

Zoetis Inc.
Form 10-K
February 14, 2019
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K
(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018

or
☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____
Commission File Number: 001-35797

Zoetis Inc.
(Exact name of registrant as specified in its charter)

Delaware 46-0696167
(State or other jurisdiction of (I.R.S. Employer Identification No.)
incorporation or organization)

10 Sylvan Way, Parsippany, New Jersey 07054
(Address of principal executive offices) (Zip Code)
(973) 822-7000

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, \$0.01 par value per share	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>	Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>	Emerging growth company	<input type="checkbox"/>
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If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. "

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes " No ☒

The aggregate market value of the voting stock held by nonaffiliates of the registrant as of June 30, 2018, the last business day of the registrant's most recently completed second fiscal quarter, was \$41,086 million. The registrant has no non-voting common stock.

The number of shares outstanding of the registrant's common stock as of February 8, 2019 was 478,771,915 shares.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the registrant's Proxy Statement for the 2019 Annual Meeting of Shareholders (hereinafter referred to as the "2019 Proxy Statement") are incorporated into Part III of this Form 10-K.

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PART I

Item 1. Business.

Overview

Zoetis Inc. is a global leader in the discovery, development, manufacture and commercialization of animal health medicines, vaccines, and diagnostic products with a focus on both livestock and companion animals. We have a diversified business, commercializing products across eight core species: cattle, swine, poultry, fish and sheep (collectively, livestock) and dogs, cats and horses (collectively, companion animals); and within six major product categories: vaccines, anti-infectives, parasiticides, medicated feed additives, animal health diagnostics and other pharmaceutical products. For more than 65 years, we have been committed to enhancing the health of animals and bringing solutions to our customers who raise and care for them.

We were incorporated in Delaware in July 2012 and prior to that the company was a business unit of Pfizer Inc. (Pfizer). The address of our principal executive offices is 10 Sylvan Way, Parsippany, New Jersey 07054. Unless the context requires otherwise, references to “Zoetis,” “the company,” “we,” “us” or “our” in this Annual Report on Form 10-K for the fiscal year ended December 31, 2018 (2018 Annual Report) refer to Zoetis Inc., a Delaware corporation, and its subsidiaries. In addition, unless the context requires otherwise, references to “Pfizer” in this 2018 Annual Report refer to Pfizer Inc., a Delaware corporation, and its subsidiaries.

Operating Segments

The animal health medicines, vaccines and diagnostics market is characterized by meaningful differences in customer needs across different regions. This is due to a variety of factors, including:

- economic differences, such as standards of living in developed markets as compared to emerging markets;
- cultural differences, such as dietary preferences for different animal proteins, pet ownership preferences and pet care standards;
- epidemiological differences, such as the prevalence of certain bacterial and viral strains and disease dynamics;
- treatment differences, such as utilization of different types of medicines and vaccines, as well as the pace of adoption of new technologies;
- environmental differences, such as seasonality, climate and the availability of arable land and fresh water; and
- regulatory differences, such as standards for product approval and manufacturing.

As a result of these differences, among other things, we organize and operate our business in two segments:

- United States with revenue of \$2,877 million, or 49% of total revenue for the year ended December 31, 2018; and
- International with revenue of \$2,890 million, or 50% of total revenue for the year ended December 31, 2018.

Within each of these operating segments, we offer a diversified product portfolio for both livestock and companion animal customers so that we can capitalize on local trends and customer needs.

In addition, our Client Supply Services (CSS) organization which provides contract manufacturing services to third parties, and our human health diagnostics products, together represented approximately 1% of our total revenue for the year ended December 31, 2018.

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Our 2018 revenue for the United States and key international markets, together with the percentage of revenue attributable to livestock and companion animal products in those markets, is as follows:

(MILLIONS OF DOLLARS) Revenue Livestock Companion Animal

United States	\$2,877	44%	56%
Australia	\$189	62%	38%
Brazil	\$295	77%	23%
Canada	\$203	58%	42%
China	\$211	60%	40%
France	\$130	58%	42%
Germany	\$147	48%	52%
Italy	\$104	47%	53%
Japan	\$149	43%	57%
Mexico	\$100	82%	18%
Spain	\$110	70%	30%
United Kingdom	\$181	42%	58%
Other Developed	\$361	64%	36%
Other Emerging	\$710	80%	20%

For additional information regarding our performance in each of these operating segments and the impact of foreign exchange rates, see Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations and Item 8. Financial Statements and Supplementary Data:

Notes to Consolidated Financial Statements—Note 4. Revenue and Note 18. Segment Information. Our 2018 reported revenue for each segment, by species, is as follows:

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Products

Over the course of our history, we have focused on developing a diverse portfolio of animal health products, including medicines, vaccines and diagnostics, complemented by biodevices, genetic tests and a range of services. We refer to a single product in all brands, or its dosage forms for all species, as a product line. We have approximately 300 comprehensive product lines, including products for both livestock and companion animals across each of our major product categories.

Our livestock products primarily help prevent or treat diseases and conditions to enable the cost-effective production of safe, high-quality animal protein. Human population growth and increasing standards of living are important long-term growth drivers for our livestock products in three major ways. First, population growth and increasing standards of living drive increased demand for improved nutrition, particularly animal protein. Second, population growth leads to increased natural resource constraints driving a need for enhanced productivity. Finally, as standards of living improve, there is increased focus on food quality and safety. Livestock products represented approximately 54% of our revenue for the year ended December 31, 2018.

Our companion animal products help extend and improve the quality of life for pets; increase convenience and compliance for pet owners; and help veterinarians improve the quality of their care and the efficiency of their businesses. Growth in the companion animal medicines, vaccines and diagnostics sector is driven by economic development, related increases in disposable income and increases in pet ownership and spending on pet care. Companion animals are also living longer, receiving increased medical treatment and benefiting from advances in animal health medicines, vaccines and diagnostics. Companion animal products represented approximately 45% of our revenue for the year ended December 31, 2018.

In addition, our CSS organization, which provides contract manufacturing services to third parties, and our human health diagnostics products, together represented approximately 1% of our total revenue for the year ended December 31, 2018.

In the third quarter of 2018, the company modified the list of major product categories to include a category for animal health diagnostics, which was previously included within other non-pharmaceutical products. The prior period presentation has been revised to reflect the new product categories.

Our major product categories are:

- vaccines: biological preparations that help prevent diseases of the respiratory, gastrointestinal and reproductive tracts or induce a specific immune response;
- other pharmaceutical products: allergy and dermatology, pain and sedation, antiemetic, reproductive, and oncology products;
- anti-infectives: products that prevent, kill or slow the growth of bacteria, fungi or protozoa;
- parasiticides: products that prevent or eliminate external and internal parasites such as fleas, ticks and worms;
- medicated feed additives: products added to animal feed that provide medicines to livestock; and
- animal health diagnostics: portable blood and urine analysis systems and point-of-care diagnostic products, including instruments and reagents, rapid immunoassay tests, reference laboratory kits and blood glucose monitors.

Our remaining revenue is derived from other non-pharmaceutical product categories, such as nutritionals and agribusiness, as well as products and services in complementary areas, including biodevices and genetic tests.

As part of our growth strategy, through our research and development (R&D) group, we focus on the discovery and development of new chemical and biological entities, as well as product lifecycle innovation. Historically, a substantial portion of our products and revenue has been the result of product lifecycle innovation where we actively work to broaden the value of existing products by developing claims in additional species, more convenient formulations and combinations, and by expanding usage into more countries. For example, the first product in our ceftiofur line was an anti-infective approved for treating bovine respiratory disease (BRD) in cattle that was administered via intramuscular injection. Through follow-on studies and reformulations, we have expanded the product line into additional cattle claims and administration routes, as well as other species and regions. The ceftiofur product line currently includes the brands Excede®, Excenel®, Naxcel® and Spectramast®.

The following are examples of our first-in-class and/or best-in-class products that we have launched in recent years and products that we believe may represent platforms for future product lifecycle innovation (listed alphabetically):

Apoquel®, the first Janus kinase inhibitor for use in veterinary medicine, was approved for the control of pruritus associated with allergic dermatitis and the control of atopic dermatitis in dogs at least 12 months of age. Since January 2014, we launched Apoquel in key markets including the United States, Europe, Japan, Brazil, and Australia; Core EQ Innovator™, the first and only vaccine for horses to contain all five core equine disease antigens - West Nile, Eastern and Western Equine encephalomyelitis, tetanus and rabies - in one combination, was approved in the United States in 2018;

Cytopoint®, the first canine monoclonal antibody to help reduce the clinical signs of atopic dermatitis (such as itching) in dogs of any age, was licensed in the United States in 2016 (and was later granted an expanded indication to treat allergic dermatitis in 2018). Since 2016, the product has been approved in major markets including Canada, the European Union, New Zealand, Australia, Brazil and Mexico. An injection given once every four to eight weeks, Cytopoint neutralizes interleukin - 31, a protein that has been demonstrated to trigger itching in dogs;

Fostera® PCV MH was introduced in November 2013 in the United States and approved in the European Union in 2015 and Australia in 2017. It was developed to help protect pigs from porcine circovirus-associated disease (PCVAD) and enzootic pneumonia caused by M. hyopneumoniae (M. hyo). The one-bottle formulation of Fostera PCV MH allows the convenience of a one-dose program or the flexibility of a two-dose program. The Fostera franchise also includes Fostera/Suvaxyn® PRRS, which was approved in the United States in 2015 and in Taiwan, Vietnam and European Union countries in 2017. This vaccine offers protection against both the respiratory and reproductive forms of disease caused by porcine reproductive and respiratory syndrome (PRRS) virus. In 2018, Fostera Gold PCV MH was approved in the United States and Canada. This is the only vaccine to contain two PCV2 genotypes and long-lasting M. hyo coverage;

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Simparica® (sarolaner) Chewables, a monthly chewable tablet for dogs to control fleas and ticks, was approved in the European Union and New Zealand in 2015, the United States, Canada, Australia, and Brazil (Simparic) in 2016, and Japan along with multiple additional European, Latin American and Asia Pacific markets in 2017. Building on this franchise, in 2017, Zoetis received European Commission approval for Stronghold® Plus (selamectin/sarolaner), a topical combination product that treats ticks, fleas, ear mites, lice and gastrointestinal worms and prevents heartworm disease in cats. In 2018, this product was approved in the United States, Japan and Canada (Revolution® Plus); Vanguard® is a market leading vaccine line for dogs intended to help prevent a range of diseases. Since 2016, Zoetis has added new and innovative enhancements to its Vanguard line with Vanguard crLyme, Vanguard Rapid Resp Intranasal, Vanguard B Oral, and Vanguard CIV H3N2/H3N8.

