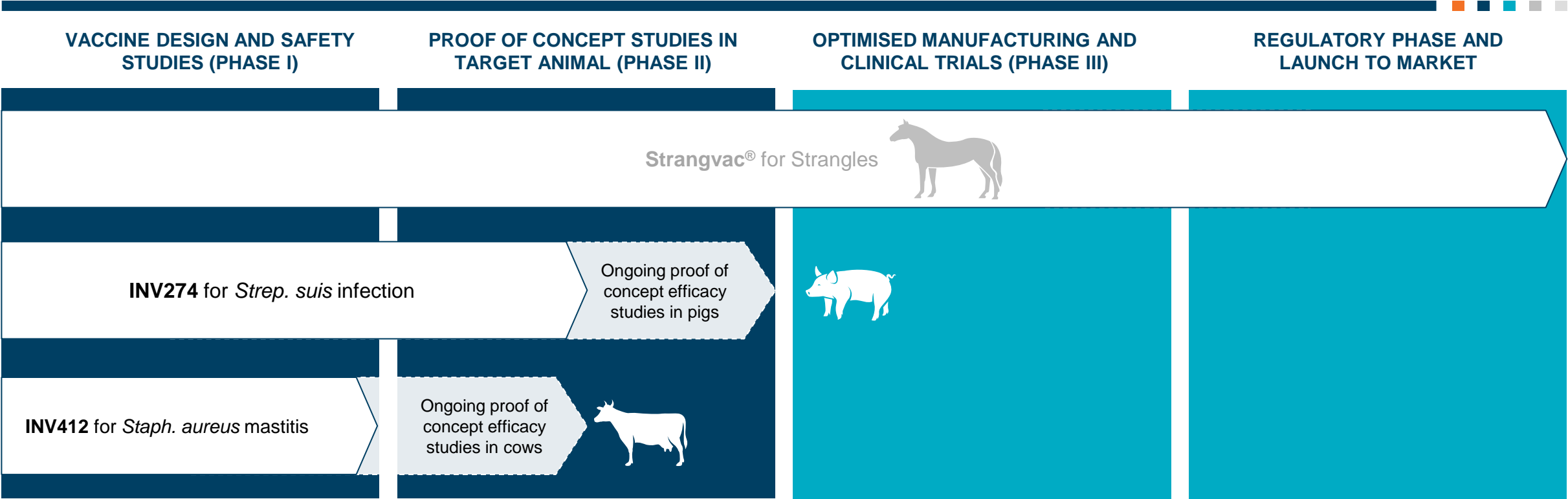


- **15 Icelandic horses** had been associated with an outbreak, but those that had not been exposed to *S. equi* were moved to another farm
- They were **vaccinated with the primary 2 Strangvac® doses**, and then moved back into the farm with endemic strangles two weeks later
- **None of the vaccinated horses developed strangles**

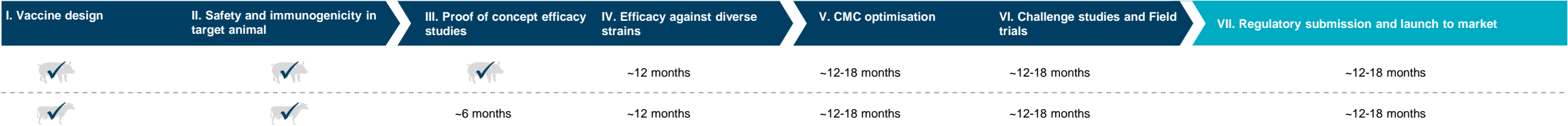


- In a recent, ongoing, outbreak in Austria, a large number of horses have been infected with Strangles, and an additionally large number of horses are at risk of being infected
- **43 healthy mixed breed horses were vaccinated with Strangvac®** in order to prevent transmission of *S. equi* to them
- Seven weeks after the first vaccination **none of the vaccinated horses has developed strangles**

# Promising pipeline targets significant unmet needs in several animal species



## Typical development stages for animal pharmaceuticals



Source: Company information.

# Animal vaccine pipeline *S. suis* causing sepsis

## INV274 FOR *STREPTOCOCCUS SUIIS* INFECTION

- *Streptococcus suis* infection in piglets is one of the most **common** bacterial causes of fatal infection in piglets leading to **big losses in production**
  - Global pig population estimated to approx. **1 billion pigs**
  - **150 million pigs in Europe, 10 million breeding sows**
- Currently **no effective vaccine** against *Streptococcus suis* infection is available
- **Patent approved in the US (Nov 2021)**
- **Positive clinical results (proof of concept) protecting piglets via vaccination of pregnant sows. Improves profitability and ease of vaccination use by the farmer**
- *Streptococcus suis* is a **zoonotic** bacteria that also **affects humans**



### Positive results in proof-of-concept study to develop a vaccine against *Streptococcus suis* infection in pigs

Stockholm, April 25, 2022 - Intervacc AB (publ) announces positive results from a proof-of-concept study where piglets from vaccinated sows were protected against experimental challenge with *Streptococcus suis*.

