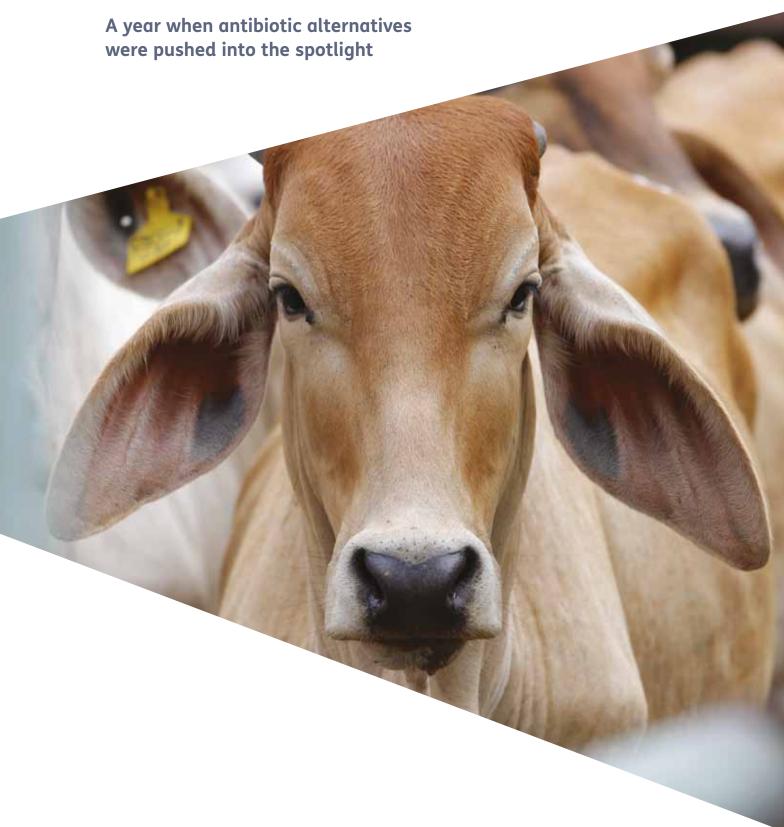
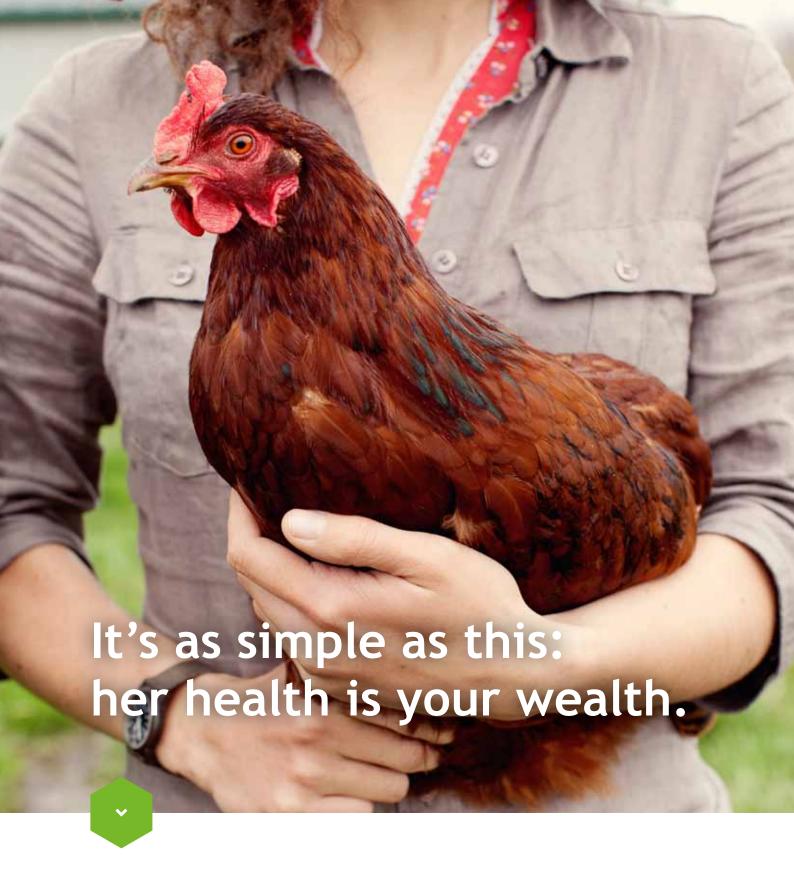


# Animal Health in 2017





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# Animal health in 2017: A year when antibiotic alternatives were pushed into the spotlight

There have been many changes across the animal health sector in 2017 both in terms of new legislation and industry consolidation.

Change was afoot literally from day one. Long-awaited guidelines were officially implemented by the US FDA on the first working day of the year, marking a milestone in the nation's campaign against antimicrobial resistance (AMR) in food animals.

The Guidance for Industry #213 (GFI #213) was first published by the FDA in 2013 to bring antimicrobial drugs with importance in human medicine under veterinary oversight. The new policies also aim to eliminate the use of antimicrobials in animals for growth promotion purposes.

As of January 3, 2017, all affected veterinary drug applications had either aligned with the recommendations

outlined in GFI #213 or their approvals had been voluntarily withdrawn.

Many companies in the animal health industry have been very vocal about this period of transition as sales of non-medically important antimicrobials decline.

While markets such as Europe have been dealing with this trend for longer, the reality of the waning influence of antimicrobials in the US hit home in 2017.

Much like in the companion animal segment, the food-producing animal portion of the industry is now seeing innovation from both multinationals and start-ups. The need for antimicrobial alternatives has stirred R&D departments

"We are at a transformational moment in our industry in the sense of how animals are being produced and how customers expect them to be produced" across the globe and seen a whole of firms focus more time of developing solutions in the animal health and nutrition such as Cargill, Evonik Industries and Royal DSM, to name a few.



#### Mind-set transformation

Animal health companies need to garner a deeper understanding of the animal microbiome if the industry is going to evolve into a sector focused on disease prevention, according to one expert from Elanco.

Speaking at a conference in London, Elanco's Scott Carter said: "We are on the cusp of a change of mind-set in the way we produce food. We have to change from measuring the feed conversions or the weight gain that we rely on to see if we did well or poorly in our production. We have to move to understanding what is going to happen before it happens; understanding what is going to happen based on small signals and biomarkers.



"We have to move from a concept of treating individual diseases to one of gut health balance. As a nutritionist, I believe our jobs are to achieve balance. We're moving from a world where the veterinarian has to deal with diseases to one where the nutritionist has more of a role to achieve balance. We have to move our mind-set from treatment to one of prevention."

Mr Carter, the company's director of enzyme research and development, said there are four key areas that need to be considered when fully understanding an animal's health. These are the microbiome, digestion, inflammation and infections.

He explained: "We can't look at these as

separate factors. They are, in reality, all intertwined and interlinked. Each factor effects the other. Changing digestion can affect the microbiome, controlling infection can have an impact on inflammation. We've got to understand there are many intended and unintended consequences of managing these things."

