



Corporate Overview

May, 2017

About the Company

- ❖ NovaVive was founded as a private company by Graeme McRae (Founder and Chairman Emeritus of Bioniche Life Sciences Inc.) in July, 2014 to introduce immunobiology-based technologies that are scientifically sound and address unmet veterinary medical needs.
- ❖ In December, 2014, NovaVive acquired the Mycobacterium Cell Wall Fraction (MCWF) technology platform that was part of Bioniche Animal Health. This potent technology is being developed by NovaVive as both non-antibiotic therapeutics and cancer therapeutics for animals.
- ❖ NovaVive also acquired the global license to MCNA for treating animal cancers. MCNA is an advanced formulation of mycobacterium cell walls and nucleic acids formulated for human applications. MCNA was advanced through Phase III in the treatment of human bladder cancer by Bioniche Life Sciences.
- ❖ NovaVive is managed by a group of experienced executives (ex-Bioniche) who collectively have successfully developed veterinary technologies that have taken large global market share in the face of rigorous competition.

The NovaVive Product Line



The NovaVive technology has been proven to successfully treat several serious animal diseases, including cancer and bacterial/viral infections.

Amplimune™ - an approved formulation of MCWF for the treatment of *E. coli* K99 infections in calves (U.S., Canada) (*antibacterial*)

Equimune® - an approved formulation of MCWF for the treatment of viral infections in horses (U.S., Australia, New Zealand) (*antiviral*)

Settle® - an approved formulation of MCWF for the treatment of endometritis in horses (U.S., Australia) (*antibacterial*)

Immunocidin® - an approved formulation of MCWF for the treatment of mammary adenocarcinoma (aggressive mammary cancer) in dogs (U.S., Canada) (*anticancer*)

Immunocidin® Equine - an approved formulation of MCWF for the treatment of sarcoids in horses (U.S., Canada) (*anticancer*)



- ❖ These products are manufactured in a single-purpose, USDA/CFIA/APVMA/ACVM-approved facility in Athens, Georgia, U.S.A.

Antibiotic Use/Resistance

- ❖ Antibiotic resistance is an ever-increasing problem in both humans and animals; in animals, this has primarily resulted from indiscriminate use and overuse of antibiotics as preventative therapy.
- ❖ In the U.S., an estimated 24.6 million pounds of antimicrobials are used for non-therapeutic purposes in chicken, cattle, and swine (compared with 3.0 million pounds used for human medicine. (Union of Concerned Scientists)
- ❖ In the EU, prophylactic antibiotic use is banned in food producing animals; in North America, the Food and Drug Administration is implementing a plan to phase out the use of certain antibiotics for enhanced food production.
- ❖ “We need to be selective about the drugs we use in animals and when we use them.” (William Flynn, DVM, MS, deputy director for science policy at FDA’s Center for Veterinary Medicine (CVM)
- ❖ There is a growing market for effective antibiotic alternatives; products that activate the body’s innate immune system to fight infection and disease are one such alternative.

MCWF Antibacterial/Antiviral Mode of Action

Overcoming Infections

MCWF stimulates cells of both the innate and adaptive immune systems:

