UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

ANNUAL REPORT UNDER SECTION 13 or 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2021

Commission file number 001-38661

Elanco Animal Health Incorporated

(Exact name of Registrant as specified in its charter)

INDIANA	82-5497352
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

2500 INNOVATION WAY, GREENFIELD, INDIANA 46140
(Address of principal executive offices)

Registrant's telephone number, including area code (877) 352-6261

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, no par value	ELAN	New York Stock Exchange
5.00% Tangible Equity Units	ELAT	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 the 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 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 a "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒	Accelerated filer ☐
Non-accelerated filer ☐	Smaller reporting company ☐
	Emerging growth company ☐

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes ☐ No ☒

Aggregate market value of the common equity held by non-affiliates computed by reference to the price at which the common equity was last sold as of June 30, 2021, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $16.4 billion. The registrant has no non-voting common stock.

The number of shares of common stock outstanding as of February 23, 2022 was 473,186,752.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy materials for its 2022 Annual Meeting of Shareholders are incorporated by reference into Part III hereof.

ELANCO ANIMAL HEALTH INCORPORATED
FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2021
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FORWARD-LOOKING STATEMENTS AND RISK FACTOR SUMMARY

This Annual Report on Form 10-K (Form 10-K) includes forward-looking statements within the meaning of the federal securities laws. These forward-looking statements, include, without limitation, statements concerning the impact on Elanco Animal Health Incorporated and its subsidiaries (collectively, Elanco, the Company, we, us, or our) caused by the integration of Kindred Biosciences, Inc. (KindredBio) and the animal health business of Bayer Aktiengesellschaft (Bayer), expected synergies and cost savings, expectations relating to the potential carve-out of the microbiome research and development (R&D) platform, the sales of manufacturing facilities, product launches, expectations relating to human capital resources, the coronavirus (COVID-19) global pandemic, reduction of debt, expectations relating to liquidity and sources of capital, our expected compliance with debt covenants, cost savings, expenses, and reserves relating to restructuring actions, our industry and our operations, performance and financial condition, and including in particular, statements relating to our business, growth strategies, distribution strategies, product development efforts and future expenses.

Forward-looking statements are based on our current expectations and assumptions regarding our business, the economy and other future conditions. Because forward-looking statements relate to the future, by their nature, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict. As a result, our actual results may differ materially from those contemplated by the forward-looking statements. Important risk factors that could cause actual results to differ materially from those in the forward-looking statements include regional, national, or global political, economic, business, competitive, market, and regulatory conditions, including but not limited to the following:

- heightened competition, including from generics;
- the impact of disruptive innovations and advances in veterinary medical practices, animal health technologies and alternatives to animal-derived protein;
- changes in regulatory restrictions on the use of antibiotics in farm animals;
- our ability to implement our business strategies or achieve targeted cost efficiencies and gross margin improvements;
- consolidation of our customers and distributors;
- an outbreak of infectious disease carried by farm animals;
- the impact on our operations, the supply chain, customer demand, and our liquidity as a result of the COVID-19 global health pandemic;
- the success of our R&D and licensing efforts;
- misuse, off-label or counterfeiting use of our products;
- unanticipated safety, quality or efficacy concerns and the impact of identified concerns associated with our products;
- fluctuations in our business results due to seasonality and other factors;
- the impact of weather conditions and the availability of natural resources;
- risks related to the modification of foreign trade policy;
- risks related to currency rate fluctuations;
- our dependence on the success of our top products;
- the impact of customer exposure to rising costs and reduced customer income and the lack of availability or significant increases in the cost of raw materials;
- use of alternative distribution channels and the impact of increased or decreased sales to our channel distributors resulting in fluctuation in our revenues;
- risks related to the write-down of goodwill or identifiable intangible assets;
- risks related to the evaluation of animals;
- manufacturing problems and capacity imbalances;
- the impact of litigation, regulatory investigations, and other legal matters and the risk that our insurance policies may be insufficient to protect us from the impact of such matters;

- actions by regulatory bodies, including as a result of their interpretation of studies on product safety;
- risks related to tax expense or exposure;
- risks related to environmental, health and safety laws and regulations;
- risks related to our presence in foreign markets;
- challenges to our intellectual property rights or our alleged violation of rights of others;
- our dependence on sophisticated information technology and infrastructure and impact of breaches of our information technology systems;
- the impact of increased regulation or decreased financial support related to farm animals;
- adverse effects of labor disputes, strikes, work stoppages, and the loss of key personnel or highly skilled employees;
- risks related to underfunded pension plan liabilities;
- our ability to complete acquisitions and successfully integrate the businesses we acquire, including KindredBio and the animal health business of Bayer (Bayer Animal Health);
- the effect of our substantial indebtedness on our business, including restrictions in our debt agreements that will limit our operating flexibility; and
- risks related to certain governance provisions in our constituent documents.

See "Risk Factors" in Part I, Item 1A of this Form 10-K for a further description of these and other factors. Although we have attempted to identify important risk factors, there may be other risk factors not presently known to us or that we presently believe are not material that could cause actual results and developments to differ materially from those made in or suggested by the forward-looking statements contained in this Form 10-K. If any of these risks materialize, or if any of the above assumptions underlying forward-looking statements prove incorrect, actual results and developments may differ materially from those made in or suggested by the forward-looking statements contained in this Form 10-K. We caution you against relying on any forward-looking statements, which should also be read in conjunction with the other cautionary statements that are included elsewhere in this Form 10-K. Any forward-looking statement made by us in this Form 10-K speaks only as of the date hereof. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to publicly update or to revise any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by law.

PART I

ITEM 1. BUSINESS

Overview

Elanco Animal Health Incorporated (Elanco Parent) and its subsidiaries (collectively, Elanco, the Company, we, us, or our) is committed to helping our customers improve the health of animals in their care, while also making a meaningful impact on the communities we serve. As a global independent animal health leader, we are dedicated to innovating and delivering products and services to prevent and treat disease in pets and farm animals, creating value for pet owners, veterinarians, farmers, stakeholders, and society as a whole. With presence in more than 90 countries, our diverse, durable portfolio serves animals across our core species consisting of: dogs and cats (collectively, pet health) and cattle, poultry, swine, sheep and aqua (collectively, farm animal). Through our *One Elanco* culture, our commitment to excellence, and ownership of our decisions, we strive to always create positive outcomes for our customers, empowering them to share our vision of Food and Companionship Enriching Life.

Formerly a business unit of Eli Lilly and Company (Lilly), we became independently incorporated on September 18, 2018. After two years of operating as a standalone company, we acquired Bayer Animal Health in August 2020, marking the largest acquisition in industry history. This addition has allowed us to expand our portfolio to provide a more comprehensive set of animal health solutions while expanding our omni-channel presence, allowing us to meet our customers where and how they want to shop. We now have increased scale and reach as well as a more balanced portfolio, equally split between pet health and farm animal. Refer to “Item 8. Financial Statements and Supplementary Data — Note 5: Acquisitions and Divestitures” for additional information.