"The microbiome varies," Mr Carter stated. "It varies from bird to bird, from pig to pig. It varies from one location in Thailand to another in the US. That microbiome changes even throughout the day and it becomes confusing to understand what to do. When you look at this at a level deeper, it's not about the microbiome; it's about how the microbiome is translating into metabolic impact."

Speaking about a wider shift in the animal health industry, Mr Carter told delegates: "We are at a transformational moment in our industry in the sense of how our animals are being produced and how our customers expect them to be produced, to what the consumer wants and how they define food; to what tools we have available to us. Science in this area is moving so rapidly.

"Antibiotics have a place. We're not talking about replacing antibiotics. It's responsible use of those antibiotics that is the key. Yet, we need to find tools to manage this in different ways because consumers are having different attitudes to antibiotics. These are major issues we have in animal production. This pressure on clean labels is growing."

#### Alternatives to antibiotics

In July, US non-profit organization Pew Charitable Trusts published a report highlighting the strengths and weaknesses of alternatives to veterinary antibiotics. Animal Pharm editor Joseph Harvey looked through the report to see where the industry's R&D budgets should be focused.

While many antibiotic alternatives have already been adopted by the food animal industry, the key takeaway from the new Pew Charitable Trusts report was that the efficacy of many of these options is yet to be validated.

The report highlights a whole variety of promising alternatives to antibiotics for animals, claiming vaccines are among the most promising and widely used.

"Many alternative products enhance animal productivity and prevent infection at the same time, which could make them particularly attractive for commercial operations," the organization said. "To date, there are fewer options available for treatment."

Pew claims more research is needed to understand why the efficacy of alternative products varies so much by species and by their purpose of use. It also said alternative products differ in how their use has to be timed to assure effectiveness.

Probiotics, prebiotics and vaccines are already widely used in the livestock industry for growth promotion and disease prevention. Additionally, a range of alternatives for growth promotion and/or disease prevention are being evaluated. While early results are positive for these products, "more data under realistic conditions are urgently needed, as are data on potential interactions among alternatives".

Pew suggested several factors may be the undoing of some of these approaches, particularly at the commercial phase. These barriers include limited market sizes and a lack of incentives to use antibiotic alternatives, especially if antibiotics continue to remain available to producers and veterinarians.

## Data exploration needed

Pew's report states: "Overall, alternatives to antibiotics are promising, as many appear to simultaneously enhance animal productivity and prevent infection.

However, in several instances, efficacy has been evaluated only experimentally, which probably neither reflects real-world husbandry conditions on commercial operations nor the target animals.

"In other cases, the approach might be broad and indirect but effective, such as biosecurity measures. Potential unintended consequences have generally not been well studied. Typically, costeffectiveness data are also not available, complicating the evaluation of incentives for implementation."

"To optimize the use of scarce public research and development resources, a priority should be placed on areas of greatest need for products to replace antibiotic use. However, to develop an evidence-based prioritization, a comprehensive understanding of animal disease conditions that necessitate antibiotic use and the mechanism of action and roles antibiotic alternatives play is crucial. Emphasis needs to be given to on-farm antibiotic use data to tailor and prioritize future research efforts."

# Alternatives to antibiotics for growth promotion

The report suggests in-feed enzymes, probiotics, prebiotics, antimicrobial peptides, organic acids, phytochemicals and heavy metals have all shown some promise as alternatives for growth promotion.

In-feed enzymes such as xylanases and beta-glucanases are already commonly added to commercial feed for broiler chickens. While there is has been positive data produced for use of in-feed enzymes in the poultry and pig industries, they are not promising alternatives for ruminants because the rumen inactivates any enzymes before they reach the intestine.

In May, Bulgarian firm Huvepharma signalled its intent to use fungal expression

technology as a way of developing animal feed enzymes. Earlier in the year, Boehringer Ingelheim Animal Health entered the poultry probiotic space by establishing a strategic collaboration with Danish specialist Novozymes.



Probiotics – live cultures of microorganisms – are also widely used in US food animal operations and a number of scientific studies have quantified the efficacy of probiotics for growth promotion and disease prevention.

According to recent USDA data, 20% of US dairy operations use probiotics to prevent disease. More than one in four large feedlots with more than 1,000 cattle also uses probiotics as disease preventatives.

However, the report points out: "For all species, storage and administration of probiotics poses a potential challenge. For instance, to create feed pellets, chicken feed is usually exposed to high heat during

manufacturing, which may inactivate probiotics, although that problem does not seem to exist in other feed forms. Because live cultures are administered, probiotics have some associated risks, for example potential unintended, undesired and detrimental changes in the microbial balance of the gut."

Prebiotics are organic compounds that are indigestible by animals but are broken down by certain beneficial microorganisms in the gut. According to Pew, prebiotics have shown inconsistent efficacy when used as growth promoters and for disease prevention.

The report noted: "In general, the efficacy of prebiotics seems to be determined by a variety of factors, including the type of prebiotic, animal age and species, animal health status, the housing type and management practices, all of which have to be considered in the decision whether to use these alternatives."

Antimicrobial peptides are short molecules with antibacterial properties that are toxic to certain bacteria but, in the case of many





of these antibiotic alternatives, they have shown variable efficacy across species.

The report also notes the growth promoting potential of organic acids (citric or acetic acids), phytochemicals (essential oils or tannins), zinc, copper and other heavy metals.

## Alternatives to antibiotics for disease prevention

In this category of antibiotic alternatives as disease preventatives, vaccines are the leading option. This has been clear following the amount of acquisitions in the animal health space dedicated to fortifying the vaccine portfolios of leading companies.

The report cites recent USDA statistics, which suggest more than 70% of US operations are estimated to vaccinate very young pigs against Mycoplasma pneumonia, while around 60% of beef cow-calf operations vaccinate against clostridial diseases caused by C chauvoei.

"Vaccines are among the most promising approaches to disease prevention but their use is not without challenges," Pew stated. "For example, many vaccines have to be given by injection, leading to increased labor costs, and the stress caused by increased handling can affect an animal's immune response and may result in reduced weight gains.

"Additionally, some vaccines have a narrow range of bacterial or viral strains against which they are effective, and others pose a risk of unintended consequences such as reversion to a pathogenic virus that can cause disease. Research efforts are ongoing to address many of these challenges, such as the potential for mass administration of vaccines or the development of strategies for eliciting more protective immune responses."

The report also assesses immune modulators, which it defines as "the transfer of antibodies to elicit passive immune responses".

Pew said – in contrast with vaccines – immune modulators stimulate the immune system in a way that is less dependent on the pathogen causing infection, which makes them effective against a broad range of pathogens.

The report stated: "The efficacy of immunostimulants relies on a functioning immune system and therefore may not always be a feasible option; for instance, in very young animals, the immune system is not yet fully functional, and severe stress and disease can also limit the functionality of the immune system. There are also safety concerns about using immunostimulants before the immune system is fully formed because of the potential risk for adverse developmental effects. In addition, the mechanisms of action are rarely well determined."

