Mazen Animal Health comes out on top at KC Investment Forum

By Sian Lazell

This year, the Kansas City Animal Health Corridor (KCAHC) Investment Forum had the highest number of applicants since its inception in 2008.

Animal health and nutrition companies from throughout the world – seeking $500,000 to $20 million in funding and have revenue projections of $20 million within five to seven years – were eligible to take part.

The forum saw 48 companies apply in 2016, with 17 ultimately selected to present their innovations and new technologies to a panel of industry experts in a bid to secure funding and win the Innovation Award.

Winner: Mazen Animal Health

The Innovation Award for 2016 was granted to Mazen Animal Health – with a funding prize of $10,000. The firm is developing an antigen expression platform for the oral delivery of vaccines, developed using maize grain.

Mazen has exclusive rights to the technology from the Applied Biotechnology Institute (ABI) in California. The company explained the corn matrix provides bio-encapsulation of antigens enabling longer availability in the digestive system to reach target cells for an immune response.

Chief executive, Jennifer Filbey, claimed proof-of-concept research has demonstrated both an immunoglobulin G and immunoglobulin A (types of antibodies) immune response following oral delivery and protection against a challenge, that is comparable to injectable vaccines in several animal species with different pathogens.

Dr Filbey said: “We are seeking strategic alliances with animal health companies to develop antigens of their interest. Mazen is focused on developing swine vaccines and wishes to partner with animal health companies to develop oral vaccines in other areas such as aquaculture, poultry and companion animals.”

The firm plans to develop, produce and commercialize oral vaccines and said it is leveraging the commercial manufacturing already developed at ABI. Projected revenue from its product development is calculated to equal approximately $8.25 million between H2 2020 and H1 2021.

Mazen is based in St Joseph, Missouri and was founded in 2015. Its funding to date includes $600,000 in work in kind and $60,000 in expenses.

Other presenting companies:

Aptimmune

Established in 2010 and located in Illinois, Aptimmune is developing and working to commercialize a portfolio of mucosal vaccines that it claims provide superior efficacy against porcine reproductive and respiratory syndrome virus (PRRSV) – the most costly disease to the swine industry – and influenza.

The company holds exclusive worldwide license to patents for three core technologies used to develop and manufacture its mucosal vaccines: nanoparticle, adjuvant, antigen composition; its ZMAC cell line – PRRSV manufacturing; and PRRSV strain. Aptimmune also holds license options to nanoparticle technology currently being evaluated that is said may enhance enable a quicker progression to market for its products.

Aptimmune’s initial product launch is expected in the fourth quarter of 2016. It will first focus on US sales and marketing, targeting the top 50 swine producers and consulting veterinarians, which it said account for around 80% of the market opportunity.

Aptimmune’s predicted product revenue by 2020 is approximately $49.66m. Its current investors are Arsenal Capital Management, Common Place Holdings, Illinois Ventures, The Yeld Lab, Fox Ventures, and Midwest Angel Investors. It has secured $2.1m in funding to date.

Arthramid Labs

Arthramid Labs is seeking a partnership in R&D, regulatory, marketing and global distribution efforts for a medical device for osteoarthritis. Its visco-elastic endoprosthesis is described by the firm as described as “an articular capsule bio-scaffold” designed for synovial membrane tissue.
The device is an injectable intra-articular soft implant made of patented viscoelastic inert hydrogel, contained in a sterile one milliliter syringe. According to Arthramid, the implant has proven long-lasting mechanical effects for osteoarthritic horses and dogs.

The firm said: “More ongoing data and publications will be generated regarding its mode of action as a regenerative mechanical solution, on equine and canine synovial membrane tissue for instance. Other uses are also very interesting, with global veterinary market needs.”

The 2.5% polyacrylamide hydrogel is the original and optimized formula with a three times patented formulation. The company claims to have strong intellectual property protection for the technology, including EU and US patents as a hydrogel for endoprosthesis. It expects additional new patents for new generation formulas as the product evolves.

Arthramid predicts revenues of around $20.51m by 2020. Founded in 2014, the firm is currently funded by Irish angel investors and has received a total of $500,000 in funding to date. Arthramid is headquartered in Dublin, Ireland.

Curtiss Healthcare
Curtiss is working on a recombinant attenuated salmonella vaccine vector platform for the development of vaccines against any bacterial, viral or parasite pathogen that only requires the identity of the protective antigens in animals and humans.

The firm said modifications used in traditional ways of developing live, infectious bacterial and viral vaccines “very much reduce immunogenicity and thus often have poor efficacy in inducing protective immunity without multiple vaccinations with high doses of the vaccine agent”. Curtiss claims its technology addresses these problems.

The company holds exclusive licenses to the core technologies invented or co-invented by one of its founders, Dr Roy Curtiss III. Its intellectual property portfolio contains over 130 patents providing global protection in over 30 different countries, with additional patents pending.

Curtiss has projected fifth-year revenues of $95.28m. The firm is seeking partnerships with animal health companies to support its R&D, sales, distribution and marketing activities.

It is currently funded by Sanofi-Sunrise and the firm has raised a total of $1.4m to date. The company is based in Florida.

EpiBiome
EpiBiome was established in 2013 and is looking to partner with animal health companies to develop US FDA-approved antibiotic alternative for livestock that have short or zero day withholding times. The company uses non-genetically modified, bacteria-specific, natural viruses that are harmless to humans.

The company’s lead candidates are ECO-01 and ADJ-02, which target E. coli and S. aureus bovine mastitis, respectively. Nick Conley, chief executive and co-founder, told forum delegates EpiBiome anticipates FDA approval to market its new animal drug in 2020 and intends to partner with veterinary pharma for distribution.

EpiBiome’s current investors are: Viking Global Investors; Matrix Capital Management; Alexandria Venture Investments; SV Tech Ventures; China Rock Capital Management; and China Ding Cheng Holding Group. Its funding so far stands at $6.1m in venture financing and $1m in debt financing. The company is located in San Francisco, California.

Healthy Cow Corporation
Healthy Cow Corporation (HCC) is a biotechnology company focused on developing natural prophylactic therapies for the dairy industry.

The firm’s first products are ProMunity and ProPreg. ProMunity is an immuno-modulator indicated to reduce bacterial infections, systemic inflammation, sick days and the need for antibiotics. It claims to reduce milk somatic cell counts, circulatory inflammatory cytokines, incidences of laminitis and retained placenta complications.

ProPreg is a reproductive probiotic indicated to provide a healthy reproductive micro-biome, decrease uterine infections and reduce calving losses. It claims to reduce milk somatic cell counts, circulating acute-phase proteins, abortion, metritis cases, calving to conception turnaround days and improve fertility rate.

HCC is looking for joint development, sale and distribution partnerships and predicts year four sales of approximately $4.27m.

The company has received $300,000 in funding since it was founded in 2012 and it is currently financially supported by its founders and dairy producer investors. It is based in Ontario, Canada.
Based in Massachusetts, HOSSO is a biotechnology firm seeking distribution, equine rehabilitation center, veterinarian and commercial partners for its FastTrack and TendonBuddy orthotic legwear to reduce the incidence of lameness and rehabilitation time.

The products are designed to redirect weight-bearing forces to enable a horse to perform moderate exercise meaning the animal can recover more quickly. FastTrack is a rehabilitative/preventative product which HOSSO plans to commercialize in H1 2017 and TendonBuddy is a preventative product the firm plans to commercialize in H2 2018.

HOSSO will develop and maintain four independent sales channels through veterinarians, rehabilitation centers, distributors, and direct sales to consumers. At the forum, chief executive of the firm and president Mouli Ramani said: “While initial sales will exclusively be made through equine rehabilitation centers and veterinarians, the emphasis over time will be to drive additional sales into higher net margin channels. Specifically, HOSSO will enter the market using a direct sales force in the United States and Canada and via a distributor network internationally.”