We are committed to fulfilling our promise: *We will rigorously innovate to benefit our customers and improve the health of animals*. We expect to capitalize on growth opportunities by advancing our pipeline of innovation and optimizing existing products, as well as through strategic business development. In 2021, we launched eight new products balanced across pet health and farm animal. Additionally, we advanced our opportunities to access the fast-growing pet dermatology market through the acquisition of KindredBio on August 27, 2021, adding three potential pipeline blockbusters with launches anticipated by 2025. We also secured full ownership of the canine parvovirus therapy that is currently in development. Further, on October 27, 2021, we announced our intent to carve out our microbiome R&D platform while simultaneously welcoming a new leader of innovation, regulatory affairs and business development. These decisions were designed to increase our focus on delivering our high-value, late-stage pet health pipeline. For further discussion of our recent business development initiatives, see the *Overview* section within "Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Item 8. Financial Statements and Supplementary Data — Note 5: Acquisitions and Divestitures.”

We have continuously strengthened and expanded our three-pronged strategy: *Innovation*, *Portfolio* and *Productivity*. It remains our foundation for sustained growth and profitability. We expect revenue growth through mid-decade to be led by a number of new launches in key market segments and in areas that balance and strengthen our portfolio. For our existing products, we intend to maximize value by investing in focus brands, those significant pet health, poultry and aqua brands that are accretive to our growth. Elanco’s core brands, the vast portion of our aggregate portfolio, are expected to remain stable and/or grow slightly. This is balanced with defend brands (e.g., *Rumensin*™, *Trifexis*™ and the *Advantage Family),* which are highly profitable and material brands where we intend to maximize profitability and preserve sales. We expect that launch excellence, price, geographic focus, digital and expanding omni-channel leadership will be key enablers of growth.

In 2021, our business, operations and financial condition and results were impacted by the COVID-19 pandemic. We continue to monitor the global outbreak of COVID-19 and have worked with our customers, employees, suppliers and other stakeholders to mitigate the risks posed by its spread. For additional information, see the *Factors Affecting Our Results of Operations* section within "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Item 1A. Risk Factors - The COVID-19 pandemic has had, and is expected to continue to have, an adverse impact on our business, our future results of operations and our overall financial performance."

Commercial Operations

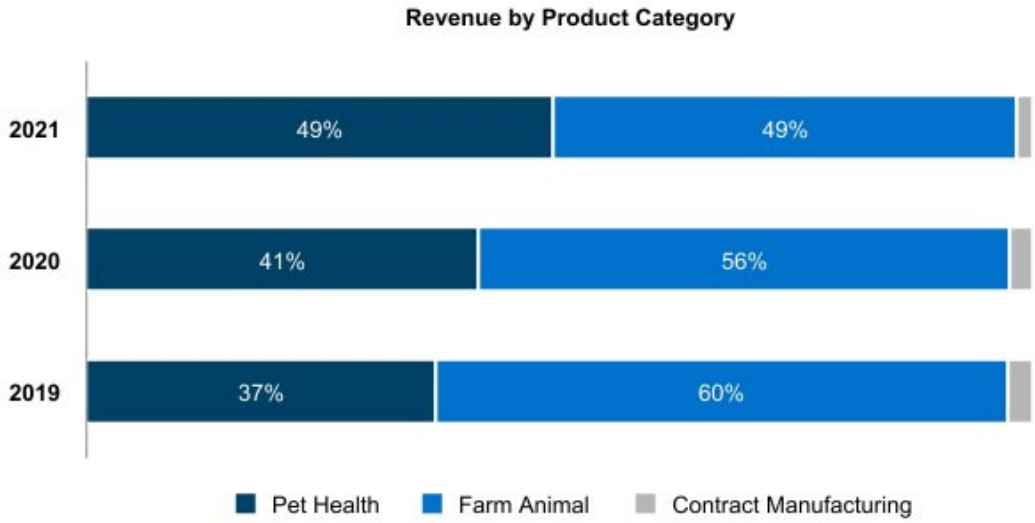
We operate our business in a single segment directed at fulfilling our vision of food and companionship enriching life – all to advance the health of animals, people and the planet. For additional information about our business segment, refer to "Item 8. Financial Statements and Supplementary Data — Note 17: Geographic Information."

We advance our vision by offering products in these two primary categories:

Pet Health: Our portfolio is focused on parasiticides, vaccines and therapeutics. We have one of the broadest parasiticid portfolios in the pet health sector based on indications, species and formulations, with products that protect pets from worm fleas and ticks. Our *Seresto*™ and *Advantage*™, *Advantix*™, and *Advocate*™ (collectively referred to as the *Advantage Family* products are over-the-counter treatments for the elimination and prevention, respectively, of fleas and ticks, and complement ou prescription parasiticide products, *Credelio*™, *Interceptor Plus*™, and *Trifexis*. Our vaccines portfolio provides differentiate prevention coverage for a number of important pet health risks and is available in the U.S. only. In therapeutics, we have a broa pain and osteoarthritis portfolio across species, modes of action, indications and disease stages. Pet owners are increasing treating osteoarthritis in their pets, and our *Galliprant*™ product is one of the fastest growing osteoarthritis treatments in the U.S Additionally, we have products that offer treatment for otitis (ear infections) with *Claro*™, as well as treatments for certa cardiovascular and dermatology indications.

Farm Animal: Our farm animal portfolio consists of products designed to prevent, control and treat health challenges primaril focused on cattle (beef and dairy), swine, poultry, and aquaculture (cold and warm water) production. Our products includ medicated feed additives, injectable antibiotics, vaccines, insecticides, and enzymes, among others. We have a wide range farm animal products, including *Rumensin* and *Baytril*™, both of which are used extensively in ruminants (e.g., cattle, sheep an goats). In poultry, our *Maxiban*™ product, is a valuable offering for the control and prevention of intestinal disease.

Our reported revenue for each product category is as follows:



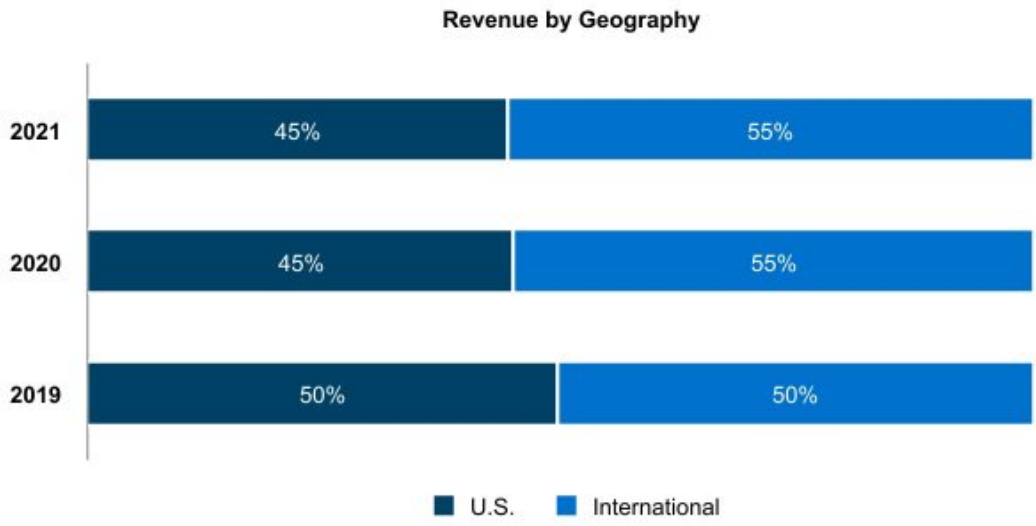
Contract manufacturing represents revenue from arrangements in which we manufacture products on behalf of a third party, including supply agreements associated with divestitures of products related to the acquisition of Bayer Animal Health.