Immune modulators include cytokines, lipopolysaccharides, short segments of bacterial DNA, antibodies derived from egg yolk and certain plant materials.

Pew's report also highlights the abilities of bacteriophages, endolysins, hydrolases, biofilm inhibitors, quorum-sensing inhibitors as other alternatives to antibiotics for disease prevention with a degree of potential.

Recently, UK research into bacteriophages has been hailed as ground-breaking in the search for natural solutions to tackle antimicrobial resistance. Currently, US firm EnBiotix is currently working with Elanco to explore the application of engineered phage technology in specific animal health targets.

Aside from the aforementioned products, the report suggested good farm management and biosecurity should not be forgotten as important preventative measures.

It said: "A comprehensive approach that includes alternative products and improved management practices is likely to be more effective than relying on a single alternative product or approach to manage health and prevent disease.

"In fact, improvements in biosecurity have been widely accepted as an effective means of preventing the introduction of diseases into herds or flocks. This concept applies widely across species, production systems, and pathogens. It addresses the risk of animal disease outbreaks such as avian or swine influenza while reducing the risk for introducing certain food-borne pathogens such as Campylobacter. In many cases, biosecurity is regarded as a prerequisite for successful herd or flock management."

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## Alternatives to antibiotics for disease treatment

While the report points out varied disease prevention and growth promotion alternatives, there are fewer options for the treatment of disease. In this area, it highlights probiotics, antibacterial peptides, immune modulators, bacteriophages and endolysins.

Pew also noted the ongoing development of predatory bacteria and Cas9, which are both far from commercialization.

"Predatory bacteria such as the Gramnegative bacteria Bdellovibrio spp and Micavibrio spp possess the ability to attack and kill certain pathogenic bacteria, for example multidrug-resistant E coli and Klebsiella strains; in vitro studies have provided some encouraging results," the report noted.

"Cas9 and similar products work by reprogramming parts of the bacterial immune system to selectively target specific parts of the bacterial genome, thereby selectively inactivating harmful bacteria that possess these virulence genes. In vitro studies have shown some promising results.

"In addition, nanoparticle-stabilized liposomes, certain metals such as silver. and other substances have also shown promising antibiotic efficacy in vitro.

"These approaches are very promising; however, none of these innovative approaches is likely to be available for use in livestock species in the foreseeable future."

## Where is investor money going?

This year has seen some interesting investment deals in the animal health space. With companion animal therapeutics always a popular target for funding, 2017 saw investments in the food animal space grow – undoubtedly caused by the ongoing quest for antibiotic alternatives.

In fact, venture capitalists have broadened their horizons within the animal health sector in recent years, with funding spreading to new segments.

In 2017, several animal nutrition companies have secured early-stage investment. This is in contrast to three or four years ago, when investment was largely directed to developers of drugs for companion animals.

To track early-stage investment in the animal health market, Animal Pharm launched a Funding Database. This tool features all of the early-stage deals covered by Animal Pharm since 2009. It highlights angel, seed and series A-D rounds, as well as initial public offerings (IPOs) from around the world. Subscribers can use the database to search for investments by country and product focus, as well as the investors behind each deal.





The database highlights the funding handed out from 2009 to 2015 for specialists in companion animal treatments such as Aratana Therapeutics, Putney, Kindred Biosciences, Nexvet Biopharma, Piedmont Pharmaceuticals and VetDC.



This initial surge of interest from the investor community led to several IPOs. However, the market for IPOs has died down in recent years. This led small businesses to look for early-stage investment from alternative sources.

Investment in the animal health arena has since spread to a wider range of targets. Veterinary vaccines, animal nutrition and data technology have become more popular destinations for venture funds.

This year, Animal Pharm has already tracked more early-stage funding deals than any other year. Of the 25 deals covered time of at the time of publication, nine were linked to food animal nutrition or feed.

Nevertheless, companion animal therapy specialists are still popular investment targets with Zomedica Pharmaceuticals, Elias Animal Health and Piedmont Pharmaceuticals all pocketing funding this year.

The location of early-stage funding in animal health also seems to be spreading. Of the 43 deals covered by *Animal Pharm* from 2009 through 2015, 14 (around 33%) were outside the US. From 2016 through 2017 so far, 19 out of 37 (51%) investments have taken place internationally.

While these positive trends will be a boost for young animal health businesses, funding is still a difficult prospect. Investors are still cautious when it comes to prospects in the animal health sector.

Notably, the new Animal Pharm database features some companies that received funding and then were acquired. These include Nexvet Biopharma, Putney and Silent Herdsman. These exit strategies may be the proof to venture capital firms that animal health companies are a sound investment.

Matthias Hofer, a partner at Stonehaven Consulting, told *Animal Pharm*: "Looking at recent exits in animal health, it appears those have been good investments. As a specialized consulting company, we are getting more and more involved with promising start-up companies in animal health. We are excited to see what seems to be a new biotech era in animal health; similar to what has happened to human health in the past."



Recently, Animal Pharm spoke to consultant Dr Sam Al-Murrani (left) echoed these sentiments by pointing out a widening sphere of investment

opportunities in animal health.

Dr Al-Murrani is the founder of Babylon BioConsulting – a specialist in counselling for pre-revenue companies across the breadth of human and animal health.

His expertise has been relied on many times at the Kansas City Animal Health Corridor Investment Forum. At the event he has featured on the selection committee, the coaching team and the judging panel.

At the most recent KC Investment Forum, Dr Al-Murrani represented two young firms vying for investor attention. NeuroCycle Therapeutics is aiming to bring its itch and epilepsy products for companion animals to commercial realization, while Prommune has a novel vaccine and immunoactivator platform for tackling zoonotic infections such as swine influenza virus.

Dr Al-Murrani told *Animal Pharm* he sees hundreds of start-up companies every year from both human and animal health. The advice he gives to these firms comes with a heavy dose of reality.

"I tell them to aim as high as they can but just don't expect a check today," he explained. "A lot of start-ups come to these investment forums, they don't get investment and they come away disappointed. But they are getting free publicity – use it to your advantage – meet and talk to people."

"We're nowhere near the hump. Animal health still hasn't explored everything. I'm optimistic for the future."

When picking out a potential prime opportunity for investors in the animal health space, Dr Al-Murrani has an equation he always keeps in mind.

"M2 – market and management," he said.
"That is what's important. You can have a good technology, but if the market is small and without good management, a good

technology will fail. But with a good market and good management even mediocre technologies can flourish."

Dr Al-Murrani also suggested a novel product is not going to excite all investors in the same manner. He said innovation is "in the eye of the beholder" and a start-up's pitch "is not going to be seen by everybody in the same way".

"There are definitely some markets worth looking into," Dr Al-Murrani said.
"Replacements for antibiotics are the Holy Grail at the moment, next-generation vaccines and immunomodulators, and medicines for allergies and itching in pets. Vaccines always interest me. Data technology is a growing segment but a lot of people don't know what to do with it."