Hosso’s projected revenues for FastTrack by 2020 are around $30m. Revenues for TendonBuddy by 2020 are predicted to reach over $90m.

HOSSO’s funding since it was established in 2011 stands at $3.5m. It has secured seed funding by a number of angel investors including industry chief executives, veterinarians for the US Olympic equestrian team and owners of elite competitive horses.

Membrane Protective Technologies
Membrane Protective Technologies (MPTI) was founded in 2012 and is focused on animal reproduction.

MPTI is gearing up to launch its first technology to improve the quality of frozen/thawed sperm and is seeking strategic partnerships for R&D, sales, distribution and marketing.

The business’ GameteGuard is a semen extender designed to prevent oxidative damage to sperm during handling, freezing and thawing, to improve artificial insemination pregnancy rates in dairy and beef cows.

MPTI explained GameteGuard can also be applied to most other agricultural species such as swine, turkeys, chickens and horses, as well as embryo production. It added that future products for other species are already being developed.

The firm told forum attendees: “The primary sales channel for MPTI’s first product, GameteGuard for bull sperm, will be direct to the bull studs. The bull studs will sell, via existing channels, to our secondary customer (their primary customer), the dairy farms and cattle ranches.”

MPTI has received $750,000 in funding to date. It is currently backed by company principals and agricultural investors and is headquartered in Fort Collins, Colorado.

Mileutis
Mileutis is looking to establish distribution agreements with leading animal health companies in “specific geographical regions” for its leading intramammary products for the treatment and prevention of mastitis, MLT – 1/3 and MLT – 2.

MLT – 1/3 is indicated to precipitously dry off mammary gland secretion in treated glands which Mileutis claims results in a higher resistance to new intramammary infections. The firm also said MLT – 1/3 has been shown to increase milk production in the next lactation following treatment.

MLT – 2 is indicated as an antibiotic residual-free product for treating clinical and subclinical mastitis during the lactation. Mileutis claims the product enables the veterinarian to milk cows and avoid the discarded milk requirement of antibiotic treatments. It added that MLT – 2 can be used to treat severe clinical mastitis cases, lowering the frequency of culling or early dry off.

The company is based in Israel and has secured $10.15m of funding since it was founded in 2004. It is currently supported by 17 angel investors, L Kobic Animal Health, and Israel-US Binational Industrial Research and Development Foundation.

NellOne Therapeutics
NellOne is developing regenerative therapeutics based on mammalian signalling protein NELL1 to treat severe soft tissue injuries that are hard to treat with currently available products.

Its first products will target equine wound healing. NT-101E is a new animal drug product already used in an FDA-approved biodegradable wound dressing. The firm said additional products in its pipeline are being developed to heal complications to wound healing and regenerate equine soft tissue. These include NT-102E, and injectable form of NELL1 which the company is filing patents for.
Co-founder and chief executive of NellOne, Tracy Warren, said the firm is looking to develop partnerships with animal health companies for co-development, marketing and/or distribution of its products to leading veterinary clinics and private hospitals.

Established in 2007, NellOne has so far received $2.9m in financial backing from its own management and individuals with close links to the firm. The company is located in Tennessee.

**Newton RFID**
Focused on animal identification and digital records management, Newton is looking to strike up strategic partnerships with existing animal ID, animal software and animal health records companies for its initial product EquipassID.

EquipassID is a radio frequency identification (RFID) injectable microchip for horses. The microchip can store a number of digital files for each animal, such as the horse’s life information, owner details, breed association details, insurance information and medical data. All information stored on the microchip can be accessed via a mobile records management application.

Tennessee-based Newton predicts year four sales of the software as a service of around $5.65m and 34,867 subscribers. The firm said its initial product launch will be in the equine market with subsequent products using the technology for ruminant and other livestock sectors.

The company was founded in 2011 and has had $10,000 of investment to date from an individual investor.

**Nuovo Biologics**
Nuovo Biologics is developing a platform of protein drugs to treat viral disease and cancer. The firm has a One Health approach to its product development and said while many drugs for treating bacterial infections already exist, there are few antiviral drugs.

The active pharmaceutical ingredient (API) of its PVX and MMX drug platforms is a short chain protein that is “derived from natural sources and subsequently chemically modified”. Nuovo said it has also produced a synthetic version of the API peptide precursor.

Florida-headquartered Nuovo has been granted an investigational new animal drug number for PVX to treat all companion animals and a second INAD for MMX to treat stage II and III canine oral malignant melanoma and a minor use designation for the same disease indication.

The firm is looking to secure funding to complete FDA animal health claims in addition to establishing strategic partnerships with animal health companies for distribution and marketing.

Nuovo was set up in 2010 and is currently funded by private equity investors.

**Philadelphia Animal Health**
Philadelphia Animal Health (PAH) develops one-time injectable therapeutics for companion animals to treat common illnesses using gene transfer technology.

PAH uses a “biologic Trojan horse” to deliver therapeutic DNA to cells for continuous production. It said data in large animals has demonstrated gene expression in this way and the platform can be used for many indications.

PAH’s lead candidate MEOW 101 will target anemia associated with chronic kidney disease in cats. The firm claimed: “As an untapped market with no species-specific biologics available, we believe there are no compelling direct market comparisons to a possible therapeutic we may sell.”

It added: “The platform can be applied to any validated infusible biologic application. Potential market opportunities can expand rapidly once other indications are pursued from the pipeline. We have validated five of these indications in final species models.”

PAH is a clinical stage company established in 2014, built on technology developed at the University of Pennsylvania’s Gene Therapy Program, which is a current investor. The firm is also financially supported by its president and so far has gathered $700,000 in funding.

Chief executive Matt Wilson said PAH is seeking to build partnerships to enhance preclinical and clinical development in the areas of anemia, allergies, cancer, diabetes and pain management in companion animals. The firm expects to generate revenues from MEOW 101 by 2020.

**Plasma Bionics**
Established in 2012, Plasma Bionics is a medical device manufacturer looking for partnerships in the animal health industry to support R&D, sales and distribution efforts for its proprietary cold sterilization technology.

The company claims to have developed a device that can sterilize medical equipment in less time with higher efficiency, using no water or harmful chemicals. The technology uses air at atmospheric pressure and room
temperature to produce cold plasma which inactivates microorganisms and toxins on the surfaces of medical instruments. Plasma Bionics said the scalability of its device enables sterilization of a broad range of medical equipment.

The company predicts revenue of around $24.48m by 2020. To date, it has secured $167,000 in funding. Its current investors are Cowboy Technologies, the OSU Research Foundation and the OSU Technology Development Center. Plasma Bionic is located in Oklahoma.

**R-NAV**

Convetra is a subsidiary of R-NAV which has developed a proprietary platform based on a novel biomedical tin isotope for veterinary and human treatments for arthritis, cancer and laminitis.

Convetra’s first product is Synovetin OA, a treatment for canine osteoarthritis which the firm expects to launch to specialty veterinary clinics by Q1 2017. Synovetin OA is an intra-articular injection designed to provide treatment for synovitis and restore patient mobility for a duration of at least six months.

Convetra projects revenue for the treatment for use in elbow osteoarthritis will equal approximately $33.87m by 2020.

The firm’s parent company R-NAV was formed in 2014 to develop and commercialize radiolabelled diagnostic and therapeutic products for rheumatologic and arthritic conditions. Since its establishment, the Texan company has received $6m in funding. Its investors are Crown Venture Fund and Infinity Capital III.

**TeleVet**

TeleVet is an animal health technology company founded in 2015. The company’s software enables digital consultations with veterinarians via a pet owner’s mobile device.

Co-founder of TeleVet, Price Fallin, explained owners log in to a portal and submit a case with a description of their pet’s condition and can upload images or videos they want to share with their veterinarian, in addition to just submitting general questions. Vets receive notifications and can provide treatment plans or answers within the time requested by the owner.