International Operations

Our operations are conducted globally, and we sell our products in over 90 countries. Emerging market economies are an important component of our growth strategy to advancing as a global leader in the animal health industry and will serve as the base upon which we build our commercial and local innovation capabilities.

Revenues from operations outside the U.S. of $2,641 million accounted for 55% of our total revenues in 2021. By total revenues, China, Brazil, and the U.K. are our largest markets outside the U.S.

The following graph illustrates our reported revenue by our key geographic regions:



Products

We have a diverse portfolio of products marketed under approximately 200 brands, including products for both pets and farm animals.

Our pet health products help veterinarians better care for pets. We partner with pet owners and veterinarians for the purpose of providing a consistent flow of innovative and effective products and support. Our R&D focuses on products that prevent and treat disease, improve and extend quality of life and improve the type of care received by pets. We also partner closely with veterinarians to provide technical support and case management for our products. Pet health products represented approximately 49% of our revenue for the year ended December 31, 2021.

Our farm animal products are designed to enable producers to keep animals healthy and deliver more food while using fewer resources. Our antibacterials, anticoccidials, vaccines and parasiticides aim to make food safer by preventing and controlling disease. We offer products and support to enhance the integrity of the food supply, while our productivity enhancers help make food more affordable and abundant by increasing the amount of meat or milk an animal can supply. Furthermore, our expertise and data analytics help our customers improve production efficiency and business performance. Farm animal products represented approximately 49% of our revenue for the year ended December 31, 2021.

We group our products into two principal categories, Pet Health and Farm Animal. Refer to the "Commercial Operations" section above for additional information.

In 2021, our top selling products as a percentage of total revenue were as follows:

	2021
Top selling products:	
Seresto	8 %
Rumensin	5 %
Top five selling products:	
Seresto, Rumensin, Advantix, Advocate, and Interceptor Plus	24 %

Set forth below is information regarding our principal products, which are defined as product lines and products that represented approximately 1% or more of our revenue in 2021:

Pet Health Products

Product	Description	Primary Species
Advantix (imidacloprid + permethrin + pyriproxyfen)	Monthly topical application that kills and repels fleas, ticks and mosquitoes, kills lice and repels biting flies. Provides broad-spectrum protection against these ectoparasites that can transmit diseases.	Dogs
Advantage (imidacloprid + pyriproxyfen)	Monthly topical flea control that kills fleas, flea eggs and larvae on contact while also treating, preventing and controlling lice infestations.	Cats, Dogs
Advocate (imidacloprid + moxidectin)	Monthly topical treatment to prevent flea infestations as well as heartworm (*Dirofilaria immitis*), lungworm (*Angiostrongylus*) and other gastrointestinal worm infections, including roundworms (*Toxocara canis* and *Toxascaris leonina*), whipworms (*Trichuris vulpis*), and hookworms (*Ancylostoma caninum*, *Ancylostoma braziliense*, and *Unicinaria stenocephala*).	Cats, Dogs
Atopica™ (cyclosporine A)	Controls atopic dermatitis in dogs weighing at least 4 lbs.	Dogs
Claro / Neptra (florfenicol + terbinafine + mometasone furoate	One-dose treatment for otitis externa associated with susceptible strains of bacteria (*Staphylococcus pseudintermedius*) and yeast (*Malassezia pachydermatis*).	Dogs
Credelio (lotilaner)	Kills adult fleas and treats flea infestations (*Ctenocephalides felis*) and treats and controls tick infestations (*Amblyomma americanum* (lone star tick), *Dermacentor variabilis* (American dog tick), *Ixodes scapularis* (black-legged tick) and *Rhipicephalus sanguineus* (brown dog tick)) for one month in dogs and puppies 8 weeks of age or older and weighing at least 4.4 lbs.	Dogs
Duramune™ (vaccines)	Includes multiple products that collectively protect against distemper, adenovirus, parvovirus, corona, parainfluenza, leptospira canicola, and other diseases.	Dogs
Galliprant (grapiprant)	Controls pain and inflammation associated with osteoarthritis.	Dogs
Interceptor Plus (milbemycin oxime/praziquantel)	Prevents heartworm disease caused by *Dirofilaria immitis* and treats and controls adult roundworm (*Toxocara canis* and *Toxascaris leonina*), adult hookworm (*Ancylostoma caninum*), adult whipworm (*Trichuris vulpis*), and adult tapeworm (*Taenia pisiformis*, *Echinococcus multilocularis*, and *Echinococcus granulosus*) infections in dogs and puppies weighing at least 2 lbs. and 6 weeks of age or older. *Interceptor Plus* is a relaunch of a previously approved formula.	Dogs

Product	Description	Primary Species
Milbemax™ (milbemycin oxime + praziquantel)	Treats and controls parasitic infections due to adult hookworm, adult roundworm and adult tapeworm and prevents heartworm disease caused by *Dirofilaria immitis*.	Cats, Dogs
Onsior™ (robenacoxib)	Controls postoperative pain and inflammation associated with soft tissue surgery in dogs weighing at least 5.5 lbs. and 4 months of age or older and controls postoperative pain and inflammation associated with orthopedic surgery, ovariohysterectomy and castration in cats weighing at least 5.5 lbs. and 6 months of age or older; for a maximum of 3 days.	Cats, Dogs
Seresto *(imidacloprid + flumethrin)*	Flea and tick collar based on a patented low dose, slow release technology that kills and repels fleas and ticks, kills lice for up to 8 months with one single application, and reduces vector-borne disease transmission risk (e.g., leishmaniosis).	Cats, Dogs
Trifexis (spinosad + milbemycin oxime)	Prevents heartworm disease (*Dirofilaria immitis*) and kills fleas. *Trifexis* is indicated for the prevention and treatment of flea infestations (*Ctenocephalides felis*), and the treatment and control of adult hookworm *(Ancylostoma caninum)*, adult roundworm (*Toxocara canis* and *Toxascaris leonina*) and adult whipworm (*Trichuris vulpis*) infections in dogs and puppies 8 weeks of age or older and weighing at least 5 lbs.	Dogs