He said innovation in animal health has to be geared towards what the consumer wants: "A lot of companies think they are business-to-business but they have to be consumer-centric regardless."

He said there is currently a high influx of other consumer-facing technology companies bringing data tools into the animal health market. While there are some interesting investment opportunities in this space, Dr Al-Murrani said it will be hard for these firms to differentiate themselves from their rivals.

He remains very positive for future investment opportunities: "We're now here near the hump – animal health still hasn't explored everything. I'm optimistic for the future. There are hundreds of technologies out there. The animal health space is just going to get bigger. It has to. Just look at the trends in pets and the need for more protein to feed the growing earth population."

One area that particularly excites Dr Al-Murrani is veterinary diagnostics. This represents a sector with few players and room for substantial growth.



He noted: "I think diagnostics are extremely undervalued. If you look at the vet diagnostics companies – IDEXX, Abaxis, Heska and Antech – versus the S&P Index, they're outperforming it. Diagnostics



companies are a huge proportion of the value in animal health and they are forgotten about.

"If you take IDEXX; its shares are doing so well. A billion dollars of sales after 20 years, now that's pretty good.

"Animal health is not just vaccines and pharma. If you add diagnostics, that's another \$10 billion. With pet food and production animal feed, which can influence health in meaningful ways, the animal health market is close to \$75bn, it just depends what you want to include."

However, while the ground seems fertile for novel ideas in animal health. Is there enough financial support for young firms?

"Lots of investors don't know much about animal health," he pointed out. "I get calls on a weekly basis from investors who have no clue. But it's a fairly complicated market. There is no cost reimbursement for pets and a limited, although growing pet insurance market. Only about 40-50% of pets go to the vet regularly. There are many things happening at the same time in this market – it's very nuanced. But you can make money in animal health; you just need to know what you're getting into."

With only a handful of venture capital firms interested in animal health, Dr Al-Murrani called for more investors to dedicate attention to opportunities in veterinary medicine.

He said this lack of venture capital or private equity support is made all the more apparent in the US, when there is no equivalent of the National Institutes of Health (NIH) in animal health. The NIH is a US government agency focused on disseminating funds for biomedical research in the human health space. It invests around \$32bn annually in medical research, with about 80% of funding awarded through 50,000 competitive grants to universities, medical schools and other research institutions.

Helping the smaller animal health companies with crucial investment will not only help bring innovation to market but it will also see the industry build a strata of mid-sized players.

"About 80% of the animal health market

is owned by 10 players and many hundreds, maybe even thousands of companies worldwide own 20%," explained Dr Al-Murrani. "This means the market is lop-sided. There are a few big fish in a small barrel and there are almost no medium-sized fish. You have poor and rich, with nothing in between. This is what we need to build up. Love them, like them or hate them, everybody has a place in the industry."

Animal health would benefit from more funds solely focused on fuelling start-ups in the veterinary medicines sector.

This year Animal Pharm spoke to another expert with his finger on the pulse of animal health's body of innovation.

When accepting this year's Iron Paw award, Rich Shuler, in addition to thanking his family, friends, teams and those that invested in his ideas, he said: "I want to thank all the people who forgave me when failures occurred – when I lost their money, struggled to make payroll, when the big idea didn't work out. Yes, I've lost people's money."

Animal Pharm asked if this statement was, in fact, true.

"Of course," Mr Shuler replied. "You always hear about the victors and never the failures. Sometimes the big idea didn't work or it took too long to get traction but I was always forgiven."

This allowed Mr Shuler to build a portfolio of success when it comes to creating animal health companies that are ahead of the curve. In 1994, he founded VetLife – a firm initially focused on non-antibiotic growth promoters for poultry. Again, in 2005, he helped found Ivy Natural Solutions. This firm developed non-antibiotic alternatives in the medicated feed sector long before the current trend towards these types of products.

Mr Shuler has also been involved in two notable data-driven ventures long before the recent influx of tech firms in animal health. He established AgSpan in 2000 to develop a database and information management service for the beef industry. The AgSpan technology was sold to Eli Lilly and is now part of Elanco Knowledge Solutions known as the Benchmark Performance Program.



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AgSpan was originally one of the failures Mr Shuler mentioned. At first, the company stuttered before Mr Shuler decided to remodel it and re-position the technology.

"With all the consolidation in the animal health industry, a lot of smaller technologies get 'parked' or lost as companies get bigger, face higher earnings requirements, and focus on large dollar products and markets. Start-ups have more freedom to innovate."

Animal Pharm first met Mr Shuler in 2014 as he represented AgLogica (now known as Vetrax) - the developer of an on-animal sensor and cloud analytics platform. The firm recently launched its Vetrax pet wearable sensor, app and online portal to veterinarians in collaboration with Hill's Pet Nutrition.



Mr Shuler said AGL is going under the radar for a soft launch of its Vetrax technology. As well as delivering sales of its pet sensor, AGL is working with animal health companies to bring behavior analytics to research projects.

"There is mountains of data out there but much of it is not in a friendly format. You need to helicopter up and look at the data from above. Then you can spot the trends and connect different silos. It's a very simple thing but not a lot of companies are doing it."

"You have to take data, turn it into usable information and then provide knowledge."

So with this experience of bringing datafocused companies to fruition in animal health, does Mr Shuler think this area of the industry is here to stay?

"If you look at the companies presenting at this investment forum over the last five years, there are many now in the tech space with IT or sensors. You wouldn't have seen this five years ago."

He pointed the high amount of tech firms in animal health at the moment, particularly highlighting the "fatigue" around the 'FitBit in the human space

where companies that were focused on just activity are now repositioning their model to focus on monitoring health conditions and trying to move from a nice to have wearable sensor to a 'must have' sensor.

Mr Shuler said: "The jury's out on a lot of these tech companies. The funding is still there but will all of these technologies be adopted?"

"Investors will see some unusual things in this space." Mr Shuler told Animal Pharm. "Emerging technologies have got to be broad enough to provide value and allow for continued innovation but not so broad that users don't see how to apply the technology and establish a foothold in a space."

He said the big investment opportunities are clear with a pressing need to provide alternatives to antibiotics, address food safety issues and ensure the utilization of useful data sets.

"There are hardly any new animal health molecules, particular for food animals. If you look at many of the companies that are receiving funding they are often in vaccines, probiotics, prebiotics and enzymes. With all the consolidation in the animal health industry, a lot of smaller technologies get 'parked' or lost as companies get bigger, face higher earnings requirements, and focus on large dollar products and markets. Start-ups have more freedom to innovate."

While Mr Shuler thinks more animal health innovation is going to come to light from start-ups, he outlines a tricky path to commercialization for these firms. He believes the characteristics a young company needs are the quality of the technology, the people and the believability of what they are offering.

He also asked of start-ups: "Can you get enough seed money for proof-of-concept studies? For regulated technologies, can you get through the initial steps with the regulators to show a potential investor enough information that a technology is worthy of considering?"