TeleVet is looking to partner with firms that have a large client base for distribution and sales, veterinary clinic franchise licensees and additional investors. It is also seeking pet hardware integration, animal pharmaceutical delivery and pet insurance partnerships.

At present, the firm is supported by three investors and has accumulated $90,000 in funding to date. It predicts total sales of $7.32m by 2018. TeleVet is headquartered in Oklahoma.

**Laboratoire M2**

Canadian firm LabM2 is seeking partnerships for sales, distribution, and marketing for its Thymox technology and next-generation product development including drug approvals and continued intellectual property.

Thymox is a patented formulation with a botanically derived active ingredient developed for a range of antimicrobial cleaning and disinfectant applications. LabM2 believes its technology “provides focused, targeted efficacy, with no environmental or worker safety hazards.”

In animal health, Thymox is used as a footbath to treat digital dermatitis of the hoof which Lab M2 said is the most costly health problem in the dairy cow industry. Thymox Footbath generates revenue on North America and China. LabM2 said it is developing European markets with a global, strategic partner. Thymox was also recently approved as an animal drug in Canada.

LabM2 predicts revenues of Can$48m ($37.34m) by 2019 – revenues for Thymox Footbath specifically are projected at over Can$30m ($23.34m) by 2019.

LabM2 was founded in 2009 and has received $7m in funding to date. It is currently backed by its founder Serge Auray, Cycle Capital, Desjardins Venture, Capital Financière, Agricole and FIER Asbestos Capital.

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**Kansas City homecoming sees launch of new service award and 2016 Iron Paw**

*BY SIAN LAZELL*

This year, the Kansas City Animal Health Corridor has once again seen a record number of attendees turn out for its annual homecoming dinner. Animal Pharm analyst Sian Lazell joined the crowd to hear about the importance of the human-animal bond and how the industry is reaching new heights in the region.
On August 29, animal health experts, industry professionals, service providers and those in between gathered in the Kansas City Animal Health Corridor (KCAHC) for its 11th annual homecoming dinner.

Every year, the event has grown in enormity – this year was no different. Around 1,100 individuals congregated in the Kansas City Convention Center to be welcomed back ahead of the upcoming Animal Health Investment Forum.

Dr Albrecht Kissel, president and chief executive of Boehringer Ingelheim Vetmedica and chair of the KCAHC, opened proceedings by highlighting the importance of the bond between animals and humans, the new Spirit of Service award to be bestowed later in the evening, and the winner of the 2016 Iron Paw award.

**Record-breaking numbers**

Speaking at a press conference prior to homecoming, Dr Kissel said: “This year we will have the 11th KCAHC homecoming dinner and again, like practically across all the years post, we have record attendance.

“We will have attendees from countries like China, Japan, Taiwan, India, Australia, New Zealand, Ireland, Scotland, the UK, France, Germany, Belgium, Portugal, Spain, Israel, Brazil, Canada, Mexico, and from more than 30 US states. I think that really shows how international this event and how big this week is for Kansas City.

“The human-animal bond will be the main theme for the homecoming dinner. The human animal bond is so important, specifically for parts of the population who are physically, emotionally or spiritually in need. Whether it is someone who is visually impaired, a veteran with post-traumatic stress disorder, a child with autism, someone who is physically or mentally disabled, the elderly or empty nesters who need connections to their pets. Or as it will appear in the keynote speech on Monday night, for homeless people for whom pets are their best friends.

“The keynote speech will be held by Dr Michelle Lem and it will be around the human-animal bond. Dr Michelle Lem is a veterinarian from Ontario, Canada, and she is the founder of Community Veterinary Outreach. They have a very specific approach to helping homeless people with pets – they not only take care or provide medical care for the pets but they also provide medical care in the same space, at the same time, for the homeless.”

**Spirit of Service award**

To her shock and delight, it was Dr Lem (pictured left) who found herself the first recipient of the Spirit of Service award. Dr Kissel handed Dr Lem a cheque for over $12,000, the total of which was funded by 100% of the proceeds from a market insight seminar, the first of its kind to be held by the KCAHC and one which will be hosted every year going forward. The new award will support organizations that do not have regular funding for their activities.

In her speech, Dr Lem spoke about how animals are sentinels of society, how we can find humanity through animals, the One Health approach and the power of human animal bond.

She explained how through her organization, she had seen how crucial animals are to people and how for many, pets improve wellbeing and give them a reason to live.

**Investment forum growth**

Speaking about the upcoming investment forum, Dr Kissel explained 2016 had seen more applicants than any other year.

“The investment forum will again have record attendance compared to last year. This investment forum is one of the biggest forums in the world for early- to mid-stage companies in the animal health industry who will present their business plans to investors in a bid to secure funding.

“Approximately 46 financial institutions and 117 animal health companies will attend the forum this year. It is the largest gathering of venture capitalists and venture capital companies in Kansas City.

Dr Kissel said since the inception of the forum in 2008, a total of $170 million has been raised in funding to support up and coming companies. Since the beginning, over 300 companies have applied to the forum, from more than 13 countries internationally and “practically all US states”.

“This year, we had 48 companies apply – that was the biggest number ever – and the committee has selected 17 companies to actually present on the day. Those companies are coming from Ireland, Canada and Israel – that’s the international component. One company is coming from here in the Kansas City region. The other companies are coming from Illinois, Florida, California, Massachusetts, Colorado, Tennessee, Pennsylvania, Oklahoma and Texas.

“That demonstrates the animal health corridor here supports the innovation for the animal health industry and for small and start-up companies to really find money to fund their innovations. You could almost say it is the deal hub for the animal health industry globally.”
Driven by dedication and commitment
Kimberly Young, president of the KCAHC, also spoke at the press conference prior to the homecoming dinner.

She said within the region there are over 300 animal health companies – the largest concentration of animal health companies and service providers in the world. These include biotech innovation laboratories, research firms, manufacturing facilities, service providers, legal companies, advertising agencies and “everything in between”, all focused on the animal health industry.

“These companies are responsible for 56% of the $88.2bn animal health nutrition and diagnostic industry – 56% of the global revenues. They employ over 20,000 individuals,” she said.

“These companies produce products from vaccines, to flea and tick collars, to research used to detect diseases in food animal populations. The companies within the corridor are doing the work that affects our global food supply and our family pets.

“The KC area is globally unique in its ability to support not only established animal health businesses but the businesses that we are working to relocate to the region. Since inception of the corridor in 2006, 46 new companies have relocated to the corridor and many existing companies continue to expand and invest.

“With industry leaders and expertise from service providers and academic curricula, the corridor is much more than a physical location. The corridor is a place where the global industry comes together. The power of this collective effort is what brings us all together.”

Ms Young (pictured left) added: “We are honoured to be hosting over 1,500 animal health executives, service providers, entrepreneurs, universities and financial firms in the corridor this week for the three events that we’re hosting for global animal health week, as well as 5,600 individuals who will be in Kansas City for the continuing veterinary education conference CVC Kansas City.

“During global animal health week there are a number of events being hosted. We will have the market insight seminar, the homecoming dinner, and the Kansas City Animal Health Investment Forum, as well as the CVC convention over the next several days.”

Building on this sentiment as she took to the stage at homecoming, Ms Young noted the corridor’s achievements and continuous growth.

“The corridor works because of the dedication and commitment from everyone. We're working to address One Health issues and improve world health. Recent companies to relocate to the corridor include Tonisty, AGL Technology, Simcro and AgriLabs.”

Iron Paw award
One especially touching tribute handed out at the annual homecoming dinner is the Iron Paw award. This year, the honour was bestowed upon Dr William P Duncan.