Farm Animal Products

Product	Description	Primary Species
AviPro™ (vaccines)	Includes multiple products that collectively protect against Newcastle disease, infectious bronchitis, fowl cholera, paramyxovirus Type 3, Bursal Disease, other diseases and foodborne pathogens like Salmonella.	Poultry
Baycox™ *(totrazuril)*	Oral treatment for control of coccidiosis caused by Isopora suis infection in swine and clinical coccidiosis caused by Eimeria bovis or Eimeria zuernii in young cattle. Attacks all stages of the parasite.	Cattle, Swine
Baytril (enrofloxacin)	Injectable antibiotic active against various bacterial diseases in cattle (major bovine pathogens) and swine (respiratory disease pathogens).	Cattle, Swine
Catosal™ / *Comforta*™ (butaphosphan + cyanocobalamin)	Injectable for prevention or treatment of deficiencies of vitamin B12, Cyanocobalamin, and phosphorous.	Cattle, Horses
Clynav™ (plasmid deoxyribonucleic acid vaccine)	Immunizes Atlantic salmon to reduce impaired daily weight gain, and reduce mortality, and cardiac, pancreatic and skeletal muscle lesions caused by pancreas disease following infection with salmonid alphavirus subtype 3 (SAV3).	Fish (Salmon)
Cydectin™ *(moxidectin)*	Injectable or pour-on for the treatment of infections and infestations due to internal and external parasites.	Cattle
Denagard™ (tiamulin)	Treats Swine Dysentery associated with Serpulina hyodysenteriae susceptible to tiamulin and swine bacterial enteritis caused by Escherichia coli and Salmonella choleraesuis sensitive to chlortetracycline and treatment of bacterial pneumonia caused by Pasteurella multocida sensitive to chlortetracycline. *Denagard* is a shared-class antibiotic.	Swine
Maxiban (narasin + nicarbazin)	Prevents coccidiosis in broiler chickens caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati* and *E. maxima. Maxiban* is an animal-only antibiotic and an ionophore.	Poultry

Product	Description	Primary Species
Monteban™ (narasin)	Prevents coccidiosis in broiler chickens caused by *Eimeria necatrix, E. tenella, E. acervulina, E. brunetti, E. mivati* and *E. maxima. Monteban* is an animal-only antibiotic and an ionophore.	Poultry
Pulmotil™ (tilmicosin)	Controls swine respiratory disease associated with *Actinobacillus pleuropneumoniae* and *Pasteurella multocida*. Controls bovine respiratory disease (BRD) associated with *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni* in groups of beef and non-lactating dairy cattle, where active BRD has been diagnosed in at least 10% of the animals in the group. Pulmotil is a shared-class antibiotic.	Cattle, Swine
Rumensin (monensin)	For cattle fed in confinement for slaughter, improves feed efficiency and prevents and controls coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*. For dairy cows, increases milk production efficiency (production of marketable solids-corrected milk per unit of feed intake). For growing cattle on pasture or in dry lot (stocker and feeder and dairy and beef replacement heifers), increases rate of weight gain and prevents and controls coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*. For mature reproducing beef cows, improves feed efficiency when receiving supplemental feed and prevents and controls coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*. For goats, prevents coccidiosis due to *Eimeria crandallis*, *Eimeria christenseni* and *Eimeria ninakohlyakimovae* in goats maintained in confinement. For calves (excluding veal calves), prevents and controls coccidiosis due to *Eimeria bovis* and *Eimeria zuernii*. *Rumensin* is an animal-only antibiotic and an ionophore.	Cattle
Surmax™ */ Maxus*™ */ Inteprity* (avilamycin)	Prevents mortality caused by necrotic enteritis associated with *Clostridium perfringens* in broiler chickens. *Surmax, Maxis* and *Inteprity* are animal-only antibiotics.	Poultry
Tylan™ *Premix* (tylosin phosphate)	Controls porcine proliferative enteropathies associated with Lawsonia intracellularis and controls porcine proliferative enteropathies associated with Lawsonia intracellularis immediately after medicating with Tylan Soluble (tylosin tartrate) in drinking water. *Tylan Premix* is a shared-class antibiotic.	Swine, Cattle, Poultry

Seasonality

While many of our products are sold consistently throughout the year, we do experience seasonality in our pet health business due to increased demand for our parasiticide product offerings in the first half of the year. For example, based upon historical results, approximately 70% and 60% of total annual revenue contributed by our higher-margin parasiticide products *Seresto* and *Advantage Family*, respectively, has occurred during the first half of the year, which is reflective of the flea and tick season in the Northern Hemisphere.

Antibiotics

Antimicrobial resistance in humans, or the risk that bacterial pathogens that cause infectious disease in humans evolve or otherwise emerge that are resistant to antibiotics or other antimicrobials, is a significant health concern, and animal agriculture can play a role in mitigating this risk. As a company dedicated to the health and well-being of animals, we seek to help veterinarians and farmers responsibly use antibiotics when treating animals. In our efforts to address antibiotic resistance while protecting animal health, we introduced a global antibiotic stewardship plan focused on increasing responsible antibiotic use; reducing the need for shared-class antibiotics; and replacing antibiotics with alternatives to help livestock producers treat and prevent animal disease. Antibiotics, used responsibly, along with good animal care practices, help enhance food safety and animal well-being.

There are two classes of antibiotics used in animal health:

Animal-only antibiotics and ionophores: Not all pathogens that cause disease in animals are infectious in humans, and accordingly animal-only antibiotics are not used in human medicine. Ionophores are a special class of animal-only antimicrobials uniquely developed only for use in animals. In Europe and certain other jurisdictions, ionophores are not currently classified as antibiotics. Because of their animal-only designation, mode of action, and spectrum of activity, their use is not considered to create the same risk of resistance in human pathogens.

Shared-class antibiotics: These are used in both humans and animals. Some antibiotics are used to treat infectious disease caused by pathogens that occur in both humans and animals. Of the 18 major antibiotic resistance threats that the Centers for Disease Control and Prevention tracks, two are associated with infectious disease in animals. As part of our global antibiotic stewardship plan and in compliance with the U.S. Food & Drug Administration (FDA) guidance, shared-class antibiotics are labeled only for the treatment of an established need in animals and only with veterinarian oversight.

We have intentionally shifted away from shared-class antibiotics, and are focusing on animal-only antibiotics, as well as antibiotic-free solutions. In 2021, 9% of our revenue was from products classified as shared-class antibiotics (3% from sales in the U.S. and 6% from international sales), which is down from 16% in 2015. Revenue from animal-only antibiotics and ionophores represented 14% of our total revenue in 2021 (12% from ionophores), which is down from 23% in 2015. The decline in animal-only antibiotics is primarily a result of the inclusion of revenues from Bayer Animal Health products, which are disproportionately more pet health-focused than the existing legacy Elanco portfolio. Through our policies and efforts in this area, we seek to protect the benefits of antibiotics in human medicine, while responsibly protecting the health of farm animals and the safety of our food supply.

Sales and Marketing

Through our global sales force comprised of approximately 2,070 sales representatives, our veterinary consultants and our key distributors, we seek to build strong customer relationships and fulfill demand for our pet health products primarily with veterinarians and, in some markets, pet owners, and for our farm animal products primarily with farm animal producers, veterinarians and nutritionists.

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. In certain markets, we sell certain products directly to retailers. Our presence in retail channels has been expanded by our acquisition of Bayer Animal Health.