Crucially, as with many good ideas, Mr Shuler stresses the importance of being one step ahead. In line with his ventures in the animal health space, he stated: "In the next five years, what spaces will still

be of significance in animal health and what new spaces will emerge? You need to have that vision today to take risk and make a difference in these spaces."

## Two deals: One closed and one pending

The last 12 months has been noticeable in terms of M&A. Not because of any deals that were announced in 2017 but by one deal that closed this year (the merger of Boehringer Ingelheim Animal Health and Merial) and one that could happen in the coming years (the potential divestment of Elanco).



On January 3, Boehringer's animal health business and Merial officially merged. The combined entity is now the second-largest animal health company globally. Sanofi and Boehringer had been negotiating on this deal since December 2015, when the merger was first announced.

The addition of the Merial assets now means Boehringer is the leading provider of veterinary products for companion animals, horses and pigs.

The company's portfolio is geared towards companion animals with 59% of sales coming from this area (54% cats and dogs/5% horses). Boehringer's remaining portfolio is now 17% cattle, 16% pigs and 8% poultry.

The merger also creates a leader in parasiticides and, crucially in a market of decreasing antibiotic use, the world's biggest provider of veterinary vaccines. Boehringer's portfolio is 44% parasiticides and 37% biologicals, while 19% of sales are derived from other products.

The company has become the largest animal health firm in Africa, the Middle East, Asia, Australia and Oceania, while it is the second largest in Europe and North America.

The combined Boehringer-Merial entity has a presence in 99 countries, while their products are available in over 150 nations. The business boasts 24 R&D centers and 24 manufacturing sites.

## Dr Joachim Hasenmaier speaks about Boehringer's future



The new Boehringer Ingelheim Animal Health business unit is headed by Dr Joachim Hasenmaier (above).

In his first public appearance following the merger, he told a conference in London: "Our portfolios perfectly complement each other. We now have scale to build animal health big for the years to come."

Then at Boehringer's annual results press conference, he said: "Our future is in prevention. I feel very good about the small share of antibiotics in our portfolio. You cannot be a prevention company and an antibiotics company at the same time."

Dr Hasenmaier said Boehringer will reinvest around 8-10% of its net sales into R&D. He said this represents the highest amount of annual R&D investment in the animal health sector.

He noted the combined firms now have a critical mass, which allows Boehringer to "go where the two companies could not go individually". Dr Hasenmaier singled out diagnostics and probiotics as areas Boehringer is particularly interested in exploring further.

Boehringer estimates the veterinary probiotics market will grow from being €3.5bn in 2016 to a size of €9.6bn in 2030. Last month, the firm struck a significant agreement with Novozymes that enabled it to enter the poultry probiotic space.

The company valued the veterinary diagnostics market at €2.6bn in 2016. Boehringer expects this to climb to €10.4bn by 2030. In this space, the company has licenced chip technology from Siemens for use in point-of-care veterinary diagnostics.

He also reiterated the groundswell of animal health interest behind data monitoring and precision farming.

In terms of geographic expansion, Dr Hasenmaier highlighted China and India as key emerging markets for Boehringer. He said: "It is only a matter of time before the Chinese market is bigger than the US."

At an event in Beijing during October, Dr Hasenmaier said: "You cannot just serve China out of your global network. We have a strategy: China for China. We want to deliver innovation to the Chinese market, leveraging our global technologies and network but also building our own capacity in China. We want to work closely with authorities and partners to streamline regulations and bring innovation quicker to the market."

# Dr Hasenmaier: 'We have seized the right moment in time'

Back in April, Dr Hasenmaier spoke to Animal Pharm editor Joseph Harvey at Boehringer's annual press conference.

"There is a Greek word – Kairos – meaning the right moment in time," explained Dr Hasenmaier. "That's what we've done. We have seized the right moment in time."

Dr Hasenmaier was describing the timing of the Merial merger, which represents one of the industry's most significant transactions ever.

He stated: "Last year was the first time human pharma was second priority at Boehringer. Our business was stretched to the limit to make this integration happen."

Dr Hasenmaier explained to Animal Pharm the rationale behind the merger and Boehringer's decision to offload its consumer healthcare business to Merial's former parent Sanofi. He noted Boehringer had a decision to either be "a mid-fielder in two businesses or a leader in one". With Dr Hasenmaier's division offering more synergies to the company's human pharma segment, Boehringer plucked for animal health.



Animal health may currently only represent 9% of Boehringer's annual sales but this is all set to change in dramatic fashion. The company believes animal health can go on to represent around 25% of its annual sales in the near future. This would put the division in a powerful position.

Elanco has grown notably in recent years and accounts for around 16% of Eli Lilly's overall annual revenues, while Merck Animal Health represents 9% of its parent company and Bayer Animal Health is at approximately 3%. Merial was 8% of Sanofi's annual revenues before the asset swap.

This is quite a turnaround for Boehringer.

Dr Hasenmaier said the firm's acquisition of Fort Dodge assets in 2009 provided Boehringer with an important learning curve in the M&A field. He said this purchase "completely changed our US and Canadian business" and gave the animal health unit experience in game-changing deals.

However, it is not often an opportunity arises to combine with a company the size of Merial – an opportunity to upgrade the business that would not have always necessarily been deemed attractive to Boehringer.

"Five years ago, we might have shied away from such a big transaction," Dr Hasenmaier explained. "Five years ago, we were under €1bn. I remember a time when Novartis Animal Health was double our size. In 2001, when I joined Boehringer, we were €300m and now we're €1.5bn. We've not just grown in size but we've also grown our capabilities too.

"We have met all of our milestones and we are confident this will be considered a successful transaction. But we can't forget why we made this transaction. We want to bring more value to our customers and we need to win over 10,000 people who support this combined business. With any large transaction there will be change but all we can do is be transparent and fair."

"If we stop innovating, we are dead," declares Dr Hasenmaier, suggesting Boehringer has its sights set on organic growth as well as the acquisitional gains it has made via Merial.

Dr Hasenmaier also highlighted probiotics and diagnostics as important areas of

growth for the company. He told Animal Pharm the company will also be looking towards veterinary biotechnologies. "Other companies are further ahead here but nobody captures the whole market," he noted.

Aside from stepping into new product areas, Boehringer also wants to build on its existing strengths. Dr Hasenmaier voiced his desire to further the company's expertise in the control and treatment of mastitis.

He said: "We have an outstanding history in treating mastitis but we wish we were able to understand the immunology behind mastitis. So, we are playing with nonantibiotic compounds for mastitis."

Not only did Dr Hasenmaier grow up on a small dairy farm where his father individually named all of their cows but he also received a doctorate in veterinary medicine from Ludwig-Maximillian's University, as well as an MBA from the Kellogg School of Management.

He joined Boehringer in 2001 and served as the divisional head for the animal health business for a decade. He then spent a year as human pharma regional business manager for Northern Europe, Canada and Australia, before returning to the helm of the animal health segment as he joined the Boehringer board of managing directors.