We pursue the development of new vaccines for emerging infectious diseases, with an operating philosophy of “first to know and fast to market.” Examples of the successful execution of this strategy include the first equine vaccine for West Nile virus in the United States and European Union; the first swine vaccine for pandemic H1N1 influenza virus in the United States; the first fully licensed vaccine to help reduce disease caused by the Georgia 08 variant of infectious bronchitis virus (IBV) in poultry; a conditionally licensed vaccine to help fight porcine epidemic diarrhea virus (PEDv) in the United States; and the first conditionally licensed vaccine to help prevent the H3N2 type of canine influenza that emerged in the United States. Additionally, the Pharmaq business of Zoetis is the global leader in vaccines and innovation for health products in aquaculture. In 2018, Pharmaq added to its leading Alpha Ject® vaccine line with approval of Alpha Ject Micro 1 Noda vaccine in Spain, Italy, Croatia and Greece. This vaccine helps protect against Viral Nervous Necrosis, the most important viral disease threatening sea bass in the Mediterranean. Also in 2018, the Alpha Ject Panga 2 vaccine was approved in Vietnam. This vaccine helps protect against two types of bacteria (Edwardsiella ictaluri and Aeromonas hydrophila) that cause significant losses in the Vietnamese pangasius industry.

Zoetis enhanced the portfolio of its diagnostic products with the acquisition in 2018 of Abaxis, a leading provider of veterinary point-of-care diagnostic instruments. With this acquisition came the VetScan® portfolio of benchtop and handheld diagnostic instruments and consumables, which serves a large customer base of veterinary practices in North America and is poised for expansion in international markets. Our diagnostic portfolio also includes the Witness®, Serelisa® and ProFlok® lines of immunodiagnostic kits, which provide disease detection capabilities for various species, including dogs, cats, cattle, pigs and poultry.

In 2018, our top two selling products, Apoquel® and Draxxin®, contributed approximately 8%, and 6%, respectively, of our revenue, and combined with our next two top selling products, the ceftiofur line and Revolution® / Stronghold®, these four contributed approximately 25% of our revenue. Our top ten product lines contributed 40% of our revenue.

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Our product lines and products that represented approximately 1% or more of our revenue in 2018, which comprise 59% of our total revenue, are as follows (listed alphabetically):

Livestock products

Product line / product	Description	Primary species
Anti-infectives		
Ceftiofur injectable line	Broad-spectrum cephalosporin antibiotic active against gram-positive and gram-negative bacteria, including β -lactamase-producing strains, with some formulations producing a single course of therapy in one injection	Cattle, sheep, swine
Draxxin®	Single-dose low-volume antibiotic for the treatment and prevention of bovine and swine respiratory disease, infectious bovine keratoconjunctivitis and bovine foot rot	Cattle, sheep, swine
Spectramast®	Treatment of subclinical or clinical mastitis in dry or lactating dairy cattle, delivered via intramammary infusion; same active ingredient as the ceftiofur line	Cattle
Terramycin® line	Antibiotic for the treatment of susceptible infections	Cattle, poultry, sheep, swine
Vaccines		
Improvac / Improvest / Vivax	Reduces boar taint, as an alternative to surgical castration	Swine
Rispoval® line	Aids in preventing three key viruses involved in cattle pneumonia-BRSV, PI 3 virus and BVD-viruses as well as other respiratory diseases, depending on formulation	Cattle
Suvaxyn® / Foster®	Aids in preventing or controlling diseases associated with major pig pathogens such as porcine circovirus type 2 (PCV2), porcine reproductive and respiratory syndrome virus (PRRSv) and Mycoplasma hyopneumoniae (M. hyo), depending on formulations	Swine
Parasiticides		
Dectomax®	Injectable or pour-on endectocide, characterized by extended duration of activity, for the treatment and control of internal and external parasite infections	Cattle, swine
Medicated Feed Additives		
Aureomycin®	Provides livestock producers control, treatment and convenience against a wide range of respiratory, enteric and reproductive diseases	Cattle, poultry, sheep, swine
BMD®	Aids in preventing and controlling enteritis; and increases rate of weight gain and improves feed efficiency in poultry and swine	Poultry, swine
Lasalocid line	Controls coccidiosis in poultry (Avatec®) and cattle (Bovatec®) and for increased rate of weight gain and improved feed efficiency in cattle	Poultry, cattle
Lincomycin line	Controls necrotic enteritis; treatment of dysentery (bloody scours), control of ileitis and treatment/reduction in severity of mycoplasmal pneumonia	Swine, poultry
Other		
Embrex® devices		Poultry

Devices for enhancing hatchery operations' efficiency through in
ovo detection and vaccination

Lutalyse®

For estrus control or in the induction of parturition or abortion

Cattle, swine

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Companion animal products

Product line / product	Description	Primary species
Anti-infectives		
Clavamox® / Synulox®	A broad-spectrum antibiotic and the first and only potentiated penicillin approved for use in dogs and cats	Cats, dogs
Convenia®	Anti-infective for the treatment of common bacterial skin infections that provides a course of treatment in a single injection	Cats, dogs
Vaccines		
Vanguard® L4 (4-way Lepto)	Compatible with the Vanguard line and helps protect against leptospirosis caused by <i>Leptospira canicola</i> , <i>L. grippotyphosa</i> , <i>L. icterohaemorrhagiae</i> and <i>L. pomona</i> . Aids in preventing canine distemper caused by canine distemper virus; infectious canine hepatitis caused by canine adenovirus type 1; respiratory disease caused by canine adenovirus type 2; canine parainfluenza caused by canine parainfluenza virus; canine parvoviral enteritis caused by canine parvovirus; Lyme disease and subclinical arthritis associated with <i>Borrelia burgdorferi</i> , the causative agent of Lyme disease; and Rapid Resp - a group of three vaccines combating infections in dogs caused by <i>Bordetella bronchiseptica</i> , canine parainfluenza and canine adenovirus; canine influenza vaccines; and an oral vaccine for <i>Bordetella bronchiseptica</i>	Dogs
Vanguard® line		Dogs
Parasiticides		
ProHeart®	Prevents heartworm infestation; also for treatment of existing larval and adult hookworm infections	Dogs
Revolution® / Stronghold® line	An antiparasitic for protection against fleas, heartworm disease and ear mites in cats and dogs; sarcoptic mites and American dog tick in dogs and roundworms and hookworms for cats	Cats, dogs
Simparica®	A monthly chewable tablet for dogs to control fleas and ticks	Dogs
Other		
Apoquel®	A selective inhibitor of the Janus Kinase 1 enzyme that controls pruritus associated with allergic dermatitis and control of atopic dermatitis in dogs at least 12 months of age	Dogs
Cerenia®	A medication that prevents and treats acute vomiting in dogs, treats acute vomiting in cats and prevents vomiting due to motion sickness in dogs	Cats, dogs
Cytopoint®	An injectable to help reduce the clinical signs such as itching of atopic dermatitis in dogs of any age	Dogs
Rimadyl®	For the relief of pain and inflammation associated with osteoarthritis and for the control of postoperative pain associated with soft tissue and orthopedic surgeries	Dogs

International Operations

We directly market our products in approximately 45 countries across North America, Europe, Africa, Asia, Australia and South America, and our products are sold in more than 100 countries. Operations outside the United States accounted for 50% of our total revenue for the year ended December 31, 2018. Through our efforts to establish an early and direct presence in many emerging markets, such as Brazil, China and Mexico, emerging markets contributed 23% of our revenue for the year ended December 31, 2018.

Our international businesses are subject, in varying degrees, to a number of risks inherent in carrying on business in other countries. These include, among other things, currency fluctuations, capital and exchange control regulations, expropriation and other restrictive government actions. See Item 1A. Risk Factors— Risks related to operating in foreign jurisdictions.

Sales and Marketing

Our sales organization includes sales representatives and technical and veterinary operations specialists. In markets where we do not have a direct commercial presence, we generally contract with distributors that provide logistics and sales and marketing support for our products.

Our sales representatives visit our customers, including veterinarians and livestock producers, to provide information and to promote and sell our products and services. Our technical and veterinary operations specialists, who generally have advanced veterinary medicine degrees, provide scientific consulting focused on disease management and herd management, training and education on diverse topics, including responsible product use. These direct relationships with customers allow us to understand the needs of our customers. Additionally, our sales representatives and technical and veterinary operations specialists partner with customers to provide training and support in areas of disease awareness and treatment protocols, including through the use of our products. As a result of these relationships, our sales and consulting visits are typically longer, more meaningful and provide us with better access to customer decision makers as compared to human health. As of December 31, 2018, our sales organization consisted of approximately 3,100 employees.

Our livestock and companion animal products are primarily available by prescription through a veterinarian. On a more limited basis, in certain markets, we sell certain products through local agricultural and farming retail outlets, pharmacies and pet stores. We also market our products by advertising to veterinarians, livestock producers and pet owners.

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Customers

We sell our livestock products directly to a diverse set of livestock producers, including beef and dairy farmers as well as pork and poultry operations, and to veterinarians, third-party veterinary distributors and retail outlets that then typically sell the products to livestock producers. We primarily sell our companion animal products to veterinarians or to third-party veterinary distributors that typically then sell our products to veterinarians, and in each case veterinarians then typically sell our products to pet owners. Our two largest customers, both distributors, represented approximately 13% and 7%, respectively, of our revenue for the year ended December 31, 2018, and no other customer represented more than 6% of our revenue for the same period.

Research and Development

Our research and development (R&D) operations are comprised of a dedicated veterinary medicine R&D organization, research alliances and other operations focused on the development, registration and regulatory maintenance of our products. In addition, we have R&D operations focused on diagnostics, data, digital and other technological innovation. We incurred R&D expense of \$432 million in 2018, \$382 million in 2017 and \$376 million in 2016.

Our R&D efforts are comprised of more than 300 programs and reflect our commitment to develop better solutions. We create new insights for preventing and treating disease, and maximizing healthy performance, that result in the development of new platforms of knowledge which become the basis for continuous innovation. Leveraging internal discoveries, complemented by diverse external research collaborations, results in the delivery of novel vaccine, pharmaceutical and biopharmaceutical products to help our customers face their toughest challenges. While the development of new chemical and biological entities through new product R&D plays a critical role in our growth strategies, a significant share of our R&D investment (including regulatory functions) is focused on product lifecycle innovation. A commitment to continuous innovation, based on customer need, ensures we actively work to broaden the value of existing products by developing claims in additional species, more convenient formulations and combinations, and by expanding usage into more countries. We also create opportunities to optimize solutions through our extensive capabilities in biodevice diagnostics and genetics research, ensuring we can help our customers predict, prevent, detect and treat a variety of conditions.