Our sales representatives visit our customers, including consultants, veterinarians, farm animal producers, and resellers, to inform, promote and sell our products and to support customers. Our veterinary consultants are available to provide scientific consulting focused on disease management and herd management, training and education on diverse topics, including responsible product use, and generally have advanced degrees in veterinary medicine, veterinary nutrition or other agriculture-related fields. These direct relationships with customers allow us to better understand their needs. Additionally, our sales representatives and veterinary consultants focus on collaborating with our customers to educate and support them on topics such as local disease awareness and to help them adopt new and more sophisticated animal health solutions, including through the use of our products. As a result of these relationships, our sales and consulting visits provide us with access to customer decision makers. In addition, our sales and marketing organization provides enhanced value by providing support to farm animal producers to help maximize their yields and reduce costs. Our analytics help customers analyze large amounts of health and production data.

Customers

We primarily sell our pet health products to third-party distributors and retailers, as well as directly to veterinarians who typically then sell our products to pet owners. We primarily sell our farm animal products to third-party distributors and directly to a diverse set of farm animal producers, including beef and dairy farmers as well as pork, poultry and aquaculture operations. With the acquisition of Bayer Animal Health, we have expanded our presence in retail and e-commerce channels in order to meet pet owners where they want to purchase. Certain principal pet health products acquired from Bayer Animal Health, including *Seresto* and the *Advantage Family*, are offered through these channels. Our largest customer, an affiliate of AmerisourceBergen Corp., is a third-party veterinary distributor and represented approximately 10% of our revenue for the year ended December 31, 2021. Our next two largest customers represented approximately 5% and 4% of our revenue for the year ended December 31, 2021.

Research and Development

Our R&D organization is comprised of internal research, global development, global regulatory and external innovation collaborations. As of December 31, 2021, we employed approximately 1,100 employees in our global R&D and Regulatory Affairs organizations. Our global R&D sites are comprised of the following:

R&D Centers of Excellence	Other R&D Operations
Greenfield, Indiana (R&D headquarters)	Sao Paulo, Brazil
Kemps Creek, Australia	Shanghai, China
Monheim, Germany	Bangalore, India
Fort Dodge, Iowa	Basel, Switzerland

We incurred R&D expenses of $369 million in 2021, $327 million in 2020 and $270 million in 2019.

New product innovation is a core part of our business strategy. Our approach is a build, buy, or ally strategy to develop compelling targets and concepts that originate from our scientists and innovators, academia, agribusiness, or human pharmaceutical and biotechnology at all stages of R&D. We focus our R&D investment on projects that target novel product introductions with active ingredients, as well as products with new indications, presentations, combinations, and species expansion.

We seek to concentrate our resources in areas where we believe the science and our capabilities best match the opportunities in the animal health market. Specifically, our R&D focuses on seven areas across pets and farm animals. We have R&D activities in therapeutics, vaccines, monoclonals and parasiticides for pets. In farm animals, we are pursuing parasiticides, pharmaceuticals, vaccines, and nutritional health.

Our R&D efforts are balanced across species and technology platforms. We apply large and small molecule approaches for both farm animals and pets. Our efforts encompass a full range of modified live, inactivated, and nucleic acid strategies in vaccines. Additionally, we employ various delivery strategies for products, including in-feed, injectable, oral and topical formulations developed in conjunction with our manufacturing team to assure production that maximizes the capabilities within our internal and external manufacturing network.

Individuals lead our R&D organization with deep technical knowledge and substantial experience in discovery research, clinical sciences, and technological development across our pet health and farm animal product categories. We execute the R&D pipeline using a fully integrated global network of labs, service centers, and development sites supported by a network of third-party alliances. We also have a significant international regulatory operation that manages new product submissions and ensures ongoing compliance for our existing commercial portfolio.

Portfolio investment decisions and prioritization are influenced by the probability of technical success, economic value, time to market, and alignment with our business strategy. We have implemented project leadership capabilities and support systems that enable us to progress on our multi-year projects, use allocated R&D resources appropriately and provide visibility on the innovation portfolio. We believe this approach will allow us to consistently gain product approvals while maintaining clear visibility to pipeline breadth and depth to support sustained launches into the future.

In addition to internal discovery, we also engage in acquisitions and licensing of pipeline assets and new technology platforms. We make and maintain capital investments in venture capital vehicles that focus on agribusiness and animal health, and we engage in risk sharing collaborations to expand our external capital sources to augment internal investments.

Manufacturing and Supply Chain

Our products are manufactured both at sites operated by us and sites operated by third-party contract manufacturing organizations (CMOs). We have a global manufacturing network of 20 sites comprised of the following:

International		U.S.
Barueri, Brazil	Kiel, Germany	Clinton, Indiana
Belford Roxo, Brazil (1)	Santa Clara, Mexico	Terre Haute, Indiana
Prince Edward Island, Canada	Manukau, New Zealand	Fort Dodge, Iowa
Chengdu, China	Banwol, South Korea	Elwood, Kansas
Wusi, China	Chungli, Taiwan	Kansas City, Kansas
Huningue, France	Speke, Liverpool, U.K. (2)	Winslow, Maine
Cuxhaven, Germany	Binh Duong, Vietnam	

(1) We expect to cease operations in Belford Roxo, Brazil during the first half of 2022, transferring operations to our Santa Clara, Mexico site and a third-party CMO in Brazil.

(2) Site is currently held for sale under a pending asset purchase agreement with TriRx Pharmaceuticals.

Our global manufacturing and supply chain is also supported by a network of CMOs. As of December 31, 2021, this network was comprised of approximately 140 CMOs. Our external manufacturing network centrally governs our global CMO relationships and provides oversight to these 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 specialty products and technologies; (iii) capacity; (iv) financial analyses; and (v) local presence. Our external manufacturing network seeks to ensure that all the CMOs we use adhere to our standards of manufacturing quality.

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 intend to continue our efficiency improvement programs in our manufacturing and supply chain organization. We have strong globally managed and coordinated quality control and quality assurance programs in place at all internal manufacturing sites and external manufacturing hubs, and we regularly inspect and audit our internal sites and CMO locations.

Competition

We face intense competition. Principal methods of competition vary depending on the particular region, species, product category, or individual product. Some of these methods include new product development, quality, price, service and promotion.

Our primary competitors include animal health medicines and vaccines companies such as Zoetis Inc.; Boehringer Ingelheim Vetmedica, Inc., the animal health division of Boehringer Ingelheim GmbH; and Merck Animal Health, the animal health division of Merck & Co., Inc. We also face competition globally from manufacturers of generic drugs, as well as from producers of nutritional health products, such as DSM Nutritional Products AG and Danisco Animal Nutrition, the animal health division of E.I. du Pont de Nemours and Company, a subsidiary of DowDuPont, Inc. There are also several new start-up companies working in the animal health area. In addition, we compete with numerous other producers of animal health products throughout the world.