"I've been in the animal health industry for more than 20 years," he said. "It's a great industry with favourable trends."

Talking about his veterinary roots, Dr Hasenmaier added: "One advantage is I know what I'm talking about. I've seen it and I've done it - I've been on the other side."

He suggested the animal health industry is just at the beginning of an all-time high of consumer influence. With calls for more natural and safe food production ever increasing on social media and online, the animal health industry is adapting to this new scrutiny.

"People never see what it takes to raise and slaughter animals," he told Animal Pharm at Boehringer's headquarters in Ingelheim. "When I was growing up, we raised the animals ourselves and we slaughtered them ourselves. We are now living in times when people are so detached. They may see videos online but these are not the reality of food production. People care more now and this will not go away.

"If our industry closes it eyes and puts its head in the sand without addressing consumer concerns, we may eventually see meat consumption go down."

## **Boehringer nears Zoetis** \$5bn top line

The merger of Boehringer and Merial has created fiercer competition at the top of the animal health industry rankings.

At the half-way point of fiscal 2017, most of the leading animal health companies were enjoying strong growth. Over the six months, the average growth rate was 28%. Factoring out Boehringer's massive 205% sales increase, this figure comes to 6% – still a healthy improvement on the previous year.

Boehringer's acquisition-fuelled H1 not only means it is now the second largest animal health company globally but also puts it

COMPANY RANKINGS FOR THE FIRST FISCAL HALF OF 2017						
Company	H1 2016 sales (local currency)	H1 2017 sales (local currency)	Sales growth	H1 sales (US dollars)	2016/17	2017/18 (October 2017 estimate)
1. Zoetis	\$2,370	\$2,500	5%	\$2,500	970,690	1,020,580
2. Boehringer Ingelheim Animal Health	€688	€2,100	205%	\$2,274	91,000	103,000
3. Merck Animal Health	\$1,729	\$1,894	9.5%	\$1,894	82,300	90,000
4. Elanco	\$1,614	\$1,554	-4%	\$1,554	40,000	43,000
5. Bayer Animal Health	€834	€890	7%	\$964	14,000	15,000
Source: company financials: average currency conversation rates used						



within touching distance of the industry's top spot. The German firm was less than \$250m of sales away from Zoetis during the first six months of 2017.

The last time the industry's top two were divided by less than \$1bn in annual sales was fiscal 2012, when Pfizer Animal Health was \$900m ahead of Merck Animal Health. A top two this close harks back to the rankings of previous decades, when the margins between competitors across the whole of the top 20 were much tighter.

While Boehringer has felt the benefits of a major acquisition, Elanco was in a slightly different situation in H1. Not so long ago, Elanco was in Boehringer's shoes. The firm has experienced significant growth through acquisitions of Novartis Animal Health and Lohmann Animal Health in recent years - purchases that helped it move up the standings.

Now, Elanco is finding a very strong acquisition boosted 2015 hard to replicate. The company said it anticipated the recent Q2 period would be a challenging guarter, largely due to higher prior-year sales. This could be the reality Boehringer faces as the huge sales growth from the Merial acquisition wears off.

## M&A brings big jumps, organic growth strong too

Zoetis, Merck Animal Health and Bayer Animal Health were all aided by organic growth and smaller acquisitions in the first half of 2017, with all three recording robust growth from 5-9%.



While Boehringer and Elanco have enacted deals that have changed the face of the industry rankings in recent years, Zoetis, Merck and Bayer's bolt-on strategy have consolidated their positions in the top five.

These three leading players have leant on big brands for growth and, in Zoetis' case, new companion animal innovations. These organic increases have been combined with deals focused on aeography (Merck's purchase of Vallée). innovation (Zoetis' capture of both Nexvet Biopharma and Scandinavian Micro Biodevices) and established products (Bayer's move for Cydectin).

It should be noted Zoetis is on track to become the first animal health company to have annual turnover in excess of \$5bn.

## Elanco could be at the center of the industry's next big change

The animal health industry did not see a megadeal actually take place in 2017. However, the scene was set for a large transaction in the coming years, as Eli Lilly began considering strategic possibilities for its animal health unit in October.



The US drugmaker is reviewing strategic alternatives for Elanco, including an initial public offering (IPO), merger, sale or retention of the business. The company said it will provide an update "no later than the middle of 2018".

This move by Lilly comes after Elanco finalized the full integration of assets from Novartis Animal Health and Boehringer Ingelheim's vaccines portfolio. The firm is also exploring options for its Posilac (rbST) portfolio and consolidating its manufacturing operations – moves that should finesse the business prior to a potential sale or other strategic route.



Lilly's chief executive and chairman Dave Ricks (top left) said: "Elanco has developed into a premier animal health company, and has been an important

growth driver and source of revenue diversification for Lilly. Through acquisitions and organic growth, we've grown Elanco to a size and scale that now allows us to consider a variety of options to maximize future value."



In a statement to Animal Pharm, Elanco president Jeff Simmons (left) said: "Elanco has a proven track record since its creation in 1954. Over the past decade, a

balanced strategy of innovation, geographic expansion and very intentional acquisitions has made us a much stronger company, with an attractive product portfolio and a more diverse, higher-quality business. We believe the outcome of a strategic review may result in more value and further enable Elanco's top-tier leadership in animal health."

In an investor call, Mr Simmons spoke about some of the challenges the company is facing at the moment.

"One [pressure] is all-around market access, which is driven by the clean food movement with antibiotics and productivity products," he explained. "I think this is an industry issue depending on the product mix. And then, I think competitive pressures that are coming from a combination in food animal. That's a mix of economics of the industry, as well as some generic pressure. So we saw that in US cattle, both with beef and dairy.

"The companion animal parasiticide space, let me just highlight - Trifexis was an issue, where we lost some share. No question, I think everyone has seen increased spending. Innovation is getting rewarded, so the new entrants have gained share.

"We still feel very good about companion animals and the parasiticide space in general, given the size of our existing portfolio in our heartworm platform as well as our pipeline. The market itself is still growing on the companion animal side and parasiticides.

"I think you've got some industry dynamics with cattle, beef and dairy, and you've got some generic pressures a little bit there where there's lacking innovation on the food animal side. But overall, we see sectors like poultry, agua and even companion animals growing in the vaccine space."

Mr Simmons also gave an overview on Elanco's goal for its margins.

"We've been hovering around 20% for the past two years," he explained. "We feel good about not only this assessment but our strategy going forward on our margin expansion opportunities. We've got a pretty aggressive agenda. We announced two events this quarter that are a part of that agenda.

"The first was consolidation of our Larchwood. Iowa manufacturina facility into our Fort Dodge facility - the Boehringer Ingelheim acquisition facility. As well, we're seeking options for rbST.

"We're working aggressively to drive these margins to 30%. That will not happen here in the short-term, but over time that'll happen by both the margin expansion productivity agenda as well as the innovation that drives our product mix change."

### More insight from Jeff Simmons

In July, Mr Simmons gave Animal Pharm exclusive insight into Elanco's growth plan.