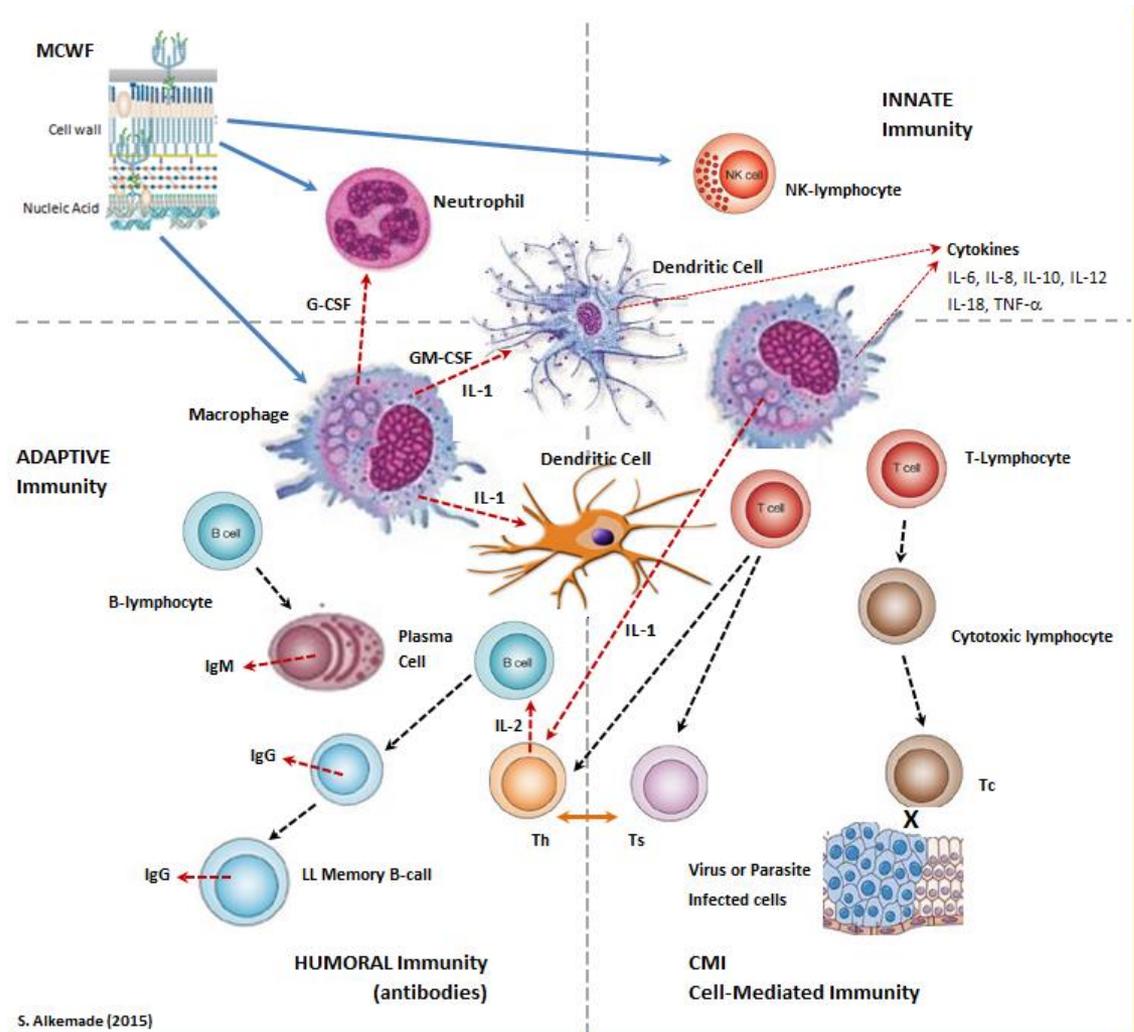
- Neutrophils (PMNs)
- Nonspecific Killer cells (NKs)
- Macrophages (& Monocytes)
- Dendritic (antigen presenting cells)

Macrophages and monocytes are stimulated to produce interleukin-1 (IL-1) which then starts an immune cascade involving many cytokines and the activation of numerous cells.

Adaptive Immune function is determined by the type of antigen presented and its relationship to body cells.

Extracellular bacteria and parasites elicit a humoral (antibody) response.

Intracellular infections (viral) and abnormal (cancer) cells induce a cell-mediated immune (CMI) response



Bovine Enteric Disease



GLOBAL CONCERN: Increasing resistance to antibiotics (lack of efficacy) due to antibiotic overuse/misuse in both humans and animals.

RESPONSIBILITY: Veterinarians are responsible for the health of the animals under their care. They are also aware and responsible for the implications associated with antibiotic overuse/misuse.

A SOLUTION: Amplimmune™ - the first immunotherapeutic registered for bovine infectious disease therapy in the U.S. (*antibacterial*)

Amplimmune™ is used in neonatal calves as a one-time treatment for the reduction of clinical signs, morbidity and mortality associated with enterotoxigenic *Escherichia coli* var. K99 diarrhea (ETEC) ('scours').

NovaVive is exploring other indications in bovines where antibiotic use may be questioned and an alternative effective therapy may be required.