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 and certain product candidates enjoy the protection of approximately 6,500 patents and applications, filed in over 90 countries, with concentration in our major markets as well as other markets with strong patent systems, such as Australia, Brazil, Canada, Europe, Japan and the U.S. Many of the patents and patent applications in our portfolio are the result of our own work, while other patents and patent applications in our portfolio were at least partially developed, and licensed to us, by third parties. A subset of our current products or product candidates are covered by patents and patent applications in our portfolio.

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. Below is a summary of our recent and upcoming key patent expirations:

- *Galliprant's* active ingredient, grapiprant, is encompassed by both compound and physical form patents in the U.S., Europe, Canada and other key markets, with terms that expire between October 2021 and March 2026. Expirations in 2021 related to compound patents in the U.S., Europe and Japan. Each of these markets have physical form patents that continue beyond 2021. At this time, there is no indication of market entry for a generic version of *Galliprant* in these regions.
- Various formulation and method of use patents encompass the spinosad pesticide products, *Comfortis* and *Trifexis*. The *Comfortis* formulation patent extends through August 2025 in Europe but expired in August 2020 in the U.S., Canada and Australia. The *Trifexis* formulation and method of use patents extends through September 2026 in Europe but expired in September 2021 in the U.S., Canada and Australia. At this time, there are no indications of market entries for generic versions of *Comfortis* or *Trifexis* in the U.S., Canada or Australia.
- The *Seresto* formulation patent will expire in the U.S. in September 2027. In Europe, the formulation patents will expire in June 2025, but in some countries, including Spain and the U.K., supplementing protection certificates (SPCs) have been granted which expire in September 2026.
- *Advantage Family* products, acquired from Bayer Animal Health, are off-patent. If our customers increase their use of new or existing generic product alternatives, *Advantage Family* revenues could be adversely affected.

We typically maintain all of our patents and assert our patent rights against third parties as appropriate.

Additionally, many of our vaccine products, including the *Duramune* family of vaccines, are based on proprietary or patented master seeds and formulations. We actively seek to protect our proprietary information, including our trade secrets and proprietary know-how, through a variety of means 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.

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. We currently maintain more than 15,000 trademark applications and registrations in major regions, primarily identifying products dedicated to the care of livestock and pets.

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 is Elanco's key interface with the relevant authorities. It is responsible for applying for and obtaining the necessary registrations and post-approvals: extending them if appropriate (e.g., developing claims in additional species), updating (e.g., changes to shelf-life or manufacturing site), and ongoing monitoring of safety and efficacy through our global pharmacovigilance system. In this way, the regulatory function ensures registrations remain valid, and the products can continue to be sold. To effectively do this, the function actively engages in dialogue with the relevant authorities regarding their policies that relate to animal health products. In most of our markets, the relevant authority is separate from those governing human medicinal products.

United States

U.S. Food and Drug Administration. The regulatory body that is responsible for the regulation of animal health pharmaceuticals in the U.S. is the Center for Veterinary Medicine (CVM), a division of the FDA. All manufacturers of animal health pharmaceuticals must demonstrate their products to be safe, effective and produced by a consistent method of manufacture as defined under the Federal Food, Drug and Cosmetic Act (FFDCA). The FDA's basis for approving a new animal 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 Office of Surveillance and Compliance. Reports of product quality defects, adverse events, or unexpected results are maintained and submitted in accordance with the law. Additionally, as part of the drug experience report, we are required to submit all new information pertaining to the safety or effectiveness of a product, regardless of the source.

U.S. Department of Agriculture. The regulatory body in the U.S. for veterinary biologicals is the U.S. Department of Agriculture (USDA). The Center for Veterinary Biologics within the Animal and Plant Health Inspection Service in the USDA is responsible for the regulation of animal health biologicals, which includes but is not limited to vaccines, bacterins, allergens, certain antibodies, antitoxins, toxoids, immunostimulants, certain cytokines, antigenic or immunizing components of live microorganisms, and diagnostic components of natural or synthetic origin, or that are derived from synthesizing or altering various substances or components of substances such as microorganisms, genes or genetic sequences, carbohydrates, proteins, antigens, allergens or antibodies. 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 maintained and submitted in accordance with the agency requirements.

Environmental Protection Agency. The main regulatory body in the U.S. for veterinary pesticides is the Environmental Protection Agency (EPA). The EPA's Office of Pesticide Programs is responsible for the regulation of most pesticide products applied to animals in accordance with a memorandum of understanding between the FDA and EPA for products that are subject to regulation under both the FFDCA and the Federal Insecticide, Fungicide and Rodenticide Act. 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 act. Within the U.S., individual state pesticide authorities must, before distribution in that state, also approve pesticide products that are approved by the EPA. Post-approval monitoring of products is required, with reports provided to the EPA and some state regulatory agencies.

Food Safety Inspection Service. The FDA is authorized to determine the safety of substances (including "generally recognized as safe" substances, food additives and color additives), as well as prescribe their 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

European Union (EU). We are governed by the following EU regulatory bodies in addition to each of the national regulatory bodies in the EU:

The European Medicines Agency (EMA) is a centralized agency of the EU responsible for the scientific evaluation of many of the Veterinary Medicinal Products (VMP) developed by pharmaceutical companies for use in the EU. The agency has a veterinary review section distinct from the medical review section for human products. The Committee for Veterinary Medicinal Products (CVMP) is responsible for scientific review of the submissions for VMP, including immunological products. If the CVMP concludes that all requirements for quality, safety and efficacy are met and the product benefits outweigh the risks, it issues a positive opinion that is forwarded to the European Commission, who takes the final decision following the European comitology procedure. The centralized marketing authorization is valid in all of the EU and in Northern Ireland. All countries that are not part of the EU but belong to the European Economic Area (EEA), i.e., Norway, Iceland and Liechtenstein, have been part of the scientific assessment done by the CVMP. These countries issue a national marketing approval in accordance with the Commission decision.

If approval is sought for products that either cannot or do not need to follow the centralized procedure, approval can also be achieved by national approval in an EEA country agency. This national authorization can be mutually recognized by other EEA countries/EU member states (Mutual Recognition Procedure). In addition, national and mutual recognition can be done in a combined procedure (Decentralized Procedure).

A series of regulations, directives, guidelines, EU Pharmacopeia Monographs and other legislation provide the requirements for approval in the EU. In general, these requirements are similar to those in the U.S., requiring demonstrated evidence of purity, safety, efficacy and consistency of manufacturing processes.

The European Food Safety Authority (EFSA) is the agency of the EU that provides scientific advice and communicates with respect to existing and emerging risks associated with the food chain. Based on EFSA's mandate, the agency evaluates applications for feed additives, including coccidiostats, enzymes and several nutritionals for animals.

The European Chemicals Agency (ECHA) is the agency of the EU for the safe use of chemicals. Based on the ECHA's mandate, the agency conducts the evaluation of biocides for the EU.

Regarding Brexit, the U.K formally left the EU on January 31, 2020. Therefore, the Veterinary Medicines Directorate (VMD) is now the main regulatory body in the U.K. responsible for regulating and controlling veterinary pharmaceuticals. The U.K. and the EU reached a trade deal, including regulatory and customs cooperation mechanisms, no tariffs/quotas on products, and certain provisions ensuring open and fair competition. The Northern Ireland protocol, which is part of the trade deal, requires that VMD follow EU rules in Northern Ireland. Laws applying to the rest of the U.K. could now diverge but currently remain largely aligned.