We prioritize our R&D spending on an annual basis with the goal of aligning our research and business objectives, and do not disaggregate our R&D operations by research stage or by therapeutic area for purposes of managing our business. We make our strategic investments in R&D based on four criteria: strategic fit and importance to our current portfolio; technical feasibility of development and manufacture; return on investment; and the needs of customers and the market. A centralized portfolio management function links development plans with financial systems to build a comprehensive view of the status of project progression and spend. This view facilitates our ability to set targets for project timing and goals for investment efficiency. The allocation of our R&D investment between product lifecycle innovation and new product development, in addition to our ability to leverage the discoveries of our existing R&D and other industries, supports a cost-effective, efficient, sustainable and relatively predictable R&D process.

We regularly enter into agreements with external parties that enable us to collaborate on research programs or gain access to substrates and technologies. Some of our external partnerships involve funding from a non-governmental organization or a government grant. We are generally responsible for providing technical direction and supplemental expertise for, as well as investment in, such external partnerships. Depending on the nature of the agreement, we may act as the commercialization partner for discoveries that originate during the period of collaborative research, or we may own or have exclusive rights to any intellectual property that enables the development of proprietary products or models.

As of December 31, 2018, we employed approximately 1,100 employees in our global R&D operations. Our R&D headquarters is located in Kalamazoo, Michigan. We have R&D operations co-located with manufacturing sites in Weibers, Austria; Louvain-la-Neuve, Belgium; Campinas, Brazil; Suzhou, China; Farum, Denmark; Olot, Spain; Union City, California; Kalamazoo, Michigan; Durham, North Carolina; and Lincoln, Nebraska, United States. We co-locate R&D operations with manufacturing sites to facilitate the efficient transfer of production processes from our laboratories to manufacturing. In addition, we maintain R&D operations in Sydney, Australia; Zaventem, Belgium; São Paulo, Brazil; Beijing, China; and Navi Mumbai, India. We also maintain R&D operations in Suzhou, China;

Thanh Binh, Vietnam; Hong Ngu, Vietnam; and Oslo, Norway, related to our acquisition of Pharmaq. Each site is designed to meet the regulatory requirements for working with chemical or infectious disease agents, as appropriate.

Manufacturing and Supply Chain

Our products are manufactured at both sites operated by us and sites operated by third-party contract manufacturing organizations, which we refer to as CMOs. We have a global manufacturing network of 25 sites.

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Our global manufacturing network is comprised of the following sites:

Site	Location	Site	Location
Campinas	Brazil	Medolla	Italy
Catania	Italy	Melbourne	Australia
Charles City	Iowa, U.S.	Olot	Spain
Chicago Heights	Illinois, U.S.	Overhalla	Norway
Durham	North Carolina, U.S.	Salisbury	Maryland, U.S.
Eagle Grove	Iowa, U.S.	San Diego	California, U.S.
Farum	Denmark	Suzhou	China
Jilin	China	Tallaght ^(a)	Ireland
Kalamazoo	Michigan, U.S.	Union City ^(b)	California, U.S.
Klofta	Norway	Wellington	New Zealand
Lincoln	Nebraska, U.S.	White Hall	Illinois, U.S.
London	Ontario, Canada	Willow Island	West Virginia, U.S.
Louvain-la-Neuve	Belgium		

^(a) In June 2018, Zoetis acquired a manufacturing facility in Tallaght, Ireland where our teat sealant products are manufactured.

^(b) In July 2018, Zoetis completed the acquisition of Abaxis, a leading global provider of veterinary point-of-care diagnostic instruments.

We own the majority of these sites, with the exception of our facilities in Durham (U.S.), Klofta (Norway), London (Canada), Medolla (Italy), Melbourne (Australia), San Diego, California (U.S.) and Union City, California (U.S.), which are leased sites.

Our global manufacturing and supply chain is supported by a network of CMOs. As of December 31, 2018, this network was comprised of approximately 172 CMOs, including those centrally managed as well as local CMOs. We select CMOs based on several factors: (i) their ability to reliably supply products or materials that meet our quality standards at an optimized cost; (ii) their access to niche products and technologies; (iii) capacity; and (iv) financial efficiency analyses. Our regional and global manufacturing teams seek to ensure that all of the CMOs we use adhere to our standards of manufacturing quality.

In addition to our global manufacturing network and our CMOs, Pfizer continues to manufacture products for us at three Pfizer sites pursuant to a master manufacturing and supply agreement.

We purchase certain raw materials necessary for the commercial production of our products from a variety of third-party suppliers. We utilize logistics service providers as a part of our global supply chain, primarily for shipping and logistics support.

We also have a leased site in Tullamore (Ireland) that we acquired in 2017 where we plan to begin commercial production in the near term. In addition, we are currently investing in a manufacturing facility in Rathdrum (Ireland) that we acquired in 2017, and in building a second manufacturing site in Suzhou (China). Both of these sites are owned by us, but are not yet ready for commercial production.

We intend to continue our efficiency improvement programs in our manufacturing and supply chain organization, including Six Sigma and Lean capabilities, which are processes intended to improve manufacturing efficiency. We have strong globally managed and coordinated quality control and quality assurance programs in place at our global manufacturing network sites, and we regularly inspect and audit our global manufacturing network and CMO sites. As a result of a review of our global manufacturing and supply network, we have exited eight manufacturing sites since 2015.

Competition

Although our business is the largest based on revenue in the animal health medicines, vaccines and diagnostics industry, we face competition in the regions in which we compete. Principal drivers of competition vary depending on the particular region, species, product category and individual product, and include new product development, quality, price, service and promotion to veterinary professionals, pet owners and livestock producers.

Our primary competitors include animal health medicines, vaccines and diagnostic companies such as Boehringer Ingelheim Animal Health Inc., the animal health division of Boehringer Ingelheim GmbH; Merck Animal Health, the animal health division of Merck & Co., Inc.; Elanco Animal Health, an independent animal health company as of September 2018, formerly the animal health division of Eli Lilly and Company; Bayer Animal Health, the animal health division of Bayer AG, and IDEXX Laboratories. There are also several new start-up companies working in the animal health area. In addition, we compete with hundreds of other producers of animal health products throughout the world.

The level of competition from generic products varies from market to market. For example, the level of generic competition is higher in Europe and certain emerging markets than in the United States. Unlike in the human health market, there is no large, well-capitalized company focused on generic animal health products that exists as a global competitor in the industry. The reasons for this include the relatively smaller average market size of each product opportunity, the importance of direct distribution and education to veterinarians and livestock producers and the primarily self-pay nature of the business. In addition, companion animal health products are often directly prescribed and dispensed by veterinarians.

The importance of quality and safety concerns to pet owners, veterinarians and livestock producers also contributes to animal health brand loyalty. As a result, we believe that significant brand loyalty to products often continues after the loss of patent-based and regulatory exclusivity.

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Intellectual Property

Our technology, brands and other intellectual property are important elements of our business. We rely on patent, trademark, copyright and trade secret laws, as well as regulatory exclusivity periods and non-disclosure agreements to protect our intellectual property rights. Our policy is to vigorously protect, enforce and defend our rights to our intellectual property, as appropriate.

Our product portfolio enjoys the protection of approximately 5,500 granted patents and 1,650 pending patent applications, filed in more than 60 countries, with a focus on our major markets, including Australia, Brazil, Canada, China, Europe, Japan and the United States, as well as other countries with strong patent systems. Many of the patents and patent applications in our portfolio are the result of our in-house research and development, while other patents and patent applications in our portfolio were wholly or partially developed by third parties and are licensed to Zoetis. Patents for individual products expire at different times based on the date of the patent filing (or sometimes the date of patent grant) and the legal term of patents in the countries where such patents are obtained. The active ingredient of Draxxin, tulathromycin, is covered by both compound and formulation patents in the United States, Europe, Canada, Australia and other key markets, with terms that expire between May 2019 and January 2021 in the United States, between November 2018 and November 2020 in Europe, and between May 2018 and November 2020 in Canada and Australia. Generic tulathromycin products are marketed in countries such as Columbia, Vietnam, Belarus and Russia. Recently marketing authorizations were granted in Europe and there is a pending marketing authorization in Australia. At this time, market entry by generic versions in the U.S. are not anticipated before January 2021. Several patents covering the ceftiofur antibiotic product line (Excede) began expiring in the United States in 2015. However, various formulation and use patents relevant to the product line extend through to 2024. A generic version of Excede has recently entered the swine market in Mexico. At this time, the market entry of a generic version of Excede in the U.S. is not anticipated before 2024. The compound patent for selamectin, the active ingredient in our parasiticide Revolution, expired in 2014. Again, we have formulation patents covering this product which expire in important markets in 2019. Generic versions of selamectin are now authorized in Europe, Australia and South Korea. The market entry of a generic version of selamectin is not anticipated in the U.S. before November 2019. The patent for the active ingredient of Convenia has expired, however, there are formulation patents relevant to the product line which expire between November 2022 and October 2023. The patent for the active ingredient of Cerenia has expired, however, there are formulation patents relevant to the product line which expire between May 2020 and January 2027. A generic version of Cerenia has been registered in Europe and is marketed in the European Union. At this time, there is no indication of market entry of a generic version of Cerenia in the U.S. Zoetis typically enforces its patents whenever appropriate both within and outside the United States, including by filing infringement claims against other parties.

Additionally, many of our vaccine products are based on proprietary master seeds and proprietary or patented adjuvant formulations. We actively seek to protect our proprietary information, including our trade secrets and proprietary know-how, including by seeking to require our employees, consultants, advisors and partners to enter into confidentiality agreements and other arrangements upon the commencement of their employment or engagement. Following our separation from Pfizer, Pfizer licenses to us the right to use certain intellectual property rights in the animal health field. We license to Pfizer the right to use certain of our trademarks and substantially all of our other intellectual property rights in the human health field and all other fields outside of animal health. In addition, Pfizer granted us a perpetual license to use certain of Pfizer's product name trademarks.

We seek to file and maintain trademarks around the world based on commercial activities in most regions where we have, or desire to have, a business presence for a particular product or service. We currently maintain more than 10,000 trademark applications and registrations in major regions, identifying goods and services dedicated to the care of livestock and companion animals.

Regulatory

The sale of animal health products is governed by the laws and regulations specific to each country in which we sell our products. To maintain compliance with these regulatory requirements, we have established processes, systems and dedicated resources with end-to-end involvement from product concept to launch and maintenance in the market. Our regulatory function actively seeks to engage in dialogue with various global agencies regarding their policies that

relate to animal health products. In the majority of our markets, the relevant animal health authority is separate from those governing human medicinal products.

United States

United States Food and Drug Administration (FDA). The regulatory body that is responsible for the regulation of animal health pharmaceuticals in the United States is the Center for Veterinary Medicine (CVM), housed within the FDA. All manufacturers of animal health pharmaceuticals must show their products to be safe, effective and produced by a consistent method of manufacture as defined under the Federal Food, Drug and Cosmetic Act. The FDA's basis for approving a drug application is documented in a Freedom of Information Summary. Post-approval monitoring of products is required by law, with reports being provided to the CVM's Surveillance and Compliance group. Reports of product quality defects, adverse events or unexpected results are produced in accordance with the law. Additionally, we are required to submit all new information for a product, regardless of the source.