Amplimune™

- ❖ Registered for the treatment of calf scours (diarrhea) caused by *Escherichia coli* K99.
- ❖ A newborn calf's immune system is immature and can be overwhelmed by disease challenges in the environment; the passive immunity transferred from colostrum in their mothers' milk is not enough. Many calves do not receive sufficient colostrum.
- ❖ Colibacillosis caused by *Escherichia coli* is one of the principal causes of neonatal calf diarrhea, occurring most often in the first week of life.
- ❖ Studies have shown that a single dose of Amplimune™ can induce an immediate innate immune response in the neonatal calf resulting in a highly effective antibacterial response.
- ❖ In addition to successfully treating a serious bacterial infection, calves given a single, IV dose of Amplimune™ have been shown to have better overall performance, increased average weight gain (+15%) (75-day feeding period) and decreased treatment costs (-18%).



Approved by regulators in U.S. and Canada

Bovine Market Opportunity

- ❖ There are approximately 10 million dairy cattle in North America (producing 9 million calves/year).
- ❖ There are approximately 90 million beef cattle in North America (producing 30 million calves/year).
- ❖ Calves today are valued at ~\$300 each.
- ❖ With one dose of Amplimune™, this represents a potential US\$150 million market in North America. Our competition is antibiotics (as feed supplements or therapeutic treatments).
- ❖ In the largest Canadian veal operation (based in Quebec), a study was conducted in 699 calves separated into two groups (MCWF-treated and control), with the following results:
 - ✓ The mortality rate was 2.33 times lower in the MCWF-treated group vs. control group.
 - ✓ The total number of treatment days was 2.9 times higher in the control group than in the MCWF-treated group.
 - ✓ Clinical conditions requiring treatment were 3 times higher in the control group compared to the MCWF-treated group (123 vs. 41).
 - ✓ The volume of supportive therapy administered in the control group was 3.6 times higher than in the MCWF-treated group (1,090mL vs. 298.5mL).



Additional Bovine Opportunities

1. Reproduction

- Antibacterial
- Evidence of safety and efficacy in horses (Settle®)
- Early data showing promise



2. Mastitis

- CSIRO in Australia now conducting studies
- Major misuse of antibiotics



3. Respiratory Disease

- Antiviral
- Evidence of safety and efficacy in horses (Equimune®)



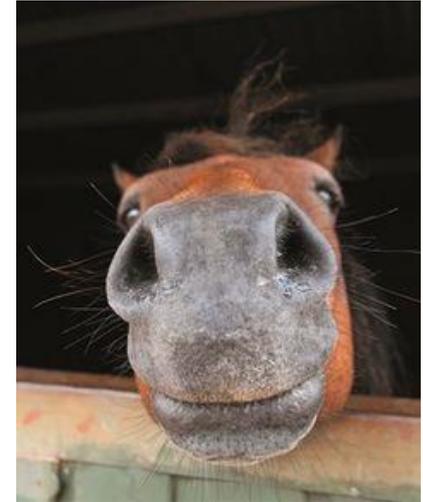
4. Other Infections

- Anti-protozoal?
 - Cryptosporidiosis
 - Coccidiosis
 - *At first symptoms of disease, seem to have effect with single dose (anecdotal)*



Equine Respiratory Disease

GLOBAL CONCERN: Antibiotics are frequently administered to the horse suffering from Equine Respiratory Disease Complex, which is usually caused by a virus or combination of viruses.



RESPONSIBILITY: Veterinarians are expected, by horse owners, to treat the disease with antibiotics, despite knowing that antibiotics have no efficacy against viral infections. The veterinarian needs to decide on a treatment modality that will treat the infection without the ramifications of inappropriate antibiotic therapy.

A SOLUTION Equimune® is approved for the treatment of Equine Respiratory Disease Complex. (*antiviral*)

NovaVive is exploring other indications in the horse where antibiotic use may be questioned and an alternative effective therapy may be required.

Equimune®



- ❖ Registered in the U.S. and Australia/New Zealand for the treatment of Equine Respiratory Disease Complex (ERDC).
- ❖ ERDC is commonly caused by the equine strains of herpesvirus or influenza A virus; it can cause severe inflammation and damage to the upper and lower respiratory tracts.
- ❖ Controlling the viral infection early can help minimize downstream bacterial complications and secondary lung damage.
- ❖ Serious respiratory infections can ruin years of training invested in the equine athlete.
- ❖ Equimune® is administered as a single dose by I.V. injection (treatment may be repeated every 1-3 weeks).
- ❖ Equimune® is safe for use in all horses, including pregnant mares.