"The drivers to improved revenue growth will come from the launch of new innovation and performance of our key growth engines," he said. "Our business mix continues to strengthen, growing in areas with fewer systemic headwinds. We expect the business to grow next year and anticipate accelerating growth after that.

"We are focused on a long-term agenda, which consists of accelerating innovation, changing portfolio mix with higher growth product segments and improving productivity.

"We have recently launched, or soon will be launching, a number of new products including two new aquaculture products a vaccine and a parasiticide - a salmonella vaccine for broilers and we recently received approval for our new flea/tick combo product, Credelio in the EU.

"Our business mix is improving with vaccines, nutritionals, and a broad companion animal portfolio becoming a larger portion of our business. Finally, we have several productivity workstreams in place to improve both manufacturing and sales efficiency.

"The drivers to improved revenue growth for Elanco will come from the launch of new innovation and performance of our key growth engines, including vaccines, nutritionals and companion animal therapeutics. Additionally, our business mix continues to strengthen, growing in areas with fewer systemic headwinds. We expect the business to grow next year and anticipate accelerating growth after that."

At a conference in London during February, Mr Simmons explained how Elanco has opened up to a One Health approach after it had reached a critical juncture in 2007, when Eli Lilly was considering what to do with its animal health business.

In 2008 – the year Mr Simmons became Elanco's president – he was faced with an obviousness: "We can't be an animal company; we've got to be a people company. This was the view we faced."

So, under Mr Simmons' guidance, Elanco began realigning and building a new portfolio. In fiscal 2007. Elanco's annual sales were \$995.8m - around 5% of the total Lilly business in terms of revenues. Nearly 10 years later, the company's animal health sales have more than tripled and now represent about 15% of its parent's yearly revenues.

"I really do think One Health is the next era of opportunity," he said.

Mr Simmons called on animal health companies to play a more involved and open role in this new era. "Let's shape the future with One Health," he said. "How can we elevate the dialogue with One Health? By bringing more credibility, more players and quit just talking to ourselves."

He urged conference attendees to "get into the tailwinds of wellbeing and sustainability" and posed three questions to the delegates: "How do we use One Health? How do we stimulate innovation? How do we drive food chain influence?"

Mr Simmons said: "In the last decade, just



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## **How to Order**

3% of the increased milk supply globally has come from improving efficiency; 82% has come from adding more cows. There are two proteins globally that are going backwards right now in productivity – eggs and beef. The two that are improving the most are poultry and fish.

"So our challenge is this: if we continue to give the retailers and consumers what they want and we don't focus on improving the health and thus the efficiency of the animal, then something has got to give. I think it's an opportunity as we come to the One Health discussion.

"I'm very bullish that we have the pipelines and innovation to solve problems and give consumers what they want. No question.

"I think there are two challenges we need to be careful of. One is that we don't get ahead of the science. We need to shape the environment, so we can bring innovation fast enough and also make sure animal welfare stays intact. Secondly, we're giving the world more protein but we're doing this by putting more animals on the earth. The question needs to be: How are we going to have less animals for that protein?"

"I think it's critical that we talk differently," he suggested. "I do think in the future, a lot of our food animal products will have environmental claims not productivity claims.

"Maple Leaf and Tyson are buying nonanimal protein companies. Yes, that is a trend, but if you look at just meeting the demand we have today, there is probably not one food segment that will have a bigger impact on people or human health than animal protein.

"Health is important but accessibility and economics are important as well if protein is truly going to be the food group that is going to have an impact on the next few years."

"I believe we need to influence the food chain more than ever," Mr Simmons continued. "There are a lot of changes that have occurred in the food chain. Animal health needs to be at the center. I define the food chain as retailers, quick service and food policy makers."

He said Elanco monitors social media to understand consumer interest and perceptions about important food and ag issues. When predicting potential future

negative product differentiation moves, Mr Simmons suggested vaccine-free animals and GMO-free milk could be just around the corner

"Animal health needs to be at the center of the food chain," he said, urging a "provocative influence" on the global food chain.

On the topic of antibiotic resistance, Mr Simmons said: "We can and will reduce the need for shared-class antibiotics significantly in the near future. I do think we need to manage this carefully, as antibiotics will be here in the future and we need to shape how antibiotics are going to be used.

"Responsible judicious use has never been more important; the vet has never been more important. Innovating quickly and finding solutions from biopharma, vaccines and nutritional health is absolutely essential.

"We can bring antibiotic alternatives but I also think it is very important we shape and manage antibiotics as we go forward."

Last year, Elanco gave an update on its eight-point antibiotic stewardship program, which it introduced following a meeting at the White House in 2015.



## Four options, one solution

Animal Pharm assesses the strategic options for Elanco.

**IPO:** This option will seem very attractive to Elanco. Zoetis has been through this process and, around four years down the line, has evolved into a much more financial stable business. Zoetis has been through streamlining of its operations, headcount and products.

Zoetis' ongoing cost-reduction scheme is currently ahead of its goals and is expected to exceed the firm's initial target of cutting \$300 million from annual costs in 2017. The company said its level of profit is not comparable to any other company in the animal health industry and has given guidance for adjusted EBIT margin this year of 34-35%.

Since emerging from Pfizer's grasp, Zoetis has established more autonomy to pursue acquisitions, partnerships and niche product approvals. Despite being a multinational and the industry leader, Zoetis is viewed by many as one of the most innovative businesses in animal health, particularly in the companion animal sector.

The Zoetis share price has regularly hit new highs over the last 12 months.

However, Zoetis remains the only large animal health business to spin-off via an IPO. Is this a large enough pool of examples for Elanco to follow?

**MERGER:** Anti-trust hurdles would not get in the way of Elanco merging with another big player in animal health, according to parent firm Eli Lilly.

Dave Ricks, chief executive of Lilly, said Elanco could possibly be part of a combination deal within the animal health sector. He said on an investor call: "Obviously, animal health has had a lot of combinations. We've been a part of that. You really have to look at the facts of the combination you might be looking at.

"So I guess it's possible but we need to look at the product mix that would be resulting in any combination and then determine the anti-trust risk. We do think that's an avenue but we'd have to look at the facts in each geography."

With Boehringer Ingelheim working through

its own megadeal and Zoetis seemingly targeting bolt-on acquisitions, the most likely candidates for a merger with Elanco are Merck Animal Health and Bayer Animal Health. Even though the latter has recently highlighted its own bolt-on strategy, an opportunity to merge with Elanco and become the animal health industry leader might be too tantalizing to pass up.

Going by 2016 sales, an Elanco merger with either Merck or Bayer would propel the resulting combined entity into the number one position in animal health. This does not take into account any divestments that would be required by anti-trust regulations.

However, Bayer's chief executive has distanced the firm from any potential bid for Elanco.

In an investor call following Bayer's thirdquarter results, chief executive Werner Baumann said: "Animal health is a business that continues to grow at least in line with markets. So as we see, we don't have an issue in keeping our relative weight."