United States Department of Agriculture (USDA). The regulatory body in the United States for veterinary vaccines is the USDA. The USDA's Center for Veterinary Biologics is responsible for the regulation of animal health vaccines, including immunotherapeutics. All manufacturers of animal health biologicals must show their products to be pure, safe, effective and produced by a consistent method of manufacture as defined under the Virus Serum Toxin Act. Post-approval monitoring of products is required. Reports of product quality defects, adverse events or unexpected results are produced in accordance with the agency requirements.

Environmental Protection Agency (EPA). The main regulatory body in the United States for veterinary pesticides is the EPA. The EPA's Office of Pesticide Programs is responsible for the regulation of pesticide products applied to animals. All manufacturers of animal health pesticides must show their products will not cause "unreasonable adverse effects to man or the environment" as stated in the Federal Insecticide, Fungicide, and Rodenticide Act. Within the United States, pesticide products that are approved by the EPA must also be approved by individual state pesticide

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authorities before distribution in that state. Post-approval monitoring of products is required, with reports provided to the EPA and some state regulatory agencies.

In addition, the U.S. Foreign Corrupt Practices Act (FCPA) prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anti-corruption laws and/or regulations.

As a result of our acquisition of Abaxis, Inc., our product portfolio now includes human medical diagnostics, which are subject to regulation in the U.S. by the FDA under the Federal Food, Drug, and Cosmetic Act, including the 1976 Medical Device Amendments and the Quality System Regulation, and the Clinical Laboratory Improvement Amendments of 1988, and by the Department of Health and Human Services Office for Civil Rights under the Health Insurance Portability and Accountability Act of 1996.

Outside the United States

European Union (EU). The European Medicines Agency (EMA) is the centralized regulatory agency of the EU, located in London. The agency is responsible for the scientific evaluation of medicines developed by healthcare companies seeking centralized approval for use in the EU. The agency has a veterinary review section distinct from the medical review section. The Committee for Veterinary Medicinal Products (CVMP) is responsible for scientific and technical review of the submissions for innovative pharmaceuticals, biopharmaceuticals and vaccines. After the CVMP issues a positive opinion on the approvability of a product, the EU commission reviews the opinion and, if they agree with the CVMP, they grant the product market authorization. Once granted by the European Commission, a centralized marketing authorization is valid in all EU and European Economic Area-European Free Trade Association states. Products can also be registered in the EU via a decentralized route under the supervision of the Co-ordination Group for Mutual Recognition and Decentralized Procedures - Veterinary (CMDv). This co-ordination group is composed of one representative per member state from each national regulatory agency, including Norway, Iceland and Liechtenstein. The CMDv reviews submissions of pharmaceuticals and vaccines for authorization of a veterinary product in two or more member states in accordance with the mutual recognition or the decentralized procedure. A series of Regulations, Directives, Guidelines and EU Pharmacopeia Monographs provide the requirements for product approval in the EU. In general, these requirements are similar to those in the United States, requiring demonstrated evidence of, safety, efficacy, and quality/consistency of manufacturing processes. We are also subject to the EU General Data Protection Regulation (GDPR) that requires us to meet enhanced requirements regarding the handling of personal data, including its use, protection and the rights of data subjects to request correction or deletion of their personal data.

Brazil. The Ministry of Agriculture, Livestock Production and Supply (MAPA) is the regulatory body in Brazil that is responsible for the regulation and control of pharmaceuticals, biologicals and medicated feed additives for animal use. MAPA's regulatory activities are conducted through the Secretary of Agricultural Defense and its Livestock Products Inspection Department. In addition, regulatory activities are conducted at a local level through the Federal Agriculture Superintendence. These activities include the inspection and licensing of both manufacturing and commercial establishments for veterinary products, as well as the submission, review and approval of pharmaceuticals, biologicals and medicated feed additives. MAPA is one of the most active regulatory agencies in Latin America, having permanent seats at several international animal health forums, such as Codex Alimentarius, World Organization for Animal Health and Committee of Veterinary Medicines for the Americas. MAPA was also invited to be a Latin American representative at meetings of the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). Several normative instructions issued by MAPA have set regulatory trends in Latin America.

Australia. The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an Australian government statutory authority established in 1993 to centralize the registration of all agricultural and veterinary products into the Australian marketplace. Previously each State and Territory government had its own system of registration. The APVMA assesses applications from companies and individuals seeking registration so they can supply their product to the marketplace. Applications undergo rigorous assessment using the expertise of the APVMA's scientific staff and

drawing on the technical knowledge of other relevant scientific organizations, Commonwealth government departments and state agriculture departments. If the product works as intended and the scientific data confirms that when used as directed on the product label it will have no harmful or unintended effects on people, animals, the environment or international trade, the APVMA will register the product. As well as registering new agricultural and veterinary products, the APVMA reviews older products that have been on the market for a substantial period of time to ensure they still do the job users expect and are safe to use. The APVMA also reviews registered products when particular concerns are raised about their safety and effectiveness. The review of a product may result in confirmation of its registration, or it may see registration continue with some changes to the way the product can be used. In some cases the review may result in the registration of a product being canceled and the product taken off the market.

Rest of world. Country-specific regulatory laws have provisions that include requirements for certain labeling, safety, efficacy and manufacturers' quality control procedures (to assure the consistency of the products), as well as company records and reports. With the exception of the EU, most other countries' regulatory agencies will generally refer to the FDA, USDA, EU and other international animal health entities, including the World Organization for Animal Health, Codex Alimentarius, in establishing standards and regulations for veterinary pharmaceuticals and vaccines.

Global policy and guidance

Joint FAO/WHO Expert Committee on Food Additives. The Joint FAO/WHO Expert Committee on Food Additives is an international expert scientific committee that is administered jointly by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). They provide a risk assessment/safety evaluation of residues of veterinary drugs in animal products, exposure and residue definition and maximum residue limit proposals for veterinary drugs. We work with them to establish acceptable safe levels of residual product in food-producing animals after treatment. This in turn enables the calculation of appropriate withdrawal times for our products prior to an animal entering the food chain.

Advertising and promotion review. Promotion of prescription animal health products is controlled by regulations in many countries. These rules generally restrict advertising and promotion to those claims and uses that have been reviewed and endorsed by the applicable agency. We conduct a review of promotion materials for compliance with the local and regional requirements in the markets where we sell animal health products.

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Food Safety Inspection Service/generally recognized as safe. The FDA is authorized to determine the safety of substances (including “generally recognized as safe” substances, food additives and color additives), as well as prescribing safe conditions of use. However, although the FDA has the responsibility for determining the safety of substances, the Food Safety and Inspection Service, the public health agency in the USDA, still retains, under the tenets of the Federal Meat Inspection Act and the Poultry Products Inspection Act and their implementing regulations, the authority to determine that new substances and new uses of previously approved substances are suitable for use in meat and poultry products.

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). VICH is a trilateral (EU-Japan-USA) program aimed at harmonizing technical requirements for veterinary product registration. The objectives of the VICH are as follows:

Establish and implement harmonized technical requirements for the registration of veterinary medicinal products in the VICH regions, which meet high quality, safety and efficacy standards and minimize the use of test animals and costs of product development.

Provide a basis for wider international harmonization of registration requirements through the VICH Outreach Forum.

Monitor and maintain existing VICH guidelines, taking particular note of the ICH work program and, where necessary, update these VICH guidelines.

Ensure efficient processes for maintaining and monitoring consistent interpretation of data requirements following the implementation of VICH guidelines.

By means of a constructive dialogue between regulatory authorities and industry, provide technical guidance enabling response to significant emerging global issues and science that impact on regulatory requirements within the VICH regions.

Employees

As of December 31, 2018, we had approximately 10,000 employees worldwide, which included approximately 4,500 employees in the United States and approximately 5,500 in other jurisdictions. Some of these employees are members of unions, works councils, trade associations or are otherwise subject to collective bargaining agreements, including approximately 50 union employees in the United States.

Environmental, Health and Safety

We are subject to various federal, state, local and foreign environmental, health and safety laws and regulations. These laws and regulations govern matters such as the emission and discharge of hazardous materials into the ground, air or water; the generation, use, storage, handling, treatment, packaging, transportation, exposure to, and disposal of hazardous and biological materials, including recordkeeping, reporting and registration requirements; and the health and safety of our employees. Due to our operations, these laws and regulations also require us to obtain, and comply with, permits, registrations or other authorizations issued by governmental authorities. These authorities can modify or revoke our permits, registrations or other authorizations and can enforce compliance through fines and injunctions. Certain environmental laws, such as the U.S. Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended (CERCLA), impose joint and several liability, without regard to fault, for cleanup costs on persons who disposed of or released hazardous substances into the environment, including at third-party sites or offsite disposal locations, or that currently own or operate (or formerly owned or operated) sites where such a release occurred. In addition to clean-up actions brought by federal, state, local and foreign governmental entities, private parties could raise personal injury or other claims against us due to the presence of, or exposure to, hazardous materials on, from or otherwise relating to such a property.

We have made, and intend to continue to make, necessary expenditures for compliance with applicable environmental, health and safety laws and regulations. We are also a party to proceedings in which the primary relief sought is the cost of past and/or future remediation, or remedial measures to mitigate or remediate pollution. In connection with such proceedings, and otherwise, we are investigating and cleaning up environmental contamination from past industrial activity at certain sites, or financing other parties' completion of such activities. As a result, we incurred capital and operational expenditures in 2018 for environmental compliance purposes and for the clean-up of certain past industrial activities as follows:

• environmental-related capital expenditures - approximately \$5 million; and

Other environmental-related expenditures - approximately \$15 million.

However, we may not have identified all of the potential environmental liabilities relating to our current and former properties, or those liabilities associated with off-site disposal locations. Such liability could have a material adverse effect on our operating results and financial condition. Furthermore, regulatory agencies are showing increasing concern over the impact of animal health products and livestock operations on the environment. This increased regulatory scrutiny may necessitate that additional time and resources be spent to address these concerns in both new and existing products.

In connection with past acquisitions and divestitures, we have undertaken certain indemnification obligations that require us, or may require us in the future, to conduct or finance environmental cleanups at sites that we no longer own or operate. We have also entered into indemnification agreements in which we are being indemnified for various environmental cleanups; however, such indemnities are limited in both time and scope and may be further limited in the presence of new information, or may not be available at all.

While we cannot predict with certainty our future capital expenditures or operating costs for environmental compliance or remediation of contaminated sites, we have no reason to believe that they will have a material adverse effect on our operating results or financial condition.