*Approved by regulators in U.S.,
Australia, New Zealand*

Market Opportunity

- ❖ There are ~9.2 million horses in the U.S.
- ❖ Equine respiratory disease affects approximately 10% of horses per year.
- ❖ The most common treatments are antibiotics, expectorants, cough suppressants and corticosteroids.
- ❖ This disease is not only detrimental to the horse, but also costly for horse owners (treatment cost, lost training days).
- ❖ The Company believes that there is an opportunity for Equimune® in addressing shipping fever among horses that are transported (performance horses, breeding horses and yearlings); a study will be required to confirm. Shipping fever occurs in ~10% of transported horses.
- ❖ The Company also believes that a low dose of Equimune® given to newborn foals on Days 1 and 8 could prevent many common health issues; a study will be required to confirm.



Equine Uterine Infections

GLOBAL CONCERN: Equine endometritis is usually caused by an infection due to the presence of a complex of bacteria. *Streptococcus zooepidemicus* is the most devastating and hardest to treat.



RESPONSIBILITY: In many cases, these bacteria have been shown to have developed resistance to many antibiotics. To treat the infection, the veterinarian may have to resort to a cocktail of antibiotics in order to overcome the resistant bacterial species.

"The increasing frequency with which antibiotic-resistant bacteria are being recovered from the equine uterus is concerning, and treatments that can reduce our dependence on traditional antibiotics alone are worthy of consideration." (Lyle *et al.*)

A SOLUTION: Settle® is approved for the intrauterine or I.V. treatment of endometritis in the mare. Its label claim is as an aid in the treatment of endometritis caused by *Streptococcus zooepidemicus*.

Settle®



- ❖ Registered in the U.S. and Australia for the treatment of equine endometritis caused by *Strep. Zooepidemicus*. (*antibacterial*)
- ❖ Endometritis, the acute or chronic inflammation of the endometrium (lining of the uterus), is a major cause of mare infertility and is often undiagnosed.
- ❖ Settle® is administered by intrauterine flush or intravenous injection.
- ❖ Settle® normalizes sub-optimal responses to infection and endometritis in problem mares.
- ❖ The product has been proven safe and effective in the treatment of post-partum endometritis, post-breeding endometritis and other infection-based endometritis.

Approved by regulators in U.S., Australia

Market Opportunity

- ❖ There are ~9.2 million horses in the U.S.
- ❖ Approximately 16% of these horses are broodmares.
- ❖ At least 10% of broodmares are susceptible to endometritis (“problem mares”).
- ❖ The most common treatments are antibiotics, corticosteroids, antifungals, mucolytics and oxytocin.
- ❖ The Company believes that routine use of Settle in every broodmare as a prophylactic therapy could result in stronger, more viable foals (see data in swine); a study will be required to confirm. If confirmed, this could generate a 10-fold increase in market potential.