Dr Kissel said: “The Iron Paw award is the industry's highest achievement. It's given to an individual from research, academia, industry or government, regardless of title or years of service. It's given to an individual that has provided a significant impact on or contribution to the global animal health industry. And this year, we have a wonderful, very deserving recipient – Dr Bill Duncan.”

Dr Duncan (pictured right) is a retired president of the Kansas City Area Life Sciences Institute (KCALSI) who now works on a consulting basis with private companies, academic institutions and research organizations, supporting projects focused on animal health and biotechnology R&D.

Dr Duncan became the first president of KCALSI in 2001 – he held the role until retirement in 2009. During his tenure at KCALSI, he oversaw the institute’s regional life sciences initiatives, including the communication of KCALSI’s aspirations to a range of community, scientific stakeholder institutions and potential funding organizations.

His leadership extended to administrative and technical support while also growing collaborations within the stakeholder research community. Initiatives included working with civic leadership organizations and stakeholder institutions to build the Animal Health Corridor and pursuing the National Bio and Agro-defense Facility at Kansas State University, which is set to replace the Plum Island facility in New York.

Before joining KCALSI, Dr Duncan worked in various technical and management roles at the MRIGlobal research institute for over 20 years. He was vice president of operations at the firm from 1999 until 2001.

At present, Dr Duncan serves on the board of directors of three animal and/or human health companies and on the advisory board of the Kansas City University of Medicine and Biosciences.

In the past, he was also a board member of KansasBio, MOBIO and other civic leadership organization boards and advisory committees.
Dr Kissel said Dr Duncan had played a pivotal role in the formation of the KCAHC and had worked closely with key leaders to identify opportunities with the US Department of Homeland Security regarding the new National Bio and Agro-defense Facility.

Dr Duncan ‘humbled’

Accepting the 2016 Iron Paw award, Dr Duncan said: "It is indeed a tremendous honour to receive the Iron Paw award as part of this animal health corridor and this homecoming event this evening.

"I am indeed very humbled, and even more humbled, when I reviewed that list of previous recipients. All of them are animal health industry leaders.

"It’s incredibly rewarding for me to witness the evolution of the animal health corridor, as evidenced by the number of attendees here tonight and the registration for the investment forum tomorrow.

"However, I must say, it has taken a host of devoted and talented people over the years to move the corridor from the very modest beginning in 2005, to the regional, national and international representation we enjoy today.

"I want to take this opportunity to collectively thank all of the attendees for your invaluable contributions, and I accept this Iron Paw award in full recognition of those contributions.

"I would like to briefly mention a couple of animal health industry related accomplishments, of which I am immensely proud to say KCALSI was instrumental in initiating. The first of course is the formation of the animal health corridor.

"Second, is the successful pursuit of the Homeland Security-sponsored National Bio and Agro-defense Facility. Of course, we were told that there is no way our region can compete and win such a national laboratory but guess what? We did.

"So today, we have a new $1.25bn facility being built in Manhattan, Kansas, and that laboratory will provide the state-of-the-art infrastructure for developing vaccines, performing diagnostics and developing counter measures against foreign, large animal and zoonotic diseases. That facility construction is well underway, next to the College of Veterinary Medicine at Kansas City University. The estimated economic impact of that national lab for the region overall, in the next 20 years, is estimated to be $3.6bn.

"I want to conclude by thanking my family for their support over the years. And of course I want to thank, last but not least, my wife Linda. My wife, partner and best friend, and most important person in my life. Frankly I don’t remember life without her and tonight, believe it or not, this is the actual 52nd wedding anniversary that we’re celebrating.

"Finally, I thank the leadership of all those that are involved in the animal health corridor for the Iron Paw award. The words I came up with simply don’t express how much I appreciate the honour. So, thank you very much."

HealthforAnimals highlights 10 ways regulations can be improved by 2025

BY JOSEPH HARVEY

Global industry body HealthforAnimals has detailed a 10-point plan to support an efficient regulatory system for veterinary medicines by 2025.

The strategy is designed to maximize innovation and increase the amount of veterinary medicines available by removing unnecessary administrative burdens, as well as initiating regulatory convergence between countries.

The organization aims to attract higher levels of R&D by creating regulatory systems that are driven by harmonized, science-based decisions with predictable timeframes.

The 10 points are:

1. Authorization decisions should be science-based solely on evaluation of benefit and risks, with no differentiation in requirements approach between local and other manufacturers, and reached by individuals with no conflicts of interest.

2. The implementation of predictable regulatory timeframes for consideration of applications, with no assessment taking longer than 24 months for a new product, and no longer than 12 months for significant changes to existing products, with all simple changes with no impact on safety and efficacy not requiring applications. Accelerated assessment pathways (less than six months) in place for vaccines and pharmaceuticals which are required to help tackle new emerging serious diseases.
3. Regulation that is efficient for industry and regulators, enabling industry to focus efforts in areas which genuinely support/maintain the quality, safety and efficacy of veterinary medicines whilst reassuring users/consumers. For example, the removal of unnecessary administrative burden imposed by individual regulatory authority requirements and/or created by different or even contradictory regulatory authority requirements.

4. More countries/regions co-operating on the core assessment of the same product, or mutually recognizing assessments from other countries/regions. Specifically implementing already existing schemes (in Africa – Southern African Development Community) and introducing new schemes.

5. A fair return on investment for innovation. All products having to demonstrate quality, safety and efficacy. Generic products having to demonstrate appropriate quality and bioequivalence in order to confirm safety and efficacy. Maintaining confidentiality of data as well as awarding appropriate protection of data (at least 10 years for new products) and hence fair returns on investment in the case of new veterinary medicines and for already registered products (five years) where significant new data are generated.

6. Regulatory frameworks and regulatory staff which can manage highly innovative products/new technologies. Regulatory frameworks need to be written so that they do not hinder future innovation and so that regulators can interpret them in a flexible way. Regulatory staff needs suitable training on new technologies, or access to impartial expertise for example from academia.

7. Ability for companies to undertake global developments, with a core set of data and studies meeting the needs of all countries/regions. VICH-conducted studies being accepted by all countries, with additional local clinical and/or safety studies only being required where there are differences in relevant factors such as breeds, husbandry, etc.

8. Ability to locate manufacturing anywhere in the world, operating to a single set of standards. More mutual recognition agreements on inspections are necessary to avoid manufacturing sites being inspected by multiple Agencies with different degrees of expertise. Quality standards applied to products intended for a specific country/region are appropriate and at the same level irrespective of the location of the manufacturing site.

9. Ability for companies to operate a single system of pharmacovigilance for the same product. With requirements and approach aligned with the HealthforAnimals description of a basic pharmacovigilance system and relevant VICH guidelines. Countries being responsible for evaluation and monitoring of events which occur in their country and not elsewhere.

10. Countries to have legal frameworks which include a cascade of what medicines may be used in animals, registered veterinary medicines being at the top of hierarchy. Appropriate Authority enforcement to deal with illegal (or illegally supplied) veterinary medicines.

**Strategy for vaccines**

Alongside its 10-point plan for the wider industry, HealthforAnimals outlined four extra regulatory changes for the veterinary vaccines segment:

1. For individual vaccine batches already performed, safety tests at the manufacturing site are not required to be repeated.

2. For inactivated vaccines with a proven record of manufacture, safety tests in the target species are not required for the purpose of batch release.

3. For vaccines produced using biotechnology, the regulatory framework applied is characterized by the fact that the product is a vaccine, and not specifically by the technology used in manufacture, with an appropriate balance in the assessment between benefits and risks.

4. Terminology used for example in labels, leaflets, public assessment reports is appropriate, being accurate whilst avoiding negative connotations.

**Supports Benchmarking work**

This plan follows HealthforAnimals’ 2015 Global Benchmarking Report, the results of which recently showed a widespread dissatisfaction with the industry’s regulatory system around the world.