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Available Information

The company's Internet website address is www.zoetis.com. On our website, the company makes available, free of charge, its annual, quarterly and current reports, including amendments to such reports, as soon as reasonably practicable after the company electronically files such material with, or furnishes such material to, the Securities and Exchange Commission (SEC).

Also available on our website is information relating to corporate governance at Zoetis and our Board of Directors, including as follows: our Corporate Governance Principles; Director Qualification Standards; Zoetis Code of Conduct (for all of our employees, including our Chief Executive Officer, Chief Financial Officer, Principal Accounting Officer, and Controller); Code of Business Conduct and Ethics for our Directors; Board Committees and Committee Charters; and ways to communicate by email with our Directors. We will provide any of the foregoing information without charge upon written request to our Corporate Secretary, Zoetis Inc., 10 Sylvan Way, Parsippany, New Jersey 07054. Information relating to shareholder services is also available on our website. We will disclose any future amendments to, or waivers from, provisions of these ethics policies and standards affecting our Chief Executive Officer, Chief Financial Officer, Principal Accounting Officer, and Controller on our website as promptly as practicable, as may be required under applicable SEC and NYSE rules.

We use our website (www.zoetis.com) as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation Fair Disclosure promulgated by the SEC. These disclosures are included in the “Investors” and “News & Media” sections of our website. Accordingly, investors should monitor these portions of our website, in addition to following our press releases, SEC filings and public conference calls and webcasts.

The information contained on our website does not constitute, and shall not be deemed to constitute, a part of this 2018 Annual Report, or any other report we file with, or furnish to, the SEC. Our references to the URLs for websites are intended to be inactive textual references only.

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Item 1A. Risk Factors.

In addition to the other information set forth in this 2018 Annual Report, any of the factors described below could materially adversely affect our operating results, financial condition and liquidity, which could cause the trading price of our securities to decline.

This report contains “forward-looking” statements within the meaning of the Private Securities Litigation Reform Act of 1995. Forward-looking statements reflect our current views with respect to, among other things, future events and performance. We generally identify forward-looking statements by words such as “anticipate,” “estimate,” “could,” “expect,” “intend,” “project,” “plan,” “predict,” “believe,” “seek,” “continue,” “outlook,” “objective,” “target,” “may,” “might,” “will,” “have,” “likely” or the negative version of these words or comparable words or by using future dates in connection with any discussion of future performance, actions or events. Forward-looking statements are based on beliefs and assumptions made by management using currently available information. These statements are not guarantees of future performance, actions or events.

In particular, forward-looking statements include statements relating to our 2019 financial guidance, future actions, business plans or prospects, prospective products, product approvals or products under development, product supply disruptions, R&D costs, timing and likelihood of success, future operating or financial performance, future results of current and anticipated products and services, strategies, sales efforts, expenses, production efficiencies, production margins, anticipated timing of generic market entries, integration of acquired businesses, interest rates, tax rates, changes in tax regimes and laws, foreign exchange rates, growth in emerging markets, the outcome of contingencies, such as legal proceedings, plans related to share repurchases and dividends, government regulation and financial results. Forward-looking statements are subject to risks and uncertainties, many of which are beyond our control, and potentially inaccurate assumptions. However, there may also be other risks that we are unable to predict at this time. If one or more of these risks or uncertainties materialize, or if management's underlying beliefs and assumptions prove to be incorrect, actual results may differ materially from those contemplated by a forward-looking statement. You should not put undue reliance on forward-looking statements. Forward-looking statements speak only as of the date on which they are made.

We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law or by the rules and regulations of the SEC. You are advised, however, to consult any further disclosures we make on related subjects in our Form 10-Q and 8-K reports and our other filings with the SEC. We note these factors for investors as permitted by the Private Securities Litigation Reform Act of 1995. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider the following to be a complete discussion of all potential risks or uncertainties.

Risks related to our business and industry

Animal health products are subject to unanticipated safety, quality or efficacy concerns.

Unanticipated safety, quality or efficacy concerns can arise with respect to animal health products, whether or not scientifically or clinically supported, leading to product recalls, withdrawals or suspended or declining sales, as well as product liability and other claims.

Regulatory actions based on these types of safety, quality or efficacy concerns could impact all or a significant portion of a product's sales and could, depending on the circumstances, materially adversely affect our operating results.

In addition, since we depend on positive perceptions of the safety, quality and efficacy of our products, and animal health products generally, by our customers, veterinarians and end-users, any concerns as to the safety, quality or efficacy of our products, whether actual or perceived, may harm our reputation. These concerns and the related harm to our reputation could materially adversely affect our operating results and financial condition, regardless of whether such reports are accurate.

Our results of operations are dependent upon the success of our top products.

If any of our top products experience issues, such as loss of patent protection, material product liability litigation, new or unexpected side effects, manufacturing disruptions, regulatory proceedings, labeling changes, negative publicity, changes to veterinarian or customer preferences, and/or disruptive innovations or the introduction of more effective products, our revenues could be negatively impacted, perhaps significantly. Our top four products, Apoquel, Draxxin, the ceftiofur product line, and the Revolution/Stronghold line, contributed approximately 25% of our revenue in

2018. Any issues with these top products would have a more significant impact to our results of operations.

Generic and other products may be viewed as more cost-effective than our products.

We face competition from products produced by other companies, including generic alternatives to our products. We depend on patents and regulatory data exclusivity periods to provide us with exclusive marketing rights for some of our products. Patents for individual products expire at different times based on the date of the patent filing (or sometimes the date of patent grant) and the legal term of patents in the countries where such patents are obtained. The extent of protection afforded by our patents varies from country to country and is limited by the scope of the claimed subject matter of our patents, the term of the patent and the availability and enforcement of legal remedies in the applicable country. As a result, we may face competition from lower-priced generic alternatives to many of our products. Generic competitors are becoming more aggressive in terms of launching at risk before patent rights expire and, because of their pricing, are an increasing percentage of overall animal health sales in certain regions. For example, several companies have launched generic versions of our Rimadyl chewable product. As a result of generic and other competition, sales of our Rimadyl chewable product in the U.S. have declined by approximately 29% in the years since their introduction. Sales of our Clavamox products in the U.S. also continue to be negatively impacted by generic competition. If animal health customers increase their use of new or existing generic products, our operating results and financial condition could be materially adversely affected.

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Over the next several years, several of our products' patents will expire. The active ingredient of Draxxin, tulathromycin, is covered by both compound and formulation patents in the United States, Europe, Canada, Australia and other key markets, with terms that expire between May 2019 and January 2021 in the United States, between November 2018 and November 2020 in Europe, and between May 2018 and November 2020 in Canada and Australia. Generic tulathromycin products are marketed in countries such as Columbia, Vietnam, Belarus and Russia. Recently marketing authorizations were granted in Europe and there is a pending marketing authorization in Australia. At this time, market entry by generic versions in the U.S. are not anticipated before January 2021. Several patents covering the ceftiofur antibiotic product line (Excede) began expiring in the United States in 2015. However, various formulation and use patents relevant to the product line extend through to 2024. A generic version of Excede has recently entered the swine market in Mexico. At this time, the market entry of a generic version of Excede in the U.S. is not anticipated before 2024. The compound patent for selamectin, the active ingredient in our parasiticides Revolution and Stronghold, expired in 2014. Again, we have formulation patents covering these products which expire in important markets in 2019. Generic versions of selamectin are now authorized in Europe, Australia and South Korea. The market entry of a generic version of selamectin is not anticipated in the U.S. before November 2019. The ceftiofur product line, Draxxin and Revolution/Stronghold, contributed approximately 18% of our revenue in 2018. In addition, the patent for the active ingredient of Convenia® has expired, however, there are formulation patents relevant to the product line which expire between November 2022 and October 2023. The patent for the active ingredient of Cerenia has expired, however, there are formulation patents relevant to the product line which expire between May 2020 and January 2027. A generic version of Cerenia has been registered in Europe and is marketed in the European Union. At this time, there is no indication of market entry of a generic version of Cerenia in the U.S. Zoetis typically enforces its patents whenever appropriate both within and outside the United States, including by filing infringement claims against other parties.

The animal health industry is highly competitive.

The animal health industry is highly competitive. We believe many of our competitors are conducting R&D activities in areas served by our products and in areas in which we are developing products. Our competitors include standalone animal health businesses and the animal health businesses of large pharmaceutical companies. There are also several new start-up companies working in the animal health area. In certain markets, we also compete with companies that produce generic products, but the level of competition from generic products varies from market to market. These competitors may have access to greater financial, marketing, technical and other resources. As a result, they may be able to devote more resources to developing, manufacturing, marketing and selling their products, initiating or withstanding substantial price competition or more readily taking advantage of acquisitions or other opportunities. Further, consolidation in the animal health industry could result in existing competitors realizing additional efficiencies or improving portfolio bundling opportunities, thereby potentially increasing their market share and pricing power, which could lead to a decrease in our revenue and profitability and an increase in competition. In addition to competition from established market participants, new entrants to the animal health medicines and vaccines industry could substantially reduce our market share or render our products obsolete.

To the extent that any of our competitors are more successful with respect to any key competitive factor or we are forced to reduce, or are unable to raise, the price of any of our products in order to remain competitive, our operating results and financial condition could be materially adversely affected. Competitive pressure could arise from, among other things, safety and efficacy concerns, limited demand growth or a significant number of additional competitive products being introduced into a particular market, price reductions by competitors, the ability of competitors to capitalize on their economies of scale, the ability of competitors to produce or otherwise procure animal health products at lower costs than us and the ability of competitors to access more or newer technology than us. Disruptive innovations and advances in medical practices and technologies could negatively affect the market for our products.

The market for our products could be impacted negatively by the introduction and/or broad market acceptance of newly-developed or alternative products that address the diseases and conditions for which we sell products, including “green” or “holistic” health products or specially bred disease-resistant animals. In addition, technological breakthroughs by others may obviate our technology and reduce or eliminate the market for our products. Introduction or acceptance

of such products or technologies could materially adversely affect our operating results and financial condition. Consolidation of our customers and distributors could negatively affect the pricing of our products.

Veterinarians and livestock producers are our primary customers. In recent years, there has been a trend towards the concentration of veterinarians in large clinics and hospitals. In addition, livestock producers, particularly swine and poultry producers, and our distributors, have seen consolidation in their industries. Furthermore, we have seen the expansion of larger cross-border corporate customers and an increase in the consolidation of buying groups (cooperatives of veterinary practices that leverage volume to pursue discounts from manufacturers). The pace of consolidation and structure of markets varies greatly across geographies. If these trends towards consolidation continue, these customers and distributors could attempt to improve their profitability by leveraging their buying power to obtain favorable pricing. The resulting decrease in our prices could have a material adverse effect on our operating results and financial condition.

Changes in distribution channels for companion animal products could negatively impact our market share, margins and distribution of our products.