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 medicinal 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 medicinal 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.

Japan. The Ministry of Agriculture, Forestry and Fishery (MAFF) is the regulatory body in Japan that is responsible for the regulation and control of pharmaceuticals (including biologicals and pesticide/disinfectant) and feed additive/feed for animal use. MAFF's regulatory activities are conducted through the Livestock & Aquaculture Product Safety Control Division under Consumer Safety Bureau. The animal drug reviews and approvals, reexamination reviews, GxP compliance checks, GxP site inspections and product assay checks (including vaccine national assays) are done by National Veterinary Assay Laboratory (NVAL). MAFF coordinates with other agencies such as Ministry of Health, Labor and Welfare (MHLW) and Food Safety Commission (FSC) to perform various license compliance checks (e.g., marketing authorization holder, manufacturer and oversea site accreditation) and ensure good promotional activities. Routine inspections, antimicrobial feed additive national assays and manufacturing inspections are done by the Food & Agriculture Material Inspection Center. For farm animal products, animal drug review is done by NVAL but the human food safety review is done by FSC (ADI establishment and antimicrobial risk assessment) and MHLW (MRL establishment). These three agencies (NVAL, FSC and MHLW) work together to approve farm animal products. In addition to those central government agencies, various licenses are delegated to the local municipal government, such as animal drug wholesaler and retailer licenses and feed additive distributor licenses.

China. The Ministry of Agriculture (MOA) is the regulatory body that is responsible for the regulation and control of pharmaceuticals, biologicals, disinfectants, medicinal feed additives, pesticide and feed/feed additives for animal use. There are three organizations under the MOA that regulate animal health:

The Institute of Veterinary Drug Control is responsible for the evaluation of new applications, renewals, variations, manufacturers, quality methods and tissue residue methods for pharmaceuticals, biologicals, disinfectants and medicinal feed additives.

The feed/feed additive office is responsible for the registration and renewal of feed and feed additives.

The pesticide bureau is responsible for the registration and renewal of pesticide products.

Australia. The Australian Pesticides and Veterinary Medicines Authority (APVMA) is an Australian government statutory authority where the registration of all agricultural and veterinary products into the Australian marketplace is centralized. The APVMA assesses applications from companies and individuals seeking registration so they can supply their product to the marketplace. Applications undergo 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. The APVMA is also responsible for post-authorization oversight, which can include reviews of registered products.

Rest of World. Country-specific regulatory laws typically have provisions that include requirements for certain labeling, safety, efficacy and manufacturers' quality control procedures (to assure the consistency of the products), manufacturing site standards, as well as company records and reports. Other countries' regulatory agencies typically either refer to some or all of the requirements of the U.S. or EU, but may have additional specific local requirements. Most authorities also consider the standards set by international animal health entities, including the World Organization for Animal Health, Codex Alimentarius and the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH).

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). It provides 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. Similarly, the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) is an international expert scientific group administered jointly by the FAO and WHO. JMPR reviews residues and analytical aspects of the pesticides, estimate the maximum residue levels, review toxicological data and estimate acceptable daily intakes for humans of the pesticides under consideration. Elanco works with these committees to establish acceptable safe levels of residual substances in food-producing animals after treatment with veterinary drugs or pesticides. 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 ethical 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 material for compliance with the local and regional requirements in the markets where we sell animal health products.

Import and Export of Products. The importation and exportation of animal health products is controlled by regulations in many countries. In some jurisdictions this may include obtaining separate permits or licenses by product or by company or filing notices with applicable regulatory agencies prior to import or export of product. We ensure compliance with local, regional and global regulations in the markets where we import/export our animal health products.

International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products. VICH is a trilateral (EU-Japan-U.S.) program launched in 1996 aimed at harmonizing technical requirements for veterinary product registration. Several other countries have obtained observer status, for example, Canada, New Zealand, Australia, South Africa, and the U.K., or are linked to VICH on the basis of the VICH Outreach Forum, a VICH initiative with the main objective of providing a basis for wider international harmonization of technical requirements. In addition, the World Organization for Animal Health is an associate member of VICH.

Human Capital

As of December 31, 2021, we employed approximately 9,000 full time employees. In addition, we employed approximately 800 fixed-duration employees, which are individuals hired for a pre-defined length of time (one to four years). Together, they total approximately 9,800 employees worldwide. Of the 9,800 global employees, approximately 28% are U.S.-based and approximately 72% are employed 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 200 union employees located at our Fort Dodge, Iowa and Santa Clara, Mexico facilities. Approximately 34% of our global employee population is in customer-facing roles, including but not limited to traditional sales roles, technical consultants, account managers and commercial and general managers.

The safety of employees, customers and suppliers with whom we frequently interact has been our highest priority since COVID-19 first spread across the globe. To limit exposure, we substantially restricted travel, required social distancing and masking when social distancing was not possible. Our essential site workers (so classified because the animal health industry has been designated an essential business) continued to be physically present in our manufacturing and research facilities and were provided additional personal protective equipment as required by their roles. Employees who are not required to be at a worksite to perform their roles were enabled to work remotely whenever possible. Our employees have demonstrated resiliency, agility and engagement in support of business continuity despite the challenges that have arisen during the COVID-19 pandemic.

At Elanco, we are committed to fostering an inclusive culture where employees can make a difference, encouraging ownership, growth, and well-being. The following gives an overview of our approach to managing human capital resources.

Our Culture. We commit to create a culture built on the foundation of three values and four behavioral pillars:

Values that Guide our Decisions:

Integrity - Do the right thing in the right way.

Respect - Respect people, our customers and the animals in their care.

Excellence - Be accountable. Continuously improve. Deliver with discipline.

Behavioral Pillars that Guide our Actions:

Involve - We seek participation and input to gain commitment and passionate performance and create an engaged community. We act with humility as One Elanco, collaborating for the best outcomes for the entire company.

Deliver - We focus on the essential, build mastery, and diligently deliver on our commitments to our colleagues, customers, and shareholders.

Own - We are accountable and empowered. We ask questions and raise concerns. We are fully invested in Elanco's success.

Innovate - We bring an innovative mindset that drives continuous improvement of our processes, products, and services.

Our employees are driven by these values and behavioral pillars. At Elanco, this culture drives employee performance. Leadership and employees are encouraged to evaluate performance with these values and behavioral pillars in mind.

Diversity, Equity and Inclusion. We are focused on discovering new ways in which healthier animals can solve the world's greatest health and environmental challenges, and this innovation is only possible through an inclusive culture of employees with diverse backgrounds, strengths, and perspectives. Diversity, equity and inclusion are critical to creating and maintaining our purpose-driven culture and strengthening our promises to our employees and customers.