The HealthforAnimals regulatory strategy looks to tackle several issues that were raised in the benchmarking report, namely: maturity of the regulatory framework; the different types of application procedures available; the many ways in which changes to products are managed; the approach to monitoring safety and efficacy of products after registration; the transparency of regulatory authorities; and resources available to the authorities.

The Benchmarking report also pinpointed existing mechanisms which would benefit the global veterinary medicines sector if they were rolled out beyond their current domestic boundaries.
Why is regulatory change needed?

Despite a new wave of innovative products in animal health – particularly for companion animals – HealthforAnimals said ongoing consolidation in the animal health sector has put “intense pressure” on R&D funding at animal health companies.

The organization said: “In the US, for a new livestock pharmaceutical product, the average development cost is $32 million, and a proportion of the available R&D budget in companies (15-31% depending on the region) has to be used to defend existing products.

“It is necessary to maximize the outputs of new products from the available R&D budgets, so that as well as ensuring efficient use of the money to support new products, less of the money should be side-tracked to keep existing products on the market.

“It is already the case that veterinarians in some countries do not have access to fundamental veterinary medicines such as effective anthelmintic, antibiotics, vaccines, anesthetics, etc. For example, even in Europe, fairly affluent countries such as Finland have very few authorized veterinary medicines.”

Earlier this year, IFAH-Europe suggested told Animal Pharm a growing veterinary generics market may signal a downward turn in innovative R&D.

AAD, Zoetis team up to bring rapid mastitis test to Europe

BY JOSEPH HARVEY

US firm Advanced Animal Diagnostics (AAD) will market its mastitis detection technology in Europe through a partnership with Zoetis.

Financial terms of the agreement between the two companies were not revealed.

While Morrisville, North Carolina-based AAD has been increasing its sales and management teams in the US, the deal with Zoetis is the first sign of the company’s expansion into global markets. Last year, AAD told Animal Pharm it had received a number of inquiries from abroad.

The agreement is another addition to Zoetis’ growing veterinary diagnostics portfolio in Europe. Last month, the industry leader further grew its diagnostic capabilities by purchasing Scandinavian Micro Biodevices for $80 million.

This acquisition was largely focused on companion animal diagnostics, while the AAD agreement helps Zoetis add to its portfolio of food animal tests.

Benefits of QScout

AAD claims its QScout MLD (milk leukocyte differential) test enables more precise use of antibiotics. The firm said the test will be especially pertinent to the European dairy industry, which is intent on reducing its use of antibiotics.

The test runs on the company’s proprietary portable lab-in-a-box diagnostic platform – the QScout Farm Lab – and according to AAD, detects infection before visual symptoms appear. The test is designed to allow vets and dairies to make earlier, more effective treatment decisions to prevent losses.

According to AAD, mastitis infections cost the dairy industry an estimated $2 billion annually in the US and over €1 billion ($1.12 billion) in Europe through reduced milk production, decreased milk quality and suppressed reproductive performance.

Traditionally, mastitis diagnostic tests have looked for the presence of live pathogens. However, AAD said this poses significant challenges for veterinarians and dairy producers due to milk sampling and handling requirements.

AAD’s alternative provides a more precise diagnosis “by decoding the immune system’s response to infection, identifying and differentiating white blood cells in milk”, the firm claims. QScout Farm Lab searches for elevated cell type ratios that indicate infection in order to calculate an accurate, quarter-level diagnosis.

AAD said: “QScout MLD can be used in Europe to guide selective dry cow therapy, which has become more prevalent due to antibiotic regulations. In US trials, QScout MLD guided selective dry cow therapy led to a 47% reduction in antibiotic use at the cow level and a 59% reduction at the quarter level.

“In addition to improving profits and fostering judicious use of antibiotics, early detection of mastitis with QScout MLD promotes animal welfare and ensures cow comfort.”
Joy Parr Drach, the president and chief executive of AAD, said: “AAD is excited to partner with Zoetis to bring our new technology to Europe at a time when pressures on antibiotic use are increasing and milk prices are struggling. We believe we can save dairies and the veterinarians who serve them money by improving milk production and quality while using antibiotics only on cows that truly need them.”

**Gunn and Stolp become founding members of new Alivira advisory board**

**BY JOSEPH HARVEY**

Indian firm Alivira Animal Health is continuing its rapid growth in the veterinary medicines industry by hiring two long-standing industry experts.

Dr George Gunn and Dr Ruurd Stolp have joined the company’s global advisory board as founding members. Alivira is currently accumulating scale in the animal health sector through acquisitions – the firm aims to become the biggest veterinary medicines business in India, whilst also building a significant international presence.

Dr Gunn was the president and chief executive of Novartis Animal Health until its merger with Elanco. Following retirement from his role at Novartis, he has taken directorships at Phibro Animal Health, Nexvet Biopharma, Pharmaq, Animalcare and Diversigen.

His industry career has spanned 30 years with roles at the Wellcome Foundation, Janssen Pharmaceuticals and Pharmacia. Dr Gunn worked as a veterinarian in Scotland before joining the UK Ministry of Agriculture as a veterinary officer, advising on notifiable disease issues.

Dr Stolp has been on Elanco’s strategic advisory board for five years. Before joining Elanco, he spent 21 years at Intervet – for six of those years he held the role of president. He was recently acting chief executive for German veterinary vaccines firm Vaxxinova.

**Growing presence for Alivira**

The firm’s parent company Sequent Scientific recently released first quarter 2017 results for the three months ended June 30. While it did not reveal Alivira’s precise revenues, it said: “The animal health business is shaping up well and now accounts for over 60% of the revenues of Sequent with products being sold in over 55 countries.”

The company revealed Alivira has begun an aggressive R&D program with over 25 finished products in various forms including orals, solids, liquids, injectables and pre-mixes.

Sequent said: “40% of these products are potential day one launch on expiry of respective patents; 40% of these products are integrated with in-house active pharmaceutical ingredient development.”

Alivira has had a rapid rise to prominence. Since embarking on its spending spree in 2015, Alivira has amassed annual revenues of approximately $120m. This means it has become a top 30 firm in less than a year.

It aims to be in the industry’s top 10 by 2020 through the acquisition of animal health firms in the US, Brazil and Australia. So far deals have been secured in Europe, Brazil, India and Turkey.

**China Animal Healthcare signals increasing focus on biologicals**

**BY JOSEPH HARVEY**

China Animal Healthcare is making a concerted effort to push its biological vaccines business in the face of a “dramatic increase” in domestic demand.

In a statement responding to investor concern, the firm said it has been largely focusing on growing its biological vaccines business over the last two years.

The Beijing-based company is aiming to expand the sales channels for its existing vaccine products, as well as develop new biologicals through in-house R&D and via research partnerships.

China’s major animal disease prevention vaccines bidding process for spring has recently ended. China Animal Healthcare said it won the tender in 25 provinces for its lead vaccines against foot-and-mouth disease and porcine reproductive and respiratory syndrome. The firm said it has made considerable sales breakthroughs in some of these provinces.
China Animal Healthcare stated: “Along with China’s economic development, consumers increasingly emphasize the safety of food products such as meat, eggs and milk etc. and dispute on the heavy use of antibiotics in the process of livestock and poultry feeding.

“Relevant mainland Chinese government departments also continue to strengthen their efforts in monitoring the overuse of antibiotics. As such, livestock and poultry enterprises are also changing their ideology from using antibiotics to cure upon certain disease outbreaks, into placing increasing emphasis on biosecurity and disease prevention.”

The company said these factors have led to a significant upturn in demand for biological vaccines in recent years.

It also noted: “Due to the relatively high threshold for enterprises to enter the biological vaccines business in respect of the requirements on production, techniques and capital, the mainland Chinese government is extremely strict in the approval and issuance of production licenses.”