In most markets, companion animal owners typically purchase their animal health products directly from veterinarians. Companion animal owners increasingly have the option to purchase animal health products from sources other than veterinarians, such as Internet-based retailers, “big-box” retail stores or other over-the-counter distribution channels. This trend has been demonstrated by the significant shift away from the veterinarian distribution channel in the sale of flea and tick products in recent years. Companion animal owners also could decrease their reliance on, and visits to, veterinarians as they rely more on Internet-based animal health information. Because we market our companion animal prescription products through the veterinarian distribution channel, any decrease in visits to veterinarians by companion animal owners could reduce our market share for such products and materially adversely affect our operating results and financial condition. In addition, companion animal owners may substitute human health products for animal health products if human health products are deemed to be lower-cost alternatives. Legislation has also been proposed in the United States in the past, and may be proposed in the United States or abroad in the future, that could impact the distribution channels for our companion animal products. For example, such legislation may require veterinarians to provide pet owners with written prescriptions and disclosure that the pet owner may fill prescriptions through a third party, which may further reduce the number of pet

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owners who purchase their animal health products directly from veterinarians. Such requirements may lead to increased use of generic alternatives to our products or the increased substitution of our products with other animal health products or human health products if such other products are deemed to be lower-cost alternatives. Many states already have regulations requiring veterinarians to provide prescriptions to pet owners upon request and the American Veterinary Medical Association has long-standing policies in place to encourage this practice.

Over time, these and other competitive conditions may increase our reliance on Internet-based retailers, “big-box” retail stores or other over-the-counter distribution channels to sell our companion animal products. We may be unable to sustain our current margins and we may not be adequately prepared or able to distribute our products if an increased portion of our sales is through these channels. Any of these events could materially adversely affect our operating results and financial condition.

We may not successfully acquire and integrate other businesses, license rights to technologies or products, form and manage alliances or divest businesses.

We pursue acquisitions, technology licensing arrangements, strategic alliances or divestitures of some of our businesses as part of our business strategy. We may not complete these transactions in a timely manner, on a cost-effective basis or at all. In addition, we may be subject to regulatory constraints or limitations or other unforeseen factors that prevent us from realizing the expected benefits. Even if we are successful in making an acquisition, the products and technologies that are acquired may not be successful or may require significantly greater resources and investments than originally anticipated. We may be unable to integrate acquisitions successfully into our existing business, and we may be unable to achieve expected gross margin improvements or efficiencies. We also could incur or assume significant debt and unknown or contingent liabilities. Our reported results of operations could be negatively affected by acquisition or disposition-related charges, amortization of expenses related to intangibles and charges for impairment of long-term assets. We may be subject to litigation in connection with, or as a result of, acquisitions, dispositions, licenses or other alliances, including claims from terminated employees, customers or third parties, and we may be liable for future or existing litigation and claims related to the acquired business, disposition, license or other alliance because either we are not indemnified for such claims or the indemnification is insufficient. These effects could cause us to incur significant expenses and could materially adversely affect our operating results and financial condition.

Restrictions and bans on the use of and consumer preferences regarding antibacterials in food-producing animals may become more prevalent.

The issue of the potential transfer of increased antibacterial resistance in bacteria from food-producing animals to human pathogens, and the causality of that transfer, continue to be the subject of global scientific and regulatory discussion. Antibacterials refer to small molecules that can be used to treat or prevent bacterial infections and are a sub-categorization of the products that make up our anti-infectives and medicated feed additives portfolios. In some countries, this issue has led to government restrictions and bans on the use of specific antibacterials in some food-producing animals, regardless of the route of administration (in feed or injectable). These restrictions are more prevalent in countries where animal protein is plentiful and governments are willing to take action even when there is scientific uncertainty. Our total revenue attributable to antibacterials for livestock was approximately \$1.3 billion for the year ended December 31, 2018.

For example, in December 2013, the FDA announced final guidance establishing procedures for the voluntary phase-out in the United States over a three-year period of the use of medically important antibacterials in animal feed for growth promotion in food production animals (medically important antibacterials include classes that are prescribed in animal and human health). The guidance provides for continued use of antibacterials in food producing animals for treatment, control and under certain circumstances for prevention of disease, all under the supervision of a veterinarian. The FDA indicated that it took this action to help preserve the efficacy of medically important antibacterials to treat infections in humans. As part of those efforts, stricter regulations governing the administration of medically important antibiotics are now effective. The use of medically important antibiotics in the water or feed of food production animals now requires written authorization by a licensed veterinarian under the FDA guidance and the related rule known as the Veterinary Feed Directive.

Two new veterinary medicines regulations in the EU were adopted in November 2018 and provide additional restrictions on the use of antibiotics in the EU. The regulations will be fully implemented by the end of 2021. In addition, other countries, such as France, Germany and Vietnam, have passed restrictions or bans on antibiotic use. In certain markets, there has been an increase in consumer preference towards proteins produced without the use of antibiotics.

We cannot predict whether antibacterial resistance concerns will result in additional restrictions or bans, expanded regulations, public pressure to discontinue or reduce use of antibacterials in food-producing animals or increased consumer preference for antibiotic-free protein, any of which could materially adversely affect our operating results and financial condition.

Perceived adverse effects on human health linked to the consumption of food derived from animals that utilize our products could cause a decline in the sales of such products.

Our livestock business depends heavily on a healthy and growing livestock industry. If the public perceives a risk to human health from the consumption of the food derived from animals that utilize our products, there may be a decline in the production of such food products and, in turn, demand for our products. For example, livestock producers may experience decreased demand for their products or reputational harm as a result of evolving consumer views of animal rights, nutrition, health-related or other concerns. Any reputational harm to the livestock industry may also extend to companies in related industries, including our company. Adverse consumer views related to the use of one or more of our products in livestock also may result in a decrease in the use of such products and could have a material adverse effect on our operating results and financial condition.

Our business is subject to risk based on global economic conditions.

Macroeconomic, business and financial disruptions could have a material adverse effect on our operating results, financial condition and liquidity. Certain of our customers and suppliers could be affected directly by an economic downturn and could face credit issues or cash flow problems that could give rise to payment delays, increased credit risk, bankruptcies and other financial hardships that could decrease the demand for our products or hinder our ability to collect amounts due from customers. If one or more of our large customers, including distributors, discontinue their relationship

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with us as a result of economic conditions or otherwise, our operating results and financial condition may be materially adversely affected. In addition, economic concerns may cause some pet owners to forgo or defer visits to veterinary practices or could reduce their willingness to treat pet health conditions or even to continue to own a pet. Furthermore, our exposure to credit and collectability risk is higher in certain international markets and our ability to mitigate such risks may be limited. While we have procedures to monitor and limit exposure to credit and collectability risk, there can be no assurances such procedures will effectively limit such risk and avoid losses. Increased regulation or decreased governmental financial support relating to the raising, processing or consumption of food-producing animals could reduce demand for our livestock products.

Companies in the livestock industries are subject to extensive and increasingly stringent regulations. If livestock producers are adversely affected by new regulations or changes to existing regulations, they may reduce herd sizes or become less profitable and, as a result, they may reduce their use of our products, which may materially adversely affect our operating results and financial condition. Furthermore, new or more stringent regulations could, directly or indirectly, impact the use of one or more of our products. More stringent regulation of the livestock industry or our products could have a material adverse effect on our operating results and financial condition. Also, many food-producing companies, including livestock producers, benefit from governmental subsidies, and if such subsidies were to be reduced or eliminated, these companies may become less profitable and, as a result, may reduce their use of our products.

An outbreak of infectious disease carried by animals could negatively affect the sale and production of our products. Sales of our livestock products could be materially adversely affected by the outbreak of disease carried by animals, which could lead to the widespread death or precautionary destruction of animals as well as the reduced consumption and demand for animal protein. In addition, outbreaks of disease carried by animals may reduce regional or global sales of particular animal-derived food products or result in reduced exports of such products, either due to heightened export restrictions or import prohibitions, which may reduce demand for our products due to reduced herd or flock sizes. In recent years, outbreaks of various diseases, including African Swine Fever, avian influenza, foot-and-mouth disease, bovine spongiform encephalopathy (otherwise known as BSE or mad cow disease) and porcine epidemic diarrhea virus (otherwise known as PEDv), have impacted the animal health business. The discovery of additional cases of any of these, or new, diseases may result in additional restrictions on animal proteins, reduced herd sizes, or reduced demand for, animal protein, which may have a material adverse effect on our operating results and financial condition. Also, the outbreak of any highly contagious disease near our main production sites could require us to immediately halt production of our products at such sites or force us to incur substantial expenses in procuring raw materials or products elsewhere.

Our business may be negatively affected by weather conditions and the availability of natural resources. The animal health industry and demand for many of our animal health products in particular regions are affected by weather conditions, as usage of our products follows varying weather patterns and weather-related pressures from pests, such as ticks. As a result, we may experience regional and seasonal fluctuations in our results of operations. In addition, veterinary hospitals and practitioners depend on visits from and access to animals under their care. Veterinarians' patient volume and ability to operate could be adversely affected if they experience prolonged snow, ice or other weather conditions, particularly in regions not accustomed to sustained inclement weather. Furthermore, livestock producers depend on the availability of natural resources, including large supplies of fresh water. Their animals' health and their ability to operate could be adversely affected if they experience a shortage of fresh water due to human population growth or floods, droughts or other weather conditions. In the event of adverse weather conditions or a shortage of fresh water, veterinarians or livestock producers may purchase less of our products. Severe droughts can lead to a decrease in harvested corn and higher corn prices, which may impact the profitability of livestock producers of cattle, pork and poultry. Higher corn prices may contribute to reductions in herd or flock sizes that may result in reduced spending on animal health products. In addition, droughts can lead to reduced availability of grazing pastures, forcing cattle producers to cull their herds. Fewer heads of cattle could result in reduced demand for our products. A prolonged drought could have a material adverse effect on our operating results and financial condition. Heat waves may cause stress in animals and lead to increased vulnerability to disease, reduced fertility rates and reduced milk production. In addition, climate change may increase the prevalence of parasites and diseases that

affect food animals.

Adverse weather conditions may also have a material impact on the aquaculture business. Changes in water temperatures could affect the timing of reproduction and growth of various fish species, as well as trigger the outbreak of certain water borne diseases.

Modification of foreign trade policy by the U.S. or foreign countries or the imposition of tariffs on U.S. or foreign goods may harm our business.

Changes in U.S. laws, agreements and policies governing foreign trade in the territories and countries where our customers do business could negatively impact such customers' businesses and adversely affect our operating results.

A number of our customers, particularly U.S.-based livestock producers, benefit from free trade agreements such as the North American Free Trade Agreement (NAFTA). The U.S., Canada and Mexico reached an agreement to replace NAFTA with the United States-Mexico-Canada Agreement (USMCA). Most provisions of the USMCA will not begin until 2020. These new provisions, as well as any other changes to international trade agreements or policies could harm our customers, and as a result, negatively impact our financial condition and results of operations.