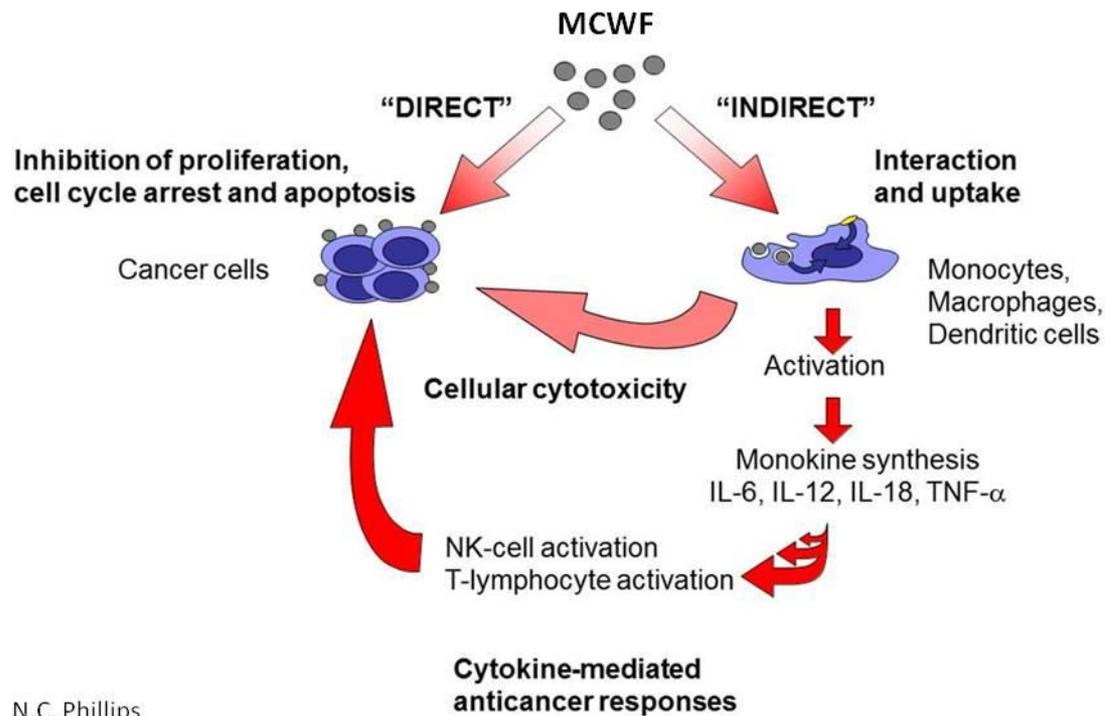


Animal Cancers

- ❖ There are more than 70 types of animal cancers.
- ❖ Cancer is the leading disease-related cause of death in dogs and cats, particularly now that more pets are living long enough (due to better health care and nutrition) to develop the disease. One in 4 dogs and cats is expected to die of cancer.
- ❖ At the same time, pet owners are seeking to treat their animals for cancer (pets are part of the family). However, there are few approved animal cancer products available to veterinarians, so they often must turn to human therapies (chemotherapies).
- ❖ Horses are also susceptible to cancer, and the number of horses with cancer is growing.
- ❖ Surgery, chemotherapy and radiation therapy are common treatments for animal cancers. There is a role for immunotherapy, and NovaVive has a registered immunotherapeutic product for the treatment of cancer in dogs and horses.

MCWF Anticancer Mode of Action

- ❖ The mycobacterial cell wall fraction (MCWF) technology uses *Mycobacterium phlei*, a non-pathogenic organism, as the source organism. MCWF modulates the body's natural immune system to fight disease.





Immunocidin[®] Equine



- ❖ Registered for the treatment of sarcoids in horses.
- ❖ It is administered by intratumoral injection, but the response is generalized.
- ❖ Equine sarcoids are one of the most common equine skin tumors, often found around the eyes, head/face, neck, chest, shoulder, and at the site of old scars.
- ❖ Current treatment options include surgery, ligation, cryotherapy, topical treatment, chemotherapy, radiation therapy, or laser removal; many of these treatments incur side effects. Immunotherapy is a new, safe and effective option.
- ❖ Immunocidin[®] has a high post-treatment, tumor-free rate, is well-tolerated, has minimal side effects and has an excellent safety profile.

Approved by regulators in U.S., Canada



Market Opportunity



- ❖ The label for this product currently includes both equine and canine claims; the Company is separating the label to have an equine-only product (5 mL).
- ❖ The Company believes that MCWF will be effective against other tumor types (e.g., squamous cell carcinoma); a clinical study will be required to confirm.
- ❖ Squamous cell carcinoma most often affects the skin, eyes, and genital system of the horse. The carcinoma begins as a wart-like growth or a flat lesion with a yellow, infected-looking base. As it grows, it becomes nodular and fleshy and bleeds easily.
- ❖ Treatment usually involves local excision. Radiation therapy may be used to reduce the size of the tumor prior to excision. Cryotherapy, radiofrequency hyperthermia or intra-lesional chemotherapy or CO₂ laser ablation are also used.

Canine Cancer Overview



GLOBAL CONCERN: Dogs are considered part of the family. When they are diagnosed with cancer, the owner faces a limited number of options. Although not approved for use in animals, human chemotherapies are often used. They cause the same debilitating side effects in dogs as in humans.

RESPONSIBILITY: With the lack of approved cancer treatments for dogs, veterinarians will use human chemotherapy and/or radiation. These treatments are cost prohibitive to many dog owners and are typically not available in front-line clinics. For those dogs receiving chemotherapy treatment, they may suffer debilitating side effects, including neutropenia (low white blood cell count). The alternative is trying to keep the dog comfortable pending euthanasia.