There is a limited number of companies with government-approved manufacturing facilities for veterinary vaccines in China. One firm that is now competing with China Animal Healthcare is Argentine business Biogénesis Bagó, which recently began production at its foot-and-mouth disease vaccine site in China.

Established in 1996, China Animal Healthcare manufactures and distributes a range of veterinary medicines including pharmaceuticals in powder, oral and injectable formulations together with vaccines.

In 2013, Elanco bought a minority stake in the Chinese firm. Last year, China Animal Healthcare claimed to have lost five years of financial statements, further compounding ongoing administrative woes. An investigation into the firm’s accounts is still ongoing.

Dechra marks strong 2016 with food animal business back on track

BY JOSEPH HARVEY

UK animal health company Dechra Pharmaceuticals has recorded 22% sales growth in fiscal 2016 with gains made both organically and through M&A.

This growth is slightly more than the 21% increase Dechra reported in a trading statement in July.

Annual sales came to £247.6 million ($330 million). The firm was able to stoke significant growth by improving its revenues in the US as well as establish positions in Austria, the Adriatic region and Mexico. Dechra also benefitted from acquisitional growth following its deals for Genera, Brovel and Putney – the three acquisitions contributed £21.7m to annual sales.

Dechra’s sales of companion animal products grew by 21% in fiscal 2016 to £137.7m. This was due to momentum in endocrinology, dermatology, cardiovascular disease, analgesia and anesthetics. Dechra said sales of Vetryl grew by 25% globally, DermaPet dermatology range saw sales improve by 32% in the US and Cardisure grew by 48%. Equine revenue was up by 19% year-on-year due to the introduction of Osphos for navicular syndrome in horses.

Sales of products for food animals increased by 40% to £38.1m after Dechra’s Polish subsidiary was established and the firm built its presence in other new markets. This halted years of revenue decline as European countries such as Germany and the Netherlands cut their usage of antimicrobial products.

Fiscal 2016 was a much stronger year for Dechra, as the previous year saw revenues improve by 5% after the company’s business declined in Europe.

Pets support European growth

Sales in Europe included an extra eight-month contribution from Genera. EU growth for the year came to 14% at constant exchange rates as sales came to £188.9m. Endocrinology products (Vetryl and Zycortal) proving to be a driving force. In Europe, Dechra’s equine portfolio performed well with Osphos being launched across all major territories.

Dechra said its food animal business showed signs of a turnaround in Europe. “The recovery in food animal products that was reported in the first half has continued in the remainder of the financial year. The decline in antibiotic sales in Germany has slowed and after several years of decline in the Netherlands we are now seeing sales flatten,” the company stated.

“Overall growth has been achieved by increasing market penetration in Poland and in countries where we had a lower market share historically, such as the UK, France, Italy and Spain.”
**North American sales up**
The company’s burgeoning North American business witnessed annual revenue growth of 38% at constant exchange rates to £58.7m. Including sales from Putney and Brovel since acquisition, annual sales growth in North America was around 60%.

Dechra is growing its presence in the US dermatology and endocrinology markets. “This growth has been enhanced by a good performance from Phycox, strong growth and traction with Osphos and the successful launch of Zycortal in March 2016,” the firm stated. “Furthermore, our biggest product, Vetoryl capsules, delivered double-digit growth as we have maintained our educational and marketing campaign and introduced a low dose 5mg capsule to increase flexibility on dosing options.”

**Year supported by approvals**
The major recent approval for Dechra was of Zycortal, a canine endocrine product for the treatment of Addison’s disease. In November 2015, Zycortal received European authorization. In March 2016, Zycortal was approved in the US. More recently, the product gained approval in Australia.

Dechra said two water soluble antibiotics for food animals – Solamoxa and Phenocillin – have been approved in 17 European member states, while liquid antibiotic Metaxol, was approved in 18 member states. Dechra’s antibiotic aerosol Cyclospray had its existing approval extended into 12 new European territories.

The company’s Croatian facility gained approval for Avishield ND, a poultry vaccine against Newcastle disease, in 12 European markets. The vaccine also achieved “a number of other national registrations including Egypt and Ukraine”.

In the course of the fiscal year, Dechra began eight new R&D projects. However, the company said it terminated an early-stage project for canine ophthalmology and a canine cardiology project.

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**Dechra seals first US generic approval since Putney purchase**

*BY JOSEPH HARVEY*

UK firm Dechra Pharmaceuticals has gained US FDA approval for a generic antibiotic developed by its Putney business.

Dechra purchased Putney in March as way of boosting its portfolio in the US. This goal has been realized with the first approval of a Putney generic since Dechra’s acquisition.

The firm did not state what the generic was indicated for but a spokesperson for Dechra told Animal Pharm more details would be available soon. The company said the product is expected to be the “first generic entrant into a substantial antibiotic market.”

At the time it was acquired by Dechra, Putney said it had a pipeline of 10 generic products which it expects to launch over the coming years – five of these were at the regulatory filing stage in April.

Dechra recently noted its 2016 sales in North America increased by 60% year-on-year when including sales of products from the Putney portfolio. Putney currently markets 11 products in the US, including generic forms of Rimadyl, Simplicef, Telazol and Dexdomitor.

Earlier this week, Dechra made a personnel change at Putney and also explained its rationalization program for acquisitions.

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**Specialized vet tech company is leading the sector it invented**

*BY DR MARGARET MAGNER*

The recent introduction of the VPR Cloud by Timeless Veterinary Systems has propelled the Canadian company to the forefront of veterinary innovation with advanced point-of-care medical technologies created on Prince Edward Island, writes Animal Pharm contributor Dr Margaret Magner.

“Our mandate is to raise the game in veterinary medicine with technology tools and world-class innovation,” said John Rowe, chief executive of Charlottetown-based Timeless Veterinary Systems.
In fact, the company is playing a pioneering role in a field it is actually inventing.

VPR Cloud is the end product of a collaboration between Timeless and Veterinary Pharmacy Reference (VPR), the most widely adopted veterinary drug formulary in the US. VPR was impressed by the success of the Timeless Vet Drug Index – an evidence-based mobile application with constantly updated drug information facilitating diagnostic decisions for cats and dogs that was quickly embraced by veterinarians in more than 100 countries. This mobile app was launched in 2013.

Seeking to upgrade its technology and incorporate peer-reviewed evidence, VPR approached Timeless to partner on an all-species cloud-based formulary. The result – the web-based VPR Cloud platform – incorporates the best of both drug formularies. Leveraging VPR's established North American relationships, Timeless will now have access to over 90% of that market and will be featured in 40,000 veterinary clinics in Canada and the US.

According to Timeless: "VPR Cloud is a comprehensive drug reference application providing enhanced software functionality, real-time drug database updates and immediate access to the VPR drug resource guide.

“The development of our web-based VPR solution allows veterinarians to instantly access relevant drug information to educate pet owners on the medical treatment being provided for their pet. VPR Cloud was created to give practitioners easy access to pertinent, current information about all medications used in veterinary medicine today.

"VPR Cloud not only provides practitioners with workflow efficiencies, it also adds a level of safety and accuracy to aid veterinarians when prescribing medications. VPR Cloud provides access to over 750 drug resources that are continually updated so that you have the most up-to-date drug information available at your fingertips from any internet enabled device."

‘Game changer’

“We created the most competitive, up-to-date veterinary tool in the world, completely web-based but delivered through Cloud infrastructure to any device,” said Mr Rowe.

“It’s a game changer for the industry and a massive opportunity for us. VPR has 15 years of established relationships. It’s opened doors to most vet clinics virtually overnight and exposes the world to our product and technology. It would have taken us years on our own.”

VPR Cloud offers a suite of tools designed to save time and elevate the user’s overall experience, with interactive antiparasitic charts, temperature conversion charts, built-in calculators and printable extra-label/anesthesia consent forms.