Bayer is currently in the midst of closing a major \$66bn deal for agricultural giant Monsanto, which is limiting its abilities to undertake any other large transactions. The company has also recently spun off a hightech polymers business called Covestro.

"Of course, we see some of the assets that are obviously up for strategic review, as Lilly just announced a couple of days ago," Mr Baumann said. "But we are currently busy and there is not an awful lot of things that our organization would volunteer to venture into at this point in time.

"Quite frankly, I also think it is prudent for us as a board to stay focused on the task at hand, whether they are operational in nature or whether it's actually bringing the transaction – the Monsanto acquisition – home and of course, also finishing up on Covestro. This is what we need to focus on.

"I really believe that these are also the biggest value levers for our shareholder base and we will not let ourselves be distracted by anything else for the next time to come."

While Merck chief executive Kenneth Frazier did not address any potential deal for Elanco directly, he supported the retention of the company's animal health unit.

In Merck's investor call for the third quarter, Mr Frazier stated: "We see animal health and the innovation we can create through that portal as a pillar of growth for the company.

"As we noted this quarter, it surpassed \$1 billion for the first time inside our portfolio, which is meaningful. We continue to see it going forward as a key growth driver because it has healthy margins as well as a strong market outlook. So, from our perspective, we see it fitting very nicely and augmenting our growth as an overall company.

"We intend, where we find opportunities, to further augment that business with additional business development. So it's an important part of our business."

**SALE:** An outright sale would seem a less likely option for Elanco. There are not many instances whereby animal health companies have been sold to acquirers outside of the industry.

This deal might not be the type of transaction a private equity company would be looking for, as it would represent a considerable long-term project to ramp up Elanco's valuation enough to warrant an exit.

With ChemChina acquiring crop protection firm Syngenta for \$43 billion, maybe a suitor from the east would be interested in Elanco.

**RETENTION:** Elanco represented 15% of Lilly's sales in 2016. This was the highest of any animal health unit within human pharma last year. Lilly would be losing a significant portion of its business if it were to divest Flanco.

If retention of animal is Lilly's final choice, it will be interesting to see how big a proportion animal health can become of Lilly. The parent company would need to support more internal R&D and even get Elanco back on its familiar M&A trail.

# Elanco aims for future growth

Even though Elanco has made some significant acquisitions recently – the firm grew its revenues 70% from 2010 to 2014 – it still finds itself in fourth position in the industry rankings. The company is also a significant amount of annual sales behind Zoetis and Boehringer, who will be battling



it out for the sector's top spot over the coming years.

The company is currently going through a transitional phase, whereby it moves from its acquire and develop strategy to a more organic model.

Elanco expects its most recent purchases to "provide the foundation for a return to top-line growth". M&A has helped Elanco report very healthy annual sales growth across many years over the last decade. However, in 2016, Elanco was unable to replicate an acquisition-fuelled 2015 and posted a drop in yearly revenues.

Mr Simmons outlined Elanco's future plan for growth to *Animal Pharm* – the firm is focusing on innovation to provide a greater product mix in its portfolio.

While the short-term outlook for Elanco looks difficult as it battles headwinds in the US cattle market, the company is predicting a brighter 2019 due to several pipeline projects coming to fruition.

Elanco is showing particular growth in the companion animal sector – a segment it boosted with the Novartis purchase, as well as the acquisition of Boehringer Ingelheim Vetmedica's US feline, canine and rabies vaccine portfolio.

Elanco is confident its product pipeline can propel future organic growth, no matter what strategic pathway the firm takes in the coming years.

In an investor call, the firm's management showcased Elanco's pipeline potential – including work in the atopic dermatitis area

– as a future driver of organic growth.

Mr Simmons said: "We feel very good about our pipeline. Also, I think we launched a series of products last year and into this year that we're going to see growth on and then we'll talk more as we get near the end of the year in our guidance call and going into next year about additional launches.

"It's not just the pipeline but I think existing launches that are occurring now and ones that are right on top of us.

"Then I think the last thing is we're shifting our mix into these faster-growing markets. So as I mentioned, the food animal vaccines, nutritional health, companion animals and aqua. As our mix gets higher in those spaces, that'll also drive more additional growth."

With treatments for atopic dermatitis becoming a popular and lucrative part of companion animal health – Apouqel is performing particularly well for Zoetis – Mr Simmons was asked about Elanco's work in this space.

He stated: "We're actively exploring several mechanisms here related to symptom treatment, as well as interruption of disease process. We're leveraging Lilly's experience here, no question, and we'll continue to advance some novel product concepts. Both large molecules and small molecule are being studied here, so it's an active platform in our pipeline and we're focused on this."

Dave Ricks: "We've built a globally competitive animal health company with a nice pipeline, with good opportunities to improve margins, and grow at pace – and in some segments above industry pace."

With the Novartis Animal Health acquisition and the purchase of pet vaccine assets from Boehringer Ingelheim, Elanco has created a platform for much stronger growth in the companion animal arena. The company's companion animal business is already outperforming its food animal unit in recent quarters and this should continue into 2018.

On the food animal side of the business, Elanco is going through something of a reorganization with a potential divestment of its recombinant bovine somatotropin assets and the introduction of innovative fish vaccines, among other projects.

Currently, sales in the companion animal market represent around 35% of Elanco's annual sales. With Elanco aiming to improve its product mix in the coming years, this proportion could creep up towards the 50% mark in the future.

#### 'A much broader lens'

Dave Ricks, Lilly's chief executive, added his own take on Elanco's organic growth aspirations: "Just to be clear, [Elanco is] not growing organically this year. The growth is the Boehringer Ingelheim addition in companion animals and we described the food animal pressures.

"We're not evaluating this business through the lens of 2017 performance. We're looking at the last 10 years and we've built a globally competitive animal health company with a nice pipeline, with good opportunities to improve margins, and grow at pace – and in some segments above industry pace.

"As we look forward and do this analysis, we'll be looking, again, at those long-term trends in animal health. Because we're broadly positioned across many of these segments, and we do have innovation coming, we do expect forward trends to reflect those assumptions as we do the analysis."

Mr Ricks said Elanco's future would be decided with the unit's long-term capabilities in mind.

He noted: "We've had some performance challenges. Boehringer Ingelheim has helped us in terms of the stated growth rate but we're looking at this decision-making through a much broader lens of time."



Policy change can have major impacts on the agri-food and bioenergy sectors, as well as on the overall macro economy. In the EU, policy makers must address the direct impact of Brexit as well as the shape of the Common Agricultural Policy post-2020. This will be impacted by the post-2020 EU budget agreement as the EU loses its second largest net contributor.

A host of policy issues – both directly and indirectly impacting agriculture – are being discussed around the world. These involve trade agreements, environmental regulations, climate change and renewable fuels/bioenergy, approach to GMOs.

There is considerable uncertainty about what the new agri-food and bioenergy policies might look like and what they may mean for businesses operating along the value chain. Are you prepared for these changes and how they will impact your business?

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