Additionally, in response to new U.S. tariffs affecting foreign exports, some foreign governments, including China, have instituted or are considering instituting tariffs on certain U.S. goods. While the scope and duration of these and any future tariffs remains uncertain, tariffs imposed by the U.S. or foreign governments on our products or the active pharmaceutical ingredients or other components thereof could negatively impact our financial condition and results of operations.

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Our business is subject to risk based on customer exposure to rising costs and reduced customer income.

Feed, fuel and transportation and other key costs for livestock producers may increase or animal protein prices or sales may decrease. Either of these trends could cause deterioration in the financial condition of our livestock product customers, potentially inhibiting their ability to purchase our products or pay us for products delivered. Our livestock product customers may offset rising costs by reducing spending on our products, including by switching to lower-cost alternatives to our products. In addition, concerns about the financial resources of pet owners also could cause veterinarians to alter their treatment recommendations in favor of lower-cost alternatives to our products. These shifts could result in a decrease in sales of our companion animal products, especially in developed countries where there is a higher rate of pet ownership.

Our business could be adversely affected by labor disputes, strikes or work stoppages.

Some of our employees are members of unions, works councils, trade associations or are otherwise subject to collective bargaining agreements in certain jurisdictions, including the United States. As a result, we are subject to the risk of labor disputes, strikes, work stoppages and other labor-relations matters. We may be unable to negotiate new collective bargaining agreements on similar or more favorable terms and may experience work stoppages or other labor problems in the future at our sites. We could experience a disruption of our operations or higher ongoing labor costs, which could have a material adverse effect on our operating results and financial condition, potentially resulting in canceled orders by customers, unanticipated inventory accumulation or shortages and reduced revenue and net income. We may also experience difficulty or delays in implementing changes to our workforce in certain markets. In addition, labor problems at our suppliers, CMOs or other service providers could have a material adverse effect on our operating results and financial condition.

Loss of our executive officers or other key personnel could disrupt our operations.

We depend on the efforts of our executive officers and certain key personnel. Our executive officers and other key personnel are not currently, and are not expected to be, subject to non-compete provisions. In addition, we generally do not enter into employment agreements with our executive officers and other key personnel. Any unplanned turnover or our failure to develop an adequate succession plan for one or more of our executive officers or other key positions could deplete our institutional knowledge base and erode our competitive advantage. The loss or limited availability of the services of one or more of our executive officers or other key personnel, or our inability to recruit and retain qualified executive officers or other key personnel in the future, could, at least temporarily, have a material adverse effect on our operating results and financial condition.

We may be required to write down goodwill or identifiable intangible assets.

Under accounting principles generally accepted in the United States of America (U.S. GAAP), if we determine goodwill or identifiable intangible assets are impaired, we will be required to write down these assets and record a non-cash impairment charge. As of December 31, 2018, we had goodwill of \$2.5 billion and identifiable intangible assets, less accumulated amortization, of \$2.0 billion. Identifiable intangible assets consist primarily of developed technology rights, brands, trademarks, license agreements, patents, acquired customer relationships and in-process R&D.

Determining whether an impairment exists and the amount of the potential impairment involves quantitative data and qualitative criteria that are based on estimates and assumptions requiring significant management judgment. Future events or new information may change management's valuation of an intangible asset in a short amount of time. The timing and amount of impairment charges recorded in our consolidated statements of income and write-downs recorded in our consolidated balance sheets could vary if management's conclusions change. Any impairment of goodwill or identifiable intangible assets could have a material adverse effect on our operating results and financial position.

Risks related to research and development

Our R&D, acquisition and licensing efforts may fail to generate new products and product lifecycle innovations. Our future success depends on both our existing product portfolio and our pipeline of new products, including new products that we may develop through joint ventures and products that we are able to obtain through license or acquisition. We commit substantial effort, funds and other resources to R&D, both through our own dedicated resources and through collaborations with third parties.

We may be unable to determine with accuracy when or whether any of our products now under development will be approved or launched, or we may be unable to develop, license or otherwise acquire product candidates or products. In addition, we cannot predict whether any products, once launched, will be commercially successful or will achieve sales and revenue that are consistent with our expectations. The animal health industry is subject to regional and local trends and regulations and, as a result, products that are successful in some of our markets may not achieve similar success when introduced into new markets. Furthermore, the timing and cost of our R&D may increase, and our R&D may become less predictable. For example, changes in regulations applicable to our industry may make it more time-consuming and/or costly to research, develop and register products. If we are unable to generate new products or expand the use of our existing products, our business, financial condition and results of operations will be materially adversely affected.

Products in the animal health industry are sometimes derived from molecules and compounds discovered or developed as part of human health research. We have and expect to continue to enter into collaboration or licensing arrangements with third parties, including Pfizer, to provide us with access to compounds and other technology for purposes of our business. Such agreements are typically complex and require time to negotiate and implement. If we enter into these arrangements, we may not be able to maintain these relationships or establish new ones in the future on acceptable terms or at all. In addition, any collaboration that we enter into may not be successful, and the success may depend on the efforts and actions of our collaborators, which we may not be able to control. If we are unable to access human health-generated molecules and compounds to conduct R&D on cost-effective terms, our ability to develop some types of new products could be limited.

Our R&D relies on evaluations in animals, which may become subject to bans or additional restrictive regulations. As an animal health medicines and vaccines business, the evaluation of our existing and new products in animals is required to register our products. Animal testing in certain industries has been the subject of controversy and adverse publicity. Some organizations and individuals have attempted to ban animal testing or encourage the adoption of additional regulations applicable to animal testing. To the extent that the activities of such

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organizations and individuals are successful, our R&D, and by extension our operating results and financial condition, could be materially adversely affected. In addition, negative publicity about us or our industry could harm our reputation.

Risks related to manufacturing

Manufacturing problems and capacity imbalances may cause product launch delays, inventory shortages, recalls or unanticipated costs.

In order to sell our products, we must be able to produce and ship our products in sufficient quantities. On December 31, 2018, we had a global manufacturing network consisting of 25 manufacturing sites located in 12 countries. We also employ a network of approximately 172 third party CMOs. Many of our products involve complex manufacturing processes and are sole-sourced from certain manufacturing sites.

Minor deviations in our manufacturing or logistical processes, such as temperature excursions or improper package sealing, could result in delays, inventory shortages, unanticipated costs, product recalls, product liability and/or regulatory action. In addition, a number of factors could cause production interruptions, including:

- the failure of us or any of our vendors or suppliers, including logistical service providers, to comply with applicable regulations and quality assurance guidelines, including any changes to Good Manufacturing Practices (GMP);
- mislabeling;
- construction delays;
- equipment malfunctions;
- shortages of materials;
- labor problems;
- delays in receiving any required governmental authorizations, including as a result of any prolonged shutdown of the U.S. government;
- natural disasters;
- power outages;
- criminal and terrorist activities;
- changes in manufacturing production sites and limits to manufacturing capacity due to regulatory requirements, changes in types of products produced, shipping distributions or physical limitations; and
- the outbreak of any highly contagious diseases near our production sites.

These interruptions could result in launch delays, inventory shortages, recalls, unanticipated costs or issues with our agreements under which we supply third parties, which may adversely affect our operating results and financial condition. For example, we experienced challenges in manufacturing Apoquel when it was initially launched in 2015 that impacted our ability to meet customer demand. As a result, we had to place limits on the amounts of this product veterinarians could purchase and delayed the launch of the product in certain markets.

Our manufacturing network may be unable to meet the demand for our products or we may have excess capacity if demand for our products changes. The unpredictability of a product's regulatory or commercial success or failure, the lead time necessary to construct highly technical and complex manufacturing sites, and shifting customer demand (including as a result of market conditions or entry of branded or generic competition) increase the potential for capacity imbalances. In addition, construction of sites is expensive, and our ability to recover costs will depend on the market acceptance and success of the products produced at the new sites, which is uncertain.

We rely on third parties to provide us with materials and services, and are subject to increased labor and material costs and potential disruptions in supply.

The materials used to manufacture our products may be subject to availability constraints and price volatility caused by changes in demand, weather conditions, supply conditions, government regulations, economic climate and other factors. In addition, labor costs may be subject to volatility caused by the supply of labor, governmental regulations, economic climate and other factors. Increases in the demand for, availability or the price of, materials used to manufacture our products and increases in labor costs could increase the costs to manufacture our products, result in product delivery delays or shortages, and impact our ability to launch new products on a timely basis or at all. We may not be able to pass all or a material portion of any higher material or labor costs on to our customers, which could materially adversely affect our operating results and financial condition.

In addition, certain third-party suppliers are the sole or exclusive source of certain materials and services necessary for production of our products. We may be unable to meet demand for certain of our products if any of our third-party suppliers cease or interrupt operations, fail to renew contracts with us or otherwise fail to meet their obligations to us. There may be delays and additional costs due to changes to our existing manufacturing facilities and the construction of new manufacturing plants.

As part of our supply network strategy, we have invested and will continue to invest in improvements to our existing manufacturing facilities and in new manufacturing plants. We are currently investing in two new plants, one in Rathdrum, Ireland for the production of active ingredients for some of our key products and one in Suzhou, China for the research and production of vaccines in China. In addition, certain of our existing manufacturing facilities are in the process of being upgraded. These types of projects are subject to risks of delay or cost overruns inherent in any large construction project, and will require licensure by various regulatory authorities. Significant cost overruns or delays in completing these projects could have an adverse effect on the Company's return on investment.

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Risks related to legal matters and regulation

Our business is subject to substantial regulation.

As a global company, we are subject to various state, federal and international laws and regulations, including regulations relating to the development, quality assurance, manufacturing, importation, distribution, marketing and sale of our products. In addition, our manufacturing facilities are subject to periodic inspections by regulatory agencies. An inspection may report conditions or practices that indicate possible violations of regulatory requirements. Our failure, or the failure of third parties we rely on, including CMOs, to comply with these regulatory requirements, allegations of such non-compliance or the discovery of previously unknown problems with a product or manufacturer could result in, among other things, inspection observation notices, warning letters or similar regulatory correspondence, fines, a partial or total shutdown of production in one or more of our facilities while an alleged violation is remediated, withdrawals or suspensions of current products from the market, and civil or criminal prosecution, as well as decreased sales as a result of negative publicity and product liability claims. Any one of these consequences could materially adversely affect our operating results and financial condition.

In addition, we will not be able to market new products unless and until we have obtained all required regulatory approvals in each jurisdiction where we propose to market those products. Even after a product reaches market, it may be subject to re-review and may lose its approvals. We have changed, and may in the future change, the locations of where certain of our products are manufactured and, because of these changes, we may be required to obtain new regulatory approvals. Our failure to obtain approvals, delays in the approval process, including any delays resulting from any prolonged shutdown of the U.S. government, or our failure to maintain approvals in any jurisdiction, may prevent us from selling products in that jurisdiction until approval or reapproval is obtained, if ever.