With two new employees on board, Timeless will be actively expanding its Charlottetown operations by hiring 10 more within the next two years. The firm will promote its proprietary information technology to other international companies looking to revenue share and pursue market prospects.

Mr Rowe is convinced information and communication technology companies can generate world-class innovation while remaining based in areas like the Prince Edward Island.

“We’ve proven we can compete toe-to-toe anywhere in the world,” he added. “Others can do it, too.”

Mr Rowe returned home to Prince Edward Island to launch Timeless, as well as honey-based product innovator Island Abbey Foods.

“There’s a competitive advantage to Prince Edward Island. We have a top veterinary college and researchers, R&D capital, public/private partnerships and talented people. Plus, the quality of life that attracts them. To succeed, we need to roll up our sleeves and get the job done.”

## Japan feed production up as PEDV subsides

**BY DR ATSUO HATA**

Annual production of animal feed in Japan rose by 0.7% to 23.542 million tons in 2015, according to the latest available figures from the Japanese Ministry of Agriculture, Forestry and Fisheries (JMAFF).

Feed production increased across all species, especially for growing pigs. This reflected a reduction of porcine epidemic diarrhea virus (PEDV) outbreaks.

PEDV previously prompted a decline in the production of animal feed during 2014.
Commercial animal feed production in Japan (2015, tons)

<table>
<thead>
<tr>
<th>Feed type</th>
<th>Fiscal 2014</th>
<th>Fiscal 2015</th>
<th>% change</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chicken replacements</td>
<td>691,707</td>
<td>698,652</td>
<td>+1.0</td>
</tr>
<tr>
<td>Laying hens</td>
<td>5,537,677</td>
<td>5,573,392</td>
<td>+0.6</td>
</tr>
<tr>
<td>Broilers</td>
<td>3,813,600</td>
<td>3,832,128</td>
<td>+0.5</td>
</tr>
<tr>
<td>Growing pigs</td>
<td>1,653,392</td>
<td>1,673,651</td>
<td>+1.2</td>
</tr>
<tr>
<td>Finishing stage pigs</td>
<td>2,286,520</td>
<td>2,301,993</td>
<td>+0.7</td>
</tr>
<tr>
<td>Breeding sows and piglets</td>
<td>1,645,331</td>
<td>1,662,702</td>
<td>+1.1</td>
</tr>
<tr>
<td>Dairy cattle</td>
<td>2,985,531</td>
<td>2,989,600</td>
<td>+0.1</td>
</tr>
<tr>
<td>Beef cattle</td>
<td>4,304,302</td>
<td>4,335,906</td>
<td>+0.7</td>
</tr>
<tr>
<td>Others</td>
<td>58,186</td>
<td>56,693</td>
<td>-2.6</td>
</tr>
<tr>
<td>Mixed feed</td>
<td>411,906</td>
<td>417,516</td>
<td>+1.4</td>
</tr>
<tr>
<td>Total</td>
<td>23,388,152</td>
<td>23,542,233</td>
<td>+0.7</td>
</tr>
</tbody>
</table>

Source: JMAFF

JMAFF also reported the number of pigs slaughtered for fiscal 2015 – ended March 31, 2016 – increased by 1.4% compared to fiscal 2014. The number of pigs slaughtered in fiscal 2014 dropped due to PEDV.

Pig numbers slaughtered in Japan 2012-2015

<table>
<thead>
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</thead>
<tbody>
<tr>
<td>Slaughtered</td>
<td>16,752,939</td>
<td>16,934,370</td>
<td>16,033,802</td>
<td>16,262,510</td>
<td>+1.43</td>
</tr>
</tbody>
</table>

Source: JMAFF

Cross Vetpharm generic injectable approved in US

BY SIAN LAZELL

Cross Vetpharm has received US FDA authorization for a generic over-the-counter injectable treatment for cattle and swine.

The product is a generic version of Elanco’s Tylan injectable treatment.

In beef and non-lactating dairy cattle, BiloVet (tylosin) is indicated for the treatment of: bovine respiratory complex (shipping fever, pneumonia) usually associated with Pasteurella multocida and Arcanobacterium pyogenes; foot rot (necrotic pododermatitis); calf diphtheria caused by Fusobacterium necrophorum; and metritis caused by Arcanobacterium pyogenes.

In pigs, the product is indicated for the treatment of: swine arthritis caused by Mycoplasma hyosynoviae; swine pneumonia caused by Pasteurella spp; swine erysipelas caused by Erysipelothrix rhusiopathiae; and for the treatment of swine dysentery associated with Treponema hyodysenteriae, when followed by appropriate medication in drinking water and/or feed.

BiloVet is injected intramuscularly and supplied in 100ml, 250ml and 500ml vials.

The product is Cross Vetpharm’s third approval so far in 2016. In August, the FDA granted the firm authorization for its Praziquantel Injection, a generic version of Bayer Animal Health’s Droncit Injectable Cestocide.

In July, the company’s generic treatment for piglet anemia was also approved in the US.
Anatara completes Detach target safety study

BY JOSEPH HARVEY

Australian animal heath firm Anatara Lifesciences has successfully completed a pivotal safety study for its Detach anti-infective.

Detach is the firm’s lead product for the control of diarrhea in piglets and the study showed it to be safe in piglets at doses higher and more frequent than the recommended rate.

The study was good laboratory practice-compliant, randomized, controlled and conducted in accordance with US FDA guidelines.

Anatara explained the methodology: “The study included 40 piglets and Detach was found to be safe when administered orally at the recommended dose rate (2mL) and also at three times and five times the recommended dose. Detach was dosed on six occasions (at 2, 5, 9, 12, 15 and 18 days of age) throughout the study, a frequency which far exceeds the recommended dosing regimen.”

Anatara’s chief scientific officer Tracey Mynott said: “Although Detach had already been proven safe in previous trials, a formal safety assessment is a requirement for registration of new active ingredients and new veterinary formulations in Australia, Europe and the US.”

The firm has previously gained positive results from a field trial focused on preventing and treating diarrhea in piglets.

The Brisbane-headquartered business said the dossier for registering Detach with the Australian Pesticides and Veterinary Medicines Authority is now in its final stages of preparation in readiness for submission in the third quarter of 2016.

The company said the Australian launch of Detach “remains on track for 2017”.

Anatara recently reported an improved net loss for the financial year after an exclusive evaluation and license option deal for Detach with Zoetis.

Jaguar secures Chinese supply agreement

BY JOSEPH HARVEY

Jaguar Animal Health has signed an exclusive supply and distribution agreement for its Croton lechleri botanical extract in China.

Jaguar has teamed up with fellow Californian firm Integrated Animal Nutrition and Health to make the extract available to dairy cattle and pigs in the Chinese marketplace.

The deal specifies annual minimum purchase amounts that are required to maintain exclusivity. It also requires Integrated Animal Nutrition and Health to be responsible for all activities, costs, product registrations, marketing authorizations and customs clearances for the Chinese market.

Jaguar said the agreement was signed after it gained encouraging topline results in two Chinese studies to evaluate the safety and effectiveness of the extract in piglets. These studies were sponsored by Integrated Animal Nutrition and Health.

Lisa Conte, Jaguar’s president and chief executive, said the firm aims to secure additional international deals of this ilk.

The Croton lechleri botanical extract is the main ingredient for Jaguar’s Neonorm line of products. Earlier this week, the firm recorded positive results from a study to evaluate the efficacy of a second-generation, powder formulation of its non-prescription Neonorm Calf treatment.
Nexvet full-year loss continues to widen

BY JOSEPH HARVEY

Veterinary biologicals specialist Nexvet Biopharma reported a widening net loss for fiscal 2016 as it continues to ramp up R&D.

Loss for the year ended June 30 came to $19.4 million. For the previous fiscal year, net loss was $11.9m.