The study showed that piglets from sows that had been vaccinated with a prototype fusion protein vaccine had significantly fewer clinical signs of disease compared to piglets from sows that received a placebo, adjuvant-only, vaccine following challenge with a virulent strain of *Streptococcus suis* at 4 or 7 weeks of age.

- Closely related to *S. equi* (>80% DNA identity)
- **Intramuscular vaccination of pregnant sows**
  - **Safe**
  - **Immunogenic**
  - **Passive transfer of immune response to piglets**
    - **Protected piglets at 4 weeks of age ( $P < 0.0001$ )**
    - **Protected piglets at 7 weeks of age ( $P = 0.03$ )**

# S. suis vaccine Total Accessible Market

## KEY MARKET DYNAMICS



Tentative vaccination schedule is based on vaccinating breeding sows with a **primary course of two doses and revaccination/booster dose** before each farrowing



**Protecting piglets in the litter via vaccination of the sow** enables protection at the most vulnerable time in a piglet's life, and is practical, efficient and economical



In Europe breeding sows have on average 2.2 litters per year with an average of 14 piglets per litter



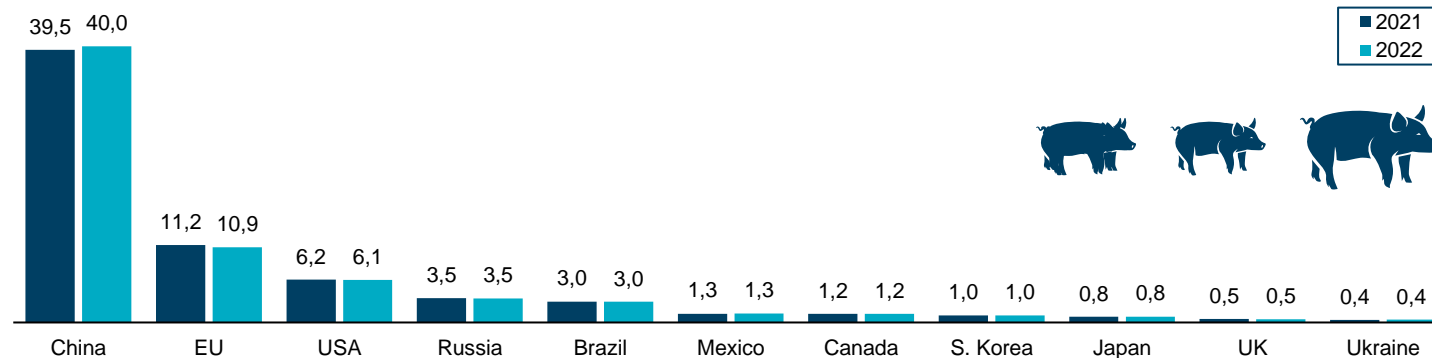
Intervacc estimates that a vaccine against *S. suis* infections that is based on sows being in a vaccination schedule with a booster before each farrowing has a **TAM value of approx. SEK 1.0 bn for Europe only**



Europe has approximately **15% of the breeding sows** in the world

## MARKET PROJECTIONS AND TRENDS

USDA projections of Sow inventory (millions)



### Key EU trends

- **2011:** The European Commission's One Health Action Plan Against Antimicrobial Resistance
- **May 2020:** Farm to Fork Strategy with an objective to reduce the total EU sales of antimicrobials for use in farmed animals and aquaculture by 50% by 2030
- **January 2022:** European Parliament approved new legislation to ban the prophylactic use of antibiotics in farmed animals

### We anticipate:

- **Near-term:** Increase in vaccinations as a disease prevention measure in healthy animals as antibiotics are phased out
- **Mid to long-term:** Further increase in vaccinations as disease rates are likely to rise among animal populations that are neither given antibiotics nor vaccines

Source: FAS, USDA, July 12, 2022, Figures in million head. Other countries approx. 6 million sows.