A SOLUTION: Immunocidin® is approved for the treatment of mixed mammary tumor and mammary adenocarcinoma (breast cancer) in dogs.
(anticancer)

NovaVive is exploring the use of Immunocidin® in other cancer indications in companion animals.

Canine Cancer Overview (cont'd.)



- ❖ Cancer is the most common cause of death in dogs over the age of 2 years, and 1 in 4 dogs will die of cancer. In the U.S., there are approximately 70 million dogs and the incidence of cancer is approximately one in ten per year.
- ❖ The Company conservatively estimates that ~1,000,000 U.S. dogs are diagnosed with cancer each year. Of these:
 - ~300,000 dogs are euthanized after diagnosis
 - ~700,000 dogs are treated at an oncology specialty clinic, where they receive long-term palliative care, surgery, or chemotherapy (alone or in combination with other therapies)
- ❖ For those dogs receiving chemotherapy treatment, they may suffer debilitating side effects, including neutropenia (low white blood cell count).
- ❖ Chemotherapy treatment can cost a dog owner thousands of dollars per course of treatment.

NOTE: Unlike human medicine, there is no universal, central reporting mechanism for collecting data on cancer cases in veterinary medicine. Also, not all suspected cancer cases are diagnostically confirmed (many animals are euthanized prior to definitive diagnosis of tumor type).



Immunocidin[®] (Canine)



- ❖ Registered in the U.S. and Canada for the treatment of mixed mammary tumor and mammary adenocarcinoma (breast cancer) in dogs.
- ❖ Administered by intratumoral injection.
- ❖ Provides increased tumor-free survival; a strong palliative response is often reported.
- ❖ Well-tolerated by dogs, including older animals and those with health complications (including chronic cardiovascular and renal disease).
- ❖ A treatment option for dogs that are poor surgical risks.
- ❖ May be used safely in-clinic with no risk to clinic personnel.
- ❖ Mammary tumors are relatively uncommon in North American dogs due to the routine spaying of female dogs.

Market Opportunity



- ❖ Canine cancer represents a large unmet need that is growing exponentially with treatments highly valued.
- ❖ Studies have demonstrated clinical response in other canine cancers, including mast cell tumors, hemangiosarcoma, osteosarcoma and transitional cell carcinoma (bladder cancer).
- ❖ Clinical response has also been seen in the restoration of white blood cell count following chemotherapy treatment, thus reversing neutropenia.
- ❖ The product has been proven safe to administer by IV injection and intravesically.

Technology Development

Beyond revenue growth through marketing and promotion of existing registered products, NovaVive will capture new market opportunities as follows:

1. Bovine Infectious Disease

- Next generation MCWF therapies are being developed to address additional viral and bacterial diseases in cattle, particularly where antibiotics are currently overused/misused

2. Equine Infectious Disease

- In addition to treating viral and bacterial infections in horses, NovaVive will explore the use of MCWF technologies for treating difficult parasitic and protozoan infections
- A second generation therapy is being developed

Technology Development (cont'd)

3. Canine Cancer/Neutropenia/Palliation

- The use of Immunocidin® to treat mammary adenocarcinoma in dogs can be rapidly expanded into treatments for other solid tumors; this requires small, clearly defined clinical studies conducted at university cancer centres of excellence

- NovaVive will investigate MCWF formulations in:
 1. The treatment of dogs with hemangiosarcoma, an aggressive, malignant tumor of blood vessel cells that usually appears in the skin, soft tissue, spleen (most common site) or liver;
 2. The treatment of dogs with chemotherapy-induced neutropenia (low white blood cell count);
 3. A palliative therapy in dogs with cancer who are at the end stage of their lives, or whose owners choose not to have treated for the cancer.

Summary

- ❖ NovaVive is a dynamic specialty animal health company with a revenue-generating base business and significant potential for growth via aggressive marketing, registrations in new jurisdictions and development of new formulations.
- ❖ With investment in further product development and marketing, and expansion into global markets, NovaVive believes it can grow revenues exponentially.
- ❖ The NovaVive management team has the experience to develop, manufacture, register and market its proprietary technologies; the Company plans to market products to veterinarians directly in the U.S., Canada, Australia and New Zealand and will utilize distribution partners in smaller markets.
- ❖ The Company has a solid marketing strategy that it expects will be well-received by veterinarians, livestock producers and horse and dog owners.

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Thank-you!