Furthermore, we cannot predict the nature of future laws, regulations, or changes in tax laws and tariffs, nor can we determine the effect that additional laws or regulations or changes in existing laws or regulations could have on our business when and if promulgated, or the impact of changes in the interpretation of these laws and regulations, or of disparate federal, state, local and foreign regulatory schemes. Changes to such laws or regulations may include, among other things, changes to taxation requirements, such as tax-rate changes and changes affecting the taxation by the United States of income earned outside the United States.

Changes in applicable federal, state, local and foreign laws and regulations could have a material adverse effect on our operating results and financial condition.

We may incur substantial costs and receive adverse outcomes in litigation and other legal matters.

Our operating results, financial condition and liquidity could be materially adversely affected by unfavorable results in pending or future litigation matters. These matters include, among other things, allegations of violation of United States and foreign competition laws, labor laws, consumer protection laws, and environmental laws and regulations, as well as claims or litigations relating to product liability, intellectual property, securities, breach of contract and tort. In addition, changes in the interpretations of laws and regulations to which we are subject, or in legal standards in one or more of the jurisdictions in which we operate, could increase our exposure to liability. For example, in the United States, attempts have been made to allow damages for emotional distress and pain and suffering in connection with the loss of, or injury to, a companion animal. If such attempts were successful, our exposure with respect to product liability claims could increase materially.

Litigation matters, regardless of their merits or their ultimate outcomes, are costly, divert management's attention and may materially adversely affect our reputation and demand for our products. We cannot predict with certainty the eventual outcome of pending or future litigation matters. An adverse outcome of litigation or legal matters could result in our being responsible for significant damages. Any of these negative effects resulting from litigation matters could materially adversely affect our operating results and financial condition.

The misuse or off-label use of our products may harm our reputation or result in financial or other damages.

Our products have been approved for use under specific circumstances for the treatment of certain diseases and conditions in specific species. There may be increased risk of product liability claims if veterinarians, livestock producers, pet owners or others attempt to use our products off-label, including the use of our products in species (including humans) for which they have not been approved. For example, Ketamine, the active pharmaceutical ingredient in our Ketaset product (a nonnarcotic agent for anesthetic use in cats), is abused by humans as a

hallucinogen. Furthermore, the use of our products for indications other than those indications for which our products have been approved may not be effective, which could harm our reputation and lead to an increased risk of litigation. If we are deemed by a governmental or regulatory agency to have engaged in the promotion of any of our products for off-label use, such agency could request that we modify our training or promotional materials and practices and we could be subject to significant fines and penalties, and the imposition of these sanctions could also affect our reputation and position within the industry. Any of these events could materially adversely affect our operating results and financial condition.

The illegal distribution and sale by third parties of counterfeit or illegally compounded versions of our products or of stolen, diverted or relabeled products could have a negative impact on our reputation and business.

Third parties may illegally distribute and sell counterfeit or illegally compounded versions of our products that do not meet the exacting standards of our development, manufacturing and distribution processes. Counterfeit or illegally compounded medicines pose a significant risk to animal health and safety because of the conditions under which they are manufactured and the lack of regulation of their contents. Counterfeit or illegally compounded products are frequently unsafe or ineffective and can be potentially life-threatening to animals. Our reputation and business could suffer harm as a result of counterfeit or illegally compounded products which are alleged to be equivalent and/or which are sold under our brand name. We are aware of at least one pharmacy in Brazil that may be engaged in the practice of illegally compounding oclacitinib, the active pharmaceutical ingredient in our Apoquel product. In addition, products stolen or unlawfully diverted from inventory, warehouses, plants or while in transit, which are not properly stored or which have an expired shelf life and which have been repackaged or relabeled and which are sold through unauthorized channels, could adversely impact animal health and safety, our reputation and our business. Public loss of confidence in the integrity of vaccines and/or pharmaceutical products as a result of counterfeiting, illegally compounding or theft could have a material adverse effect on our product sales, business and results of operations.

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We are subject to complex environmental, health and safety laws and regulations.

We are subject to various federal, state, local and foreign environmental, health and safety laws and regulations. These laws and regulations govern matters such as the emission and discharge of hazardous materials into the ground, air or water; the generation, use, storage, handling, treatment, packaging, transportation, exposure to, and disposal of hazardous and biological materials, including recordkeeping, reporting and registration requirements; and the health and safety of our employees. Due to our operations, these laws and regulations also require us to obtain, and comply with, permits, registrations or other authorizations issued by governmental authorities. These authorities can modify or revoke our permits, registrations or other authorizations and can enforce compliance through fines and injunctions. Given the nature of our business, we have incurred, are currently incurring and may in the future incur, liabilities under CERCLA or under other federal, state, local and foreign environmental cleanup laws, with respect to our current or former sites, adjacent or nearby third-party sites, or offsite disposal locations. See Item 1. Business—Environmental, Health and Safety. The costs associated with future cleanup activities that we may be required to conduct or finance could be material. Additionally, we may become liable to third parties for damages, including personal injury and property damage, resulting from the disposal or release of hazardous materials into the environment. Such liability could materially adversely affect our operating results and financial condition. Furthermore, regulatory agencies are showing increasing concern over the impact of animal health products and livestock operations on the environment. This increased regulatory scrutiny may necessitate that additional time and resources be spent to address these concerns in both new and existing products.

A failure to comply with the environmental, health and safety laws and regulations to which we are subject, including any permits issued thereunder, may result in environmental remediation costs, loss of permits, fines, penalties or other adverse governmental or private actions, including regulatory or judicial orders enjoining or curtailing operations or requiring corrective measures, installation of pollution control equipment or remedial measures. We could also be held liable for any and all consequences arising out of human exposure to hazardous materials or environmental damage. Environmental laws and regulations are complex, change frequently, have tended to become more stringent and stringently enforced over time and may be subject to new interpretation. We cannot assure you that our costs of complying with current and future environmental, health and safety laws, and our liabilities arising from past or future releases of, or exposure to, hazardous materials will not materially adversely affect our business, results of operations or financial condition.

Risks related to operating in foreign jurisdictions

A significant portion of our operations are conducted in foreign jurisdictions, including jurisdictions presenting a high risk of bribery and corruption, and are subject to the economic, political, legal and business environments of the countries in which we do business.

Our international operations could be limited or disrupted by any of the following:

- volatility in the international financial markets;
- compliance with governmental controls;
- difficulties enforcing contractual and intellectual property rights;
- parallel trade in our products (importation of our products from European Union countries where our products are sold at lower prices into European Union countries where the products are sold at higher prices);
- compliance with a wide variety of laws and regulations, such as the FCPA and similar non-U.S. laws and regulations;
- compliance with foreign labor laws;
- burdens to comply with multiple and potentially conflicting foreign laws and regulations, including those relating to environmental, health and safety requirements;
- changes in laws, regulations, government controls or enforcement practices with respect to our business and the businesses of our customers, including the imposition of limits on our profitability;
- political and social instability, including crime, civil disturbance, terrorist activities and armed conflicts;
- trade restrictions and restrictions on direct investments by foreign entities, including restrictions administered by the Office of Foreign Assets Control of the U.S. Department of Treasury (OFAC) and the European Union, in relation to our products or the products of farmers and other customers (e.g., restrictions on the importation of agricultural

products from the European Union to Russia);
government limitations on foreign ownership;
government takeover or nationalization of business;
changes in tax laws and tariffs;
imposition of anti-dumping and countervailing duties or other trade-related sanctions;
costs and difficulties and compliance risks in staffing, managing and monitoring international operations, including the use of overseas third-party goods and service providers;
• corruption risk inherent in business arrangements and regulatory contacts with foreign government entities;
longer payment cycles and increased exposure to counterparty risk; and
• additional limitations on transferring personal information between countries or other restrictions on the processing of personal information.

In addition, international transactions may involve increased financial and legal risks due to differing legal systems and customs. Compliance with these requirements may prohibit the import or export of certain products and technologies or may require us to obtain a license before importing or exporting certain products or technology. A failure to comply with any of these laws, regulations or requirements could result in civil or criminal legal proceedings, monetary or non-monetary penalties, or both, disruptions to our business, limitations on our ability to import and export products and services, and damage to our reputation. In addition, variations in the pricing of our products between jurisdictions may result in the unauthorized

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importation or unauthorized re-importation of our products between jurisdictions and may also result in the imposition of anti-dumping and countervailing duties or other trade-related sanctions. While the impact of these factors is difficult to predict, any of them could materially adversely affect our operating results and financial condition. Changes in any of these laws, regulations or requirements, or the political environment in a particular country, may affect our ability to engage in business transactions in certain markets, including investment, procurement and repatriation of earnings.

In June 2016, voters in the United Kingdom (UK) approved an advisory referendum to withdraw from the European Union, commonly referred to as "Brexit." This referendum has created political and economic uncertainty, particularly in the United Kingdom and the European Union, and this uncertainty may persist for years. A withdrawal without a trade agreement in place could significantly disrupt the free movement of goods, services, and people between the United Kingdom and the European Union, and result in increased legal and regulatory complexities, as well as potential higher costs of conducting business in Europe. Additional Brexit-related impacts on our business could include potential inventory shortages in the UK, increased regulatory burdens and costs to comply with UK-specific regulations and higher transportation costs for our products coming into and out of the UK. The United Kingdom's vote to exit the European Union could also result in similar referendums or votes in other European countries in which we do business. On March 29, 2017, United Kingdom Prime Minister Theresa May formally notified the European Council of the UK's intention to withdraw from the European Union under Article 50 of the Treaty of Lisbon. The notice began the two-year negotiation period to establish the withdrawal terms. While no agreement has yet been reached, the UK's separation will still become effective on March 29, 2019, unless the remaining European Union members unanimously agree to an extension. The uncertainty surrounding the terms of the United Kingdom's withdrawal and its consequences could adversely impact consumer and investor confidence, and could affect sales or regulation of our products. Any of these effects, among others, could materially and adversely affect our business, results of operations, and financial condition.

Foreign exchange rate fluctuations and potential currency controls affect our results of operations, as reported in our financial statements.

We conduct operations in many areas of the world, involving transactions denominated in a variety of currencies. In 2018, we generated approximately 47% of our revenue in currencies other than the U.S. dollar, principally the euro, Brazilian real, Chinese renminbi, Canadian dollar, Australian dollar, and U.K. pound. We are subject to currency exchange rate risk to the extent that our costs are denominated in currencies other than those in which we earn revenue. In addition, because our financial statements are reported in U.S. dollars, changes in currency exchange rates between the U.S. dollar and other currencies have had, and will continue to have, an impact on our results of operations.