# Animal vaccine pipeline *S. aureus* causing mastitis

## INV412 FOR *STAPHYLOCOCCUS AUREUS* MASTITIS

- Mastitis, caused by *Staphylococcus aureus* infections, is a common problem that causes **significant production losses** in the dairy industry
  - Global dairy cow population estimated to approx. **250 million cows**
  - 2.6 million cases of disease in Europe each year
  - Estimated to cost European farms 600M€ each year
- Need for a **more effective vaccine** against *Staphylococcus aureus* infections in cows
- *Staphylococcus aureus* is also a **problem for humans** (MRSA)

- Intervacc's prototype vaccine was safe and immunogenic in pregnant cows
- VetBioNet funded proof-of-concept study to measure protection ongoing



### Intervacc progresses vaccine to prevent mastitis in dairy cows caused by *Staphylococcus aureus*

Stockholm, May 19, 2022 - Intervacc AB (publ) announces the initiation of a proof-of-concept study to measure the effectiveness of a vaccine to protect dairy cows against mastitis caused by *Staphylococcus aureus* following successful safety and immunogenicity studies testing this prototype vaccine in pregnant heifers. This next phase of the project will be receiving a grant of 80k Euro from the EU's VetBioNet initiative.

Mastitis is one of the most important diseases of dairy cattle worldwide. Over 2.6 million cases of disease, causing losses of approximately 600M€, occur in European farms each year. Approximately 25% of contagious mastitis cases are caused by *Staphylococcus aureus* and the control of mastitis is the most common reason for antibiotic use in dairy cows.

Therefore, the development of safe and effective vaccines against *Staphylococcus aureus* would improve the health of dairy cows, reduce the use of antibiotics and reduce the impact of this disease on milk production. Vaccines against *Staphylococcus aureus* may also have wider potential to prevent disease in other animal species.

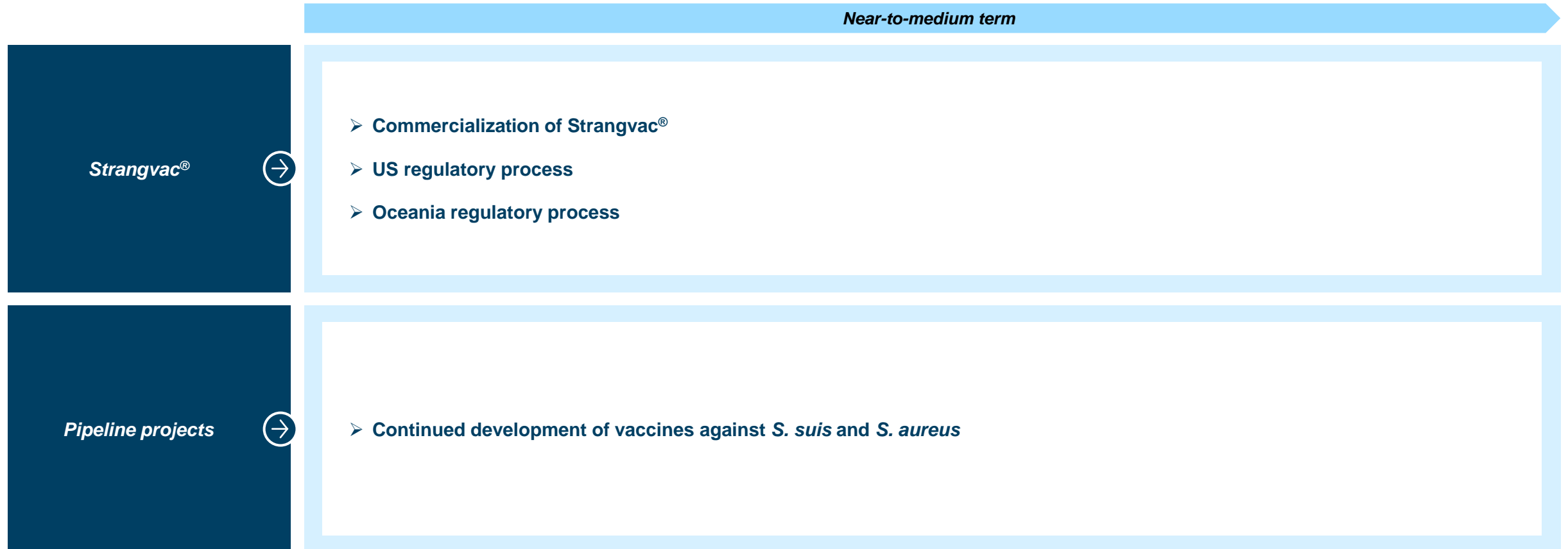
### Mastitis (udder inflammation) is the most common and loss-making disease among Sweden's dairy cows.

*S. aureus* is the most common udder pathogen in Sweden. According to national studies of bacterial agents in mastitis, *S. aureus* causes 28 percent of acute clinical mastitis (2013/2018 study) and 19 percent of subclinical mastitis (2009/2010 study). In chronic mastitis (regardless of the bacterial agent), culling cows should be considered, especially if it is difficult to group the cows according to udder health. Decisions about culling are based on the status and conditions of the herd, but culling should usually be done promptly in case of udder infection with penicillin-resistant strains of *S. aureus*.

Source: SVA



# Our strategic priorities



# Q&A

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