During fiscal 2016, R&D expenses went up by around 50% to $14.9m. Total operating expenses climbed by 11% to $22.2m. As well as higher R&D expenses, Nexvet incurred operating expenses for its new manufacturing facility. Extra costs were offset by a $2.9m decrease in general and administrative expenses.

As of June 30, 2016, Nexvet had cash of $31.5m. The firm said it believes this cash will be sufficient to fund operations through fiscal 2017.

Over the past year, Nexvet has continued to validate its PETization platform in studies. At the same time, the firm has become a vertically integrated entity by adding internal manufacturing capabilities in the shape of its BioNua facility.

Dublin, Ireland-based Nexvet said this facility is now capable of producing drug substance in quantities sufficient for further pivotal studies of its lead product candidates.

Nexvet said it will be focusing on further pivotal studies of its lead product candidates ranevetmab and frunevetmab in the coming year.

“The company intends to commence pivotal safety and efficacy studies of frunevetmab in the fourth quarter of 2016,” Nexvet stated. “The company also intends to commence a pivotal safety study of ranevetmab dogs in the first half of 2017. Nexvet expects further data from its PD-1 and tumor necrosis factor programs over the course of the year.”

Alltech creates alliance for Chinese market

BY JOSEPH HARVEY

US animal nutrition specialist Alltech has joined a long-term strategic alliance that will allow it to take its expertise to the Chinese market.

Alltech has partnered with Chinese company Haier Financial Services to build a sustainable agricultural ecosystem in China.

Under the terms of the alliance, Alltech will provide its services to the Chinese farming sector including: antibiotic-free feeding solutions; feed safety and traceability; and on-farm support. Alltech’s recently-acquired Irish animal diet equipment maker Keenan will deliver its feed mixers and InTouch technology to China. Haier will offer financial and capital support to customers.

Alltech said it has been involved in the Chinese agriculture market for over 30 years and has a local office in Beijing, which has been operational for around 22 years.

Dr Mark Lyons, global vice president and head of Greater China for Alltech, said: “Over our time here, we have witnessed dramatic changes within the industry as China has grown to be the largest feed market in the world.

“Today, as China pushes for scale, efficiency, quality and safety, new investment and new thinking are required.”

Elanco chicken antiparasitic approved in Japan

BY DR ATSUO HATA

Elanco has received Japanese approval for a treatment for chicken mites.

The firm, which is based in Kobe, gained authorization for Econosad (spinosad) to eliminate chicken mite (Dermanyssus gallinae). The product is designed for chickens fed in poultry houses.
In the US, Elanco sells Elector PSP (spinosad) to control houseflies, darkling beetles and northern fowl mites.

Spinosad features in many Elanco products, including its canine antiparasitic Panoramis (spinosad plus milbemycin oxime). Panoramis was approved in Japan in 2014. Spinosad is also the active ingredient of the firm's leading Comfortis antiparasitic for companion animals.

This is Elanco's first product authorization in Japan since its Osurnia (florfenicol, telbinafine, betamethasone acetate) treatment for bacterial and fungal otitis externa in dogs was introduced in October 2015.

Azabu University develops new bird flu test

BY DR ATSUO HATA

Scientists at Japan's Azabu University have developed a new diagnostic test for avian influenza subtype H5.

Dr Kenji Tsukamoto, professor of the university's veterinary school in Kanagawa, has produced a new diagnostic test to detect almost all subtypes of the H5 avian influenza virus using a loop-mediated isothermal amplification (LAMP) method with a special primer.

The current LAMP method has a wide spectrum to detect 99.9% of H5 virus strains recognized so far. Dr Tsukamoto said the new test is low-cost, easy to use and able to obtain a test result in 30-60 minutes.

LAMP – an isothermal nucleic acid amplification technique – was also recently employed by researchers at the UK's Pirbright Institute to develop field tests for Indian strains of the bluetongue virus.

Japanese pet business on the up

BY DR ATSUO HATA

The size of the pet industry in Japan rose by 1.3% in fiscal 2015.

According to Tokyo-based analyst firm Yano Keizai Kenkyusho, the size of the market for pet-related business in Japan is now worth ¥1,468.9 billion ($14.69 billion).

The company claims the market will increase by 1.1% to ¥1,484.5bn in fiscal 2016.

The market size encompasses all aspects of spending on pets, including treatments, vaccines, food, accessories, toys, dental goods, equipment, insurance, funeral services and much more.

Many aspects of the Japanese companion animal health market are growing. Pet lifespans are increasing in Japan, while the country's pet food industry has witnessed recent growth. This has led to an increased interest in companion animal R&D from domestic biological firms such as Nippon Zenyaku Kogyo.

Jaguar adds topline Neonorm Calf data

BY JOSEPH HARVEY

Jaguar Animal Health has recorded positive results from a study to evaluate the efficacy of a second-generation, powder formulation of its non-prescription Neonorm Calf treatment.

The study gauged the performance of the prophylactic use of the product, administered as a liquid, on naturally occurring diarrhea and dehydration in pre-weaned dairy calves.

The results showed calves under prophylactic administration of Neonorm had "significantly lower water content in fecal samples at multiple measurement points, lower incidence of diarrhea, and had fewer fluid therapy interventions".

Fecal scoring was conducted daily during the study and indicated a significantly lower incidence of diarrhea among calves treated with Neonorm on most treatment days, compared to the placebo group.
Jaguar said: “The study also assessed the incidence of diarrhea from days 1-25 of life. Calves in the Neonorm-treated group experienced a highly significant reduction in the incidence of diarrhea during this period compared to those in the placebo group.”

Dehydration was assessed twice daily and results showed severe dehydration requiring the administration of intravenous fluid therapy was reduced by approximately 50% in calves treated with Neonorm. Additionally, rescue therapy – requiring either oral or intravenous fluid administration for both severe and moderate dehydration – was significantly reduced in the Neonorm-treated calves.

**Study methodology**

The research was conducted in conjunction with the Cornell University College of Veterinary Medicine in New York.

It was a double-blind, randomized study featuring 40 newborn Holstein bull calves and compared the prophylactic use of Neonorm against a placebo.

San Francisco-based Jaguar stated: “Treatment administration was performed twice daily for 14 days starting on the first feeding after colostrum administration. The calves were kept for an additional 10 days after the final treatment administration for clinical observation and sample collection. Calves were housed in individual pens and feeding was restricted to saleable whole milk. Data regarding fecal dry matter were used to measure water loss due to secretory diarrhea.”

The latest study results complement recent findings. In June, Jaguar announced topline results from a Cornell study also designed to evaluate the efficacy of the prophylactic use of a second-generation, powder formulation of Neonorm Calf. Last year, research by Cornell detailed how Neonorm Calf can be beneficial to the optimization of the intestinal microbiome profile in pre-weaned dairy calves.

While Neonorm Calf is already available in the US, Jaguar has entered into negotiations for a potential exclusive distribution relationship for the product in China.

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**Virbac appoints new general counsel**

**BY JOSEPH HARVEY**

Virbac has made Marie-Paule Porte its group general counsel.

She will be in charge of the company’s legal matters at a global level and will provide support to Virbac’s management in relation to strategic decisions. Ms Porte will report directly to Habib Ramdani, the firm’s chief financial officer.

Ms Porte began her career in 1985 as a lawyer with a “mid-cap company” after graduating from the University of Aix-Marseille. She then became legal director at Pasteur Mérieux Sérums & Vaccins.

She later joined the French manufacturer Rhodia as a general counsel of one of its divisions. Ms Porte then joined Novacap – a chemical company and spin-off from Rhodia – as a member of its executive committee. Prior to joining Virbac, she was group general counsel at French pharmaceutical business Pierre Fabre since 2011.

Ms Porte succeeds Florence Bambuck, who was the firm’s group general counsel since 2006. Ms Bambuck leaves Virbac after deciding to retire.