Formed in 2015, our Global Elanco Diversity, Equity and Inclusion Council (EDEIC) serves as a catalyst for a culture where diversity, equity and inclusion are embraced and recognized as a business-result driver. Within this framework, employee development is better supported, opinions and diverse backgrounds are embraced, and we are a stronger company. Current EDEIC focus areas include our *Be You!* Seminar series to raise awareness and provide a forum for an open discussion on the importance of a diverse and inclusive workplace at Elanco, strong Employee Resource Groups, an annual Multi-Cultural Summit, and actionable goals for representation of women (globally) and minority group members (U.S.) in leadership. In addition, a clear direction has been established for the post COVID-19 pandemic "future of work" including a new global flexible worker standard introduced in 2021 that will enable greater flexibility and access to more diverse talent in a wider range of locations.

Total Rewards. We invest in our workforce by offering competitive salaries, incentives, and benefits. Our pay for performance philosophy is designed to create ownership and help ensure that we attract and retain talent as well as reward and recognize top-performing employees through merit increases and other rewards. We benchmark our total rewards annually to ensure our compensation and benefit programs remain competitive with our peers. Our benefits are one way we support our employees' well-being and live up to our employee promise.

Development. We offer our employees opportunities to advance their careers at Elanco and are passionate about equipping employees with skills and development opportunities to help them thrive and continually meet the ever-changing needs of our customers and other stakeholders in a dynamic and growing industry.

Beyond professional growth and development, Elanco employees actively engage in Elanco's *Healthy Purpose*™, which is our initiative to advance the well-being of animals, people and the planet, enabling us to realize our vision of "Food and Companionship Enriching Life." This vision is built on a fundamental belief uniting the purpose of all Elanco employees – healthier animals are the key to solving some of the world's most pressing issues.

Environmental, Health and Safety

We are subject to various federal, state, local and foreign environmental, health and safety (EHS) 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 impose joint and several liability, without regard to fault, for clean-up costs on persons who have 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. We could be subject to liability for the investigation and remediation of legacy environmental contamination caused by historical industrial activity at sites that we own or on which we operate. 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 EHS laws and regulations. We are also monitoring and investigating environmental contamination from past industrial activity at certain sites. As a result, we incurred capital and operational expenditures in 2021 for environmental compliance purposes and for the clean-up of certain past industrial activities. We made no expenditures for environmental-related capital items in 2021. Other environmental-related expenditures during the year totaled $1 million.

In connection with past divestitures, we have undertaken certain indemnification obligations that may require us, in the future, to conduct or finance environmental clean-ups at sites that we no longer own or operate. In connection with certain of our acquisitions, we have also entered into indemnification agreements pursuant to which we are, or may be, indemnified for various environmental clean-ups; 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.

Available Information

Our website address is www.elanco.com. On our website, we make available, free of charge, our annual, quarterly and current reports, including amendments to such reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the U.S. Securities and Exchange Commission (the SEC). In addition, the SEC maintains an internet site that contains reports, proxy and information statements, and other information regarding issuers, including Elanco, that file electronically with the SEC at www.sec.gov.

Information relating to corporate governance at Elanco, including our Corporate Governance Guidelines, Code of Conduct, Financial Code of Ethics, Articles of Incorporation, Bylaws, Committee Charters; information concerning our executive officers and members of our board of directors; and ways to communicate are available on our website. We will provide any of the foregoing information without charge upon written request to Elanco's Corporate Secretary, Elanco, 2500 Innovation Way, Greenfield, Indiana 46140. Information relating to shareholder services is also available on our website.

Information contained on our website is not part of, or incorporated by reference, in this Form 10-K.

ITEM 1A. RISK FACTORS

Our business, financial condition and results of operations are subject to various risks, including but not limited to the risks described below. If any of such risks actually materializes, our business, financial condition and results of operations could be materially adversely affected.

Risks Related to Elanco's Business and Industry

The animal health industry is highly competitive.

The animal health industry is highly competitive. Our competitors include standalone animal health businesses, the animal health businesses of large pharmaceutical companies, specialty animal health businesses and companies that mainly produce generic products. 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. Several new start-up companies also compete in the animal health industry. We also face competition from manufacturers of drugs globally, as well as producers of nutritional health products. 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. For example, many of our competitors have relationships with key distributors and, because of their size, the ability to offer attractive pricing incentives, which may negatively impact or hinder our relationships with these distributors. In addition to competition from established market participants, new entrants to the animal health medicines and vaccines industry could substantially reduce our market share, render our products obsolete or disrupt our business model.

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 business, financial condition and results of operations could be materially adversely affected. Competitive pressure could arise from, among other things, more favorable safety and efficacy product profiles, 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 innovation and advances in veterinary medical practices, animal health technologies and alternatives to animal-derived protein could negatively affect the market for our products.

The markets for our products are regularly impacted 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, specially bred disease-resistant animals or replacements for meat, milk, eggs or fish from alternative natural or synthetic sources. For example, the market for our pet health therapeutics has been particularly affected by innovation in new molecules and delivery formulations in recent years. Technological breakthroughs by others may render obsolete our products and reduce or eliminate the market for our products. Introduction or acceptance of competing animal health products and innovation or disruptive protein alternatives could materially adversely affect our business, financial condition and results of operations.

Regulatory restrictions and bans on the use of antibiotics and productivity products in farm animals, as well as changing market demand, may continue to negatively affect demand for certain of our farm animal products.

Over the past few years, our operational results have been, and may continue to be, affected by regulations and changing market demand. In certain markets, including the U.S., sales of certain of our farm animal products have been negatively affected by an increase in consumer sentiment for proteins and dairy products produced without the use of antibiotics or other products intended to increase animal production.

There are two classes of antibiotics used in animal health: shared-class, or medically important, antibiotics, which are used to treat infectious disease caused by pathogens that occur in both humans and animals; and animal-only antibiotics, which are used to treat infectious disease caused by pathogens that occur in animals only. See “Business of Elanco - Products - Antibiotics.” Concerns that the use of antibiotics in farm animal production may lead to increased antibiotic resistance of human pathogens have resulted in increased regulation and changing market demand. In December 2013, the FDA announced final guidance establishing procedures for the voluntary phase-out in the U.S. over a three-year period of the use of shared-class antibiotics in animal feed or water for growth promotion in farm animal production. The guidance allows for continued use of shared-class antibiotics in food-producing animals under the supervision of a veterinarian for treatment, control and, under certain circumstances, for prevention of disease. The FDA indicated that it took this action to help preserve the efficacy of shared-class antibiotics to treat infections in humans. As of January 1, 2017, under the FDA’s guidance and the related rule known as the Veterinary Feed Directive, the use of shared-class antibiotics in the water or feed of food-producing animals requires written authorization by a licensed veterinarian. In June 2021, the FDA announced final guidance establishing procedures for drug sponsors to make similar changes to the approved marketing status of all other dosage forms of shared-class antibiotics to permit their use only under the supervision of a veterinarian, and only when necessary for treatment, control or prevention of specific diseases. The only products we currently market that are impacted by this guidance are *Tylan™ 200* and *Tylan™ 50*, which will be transitioned from over-the-counter to prescription status. In addition, other countries in which we sell or plan to sell our products, such as France and Vietnam, have passed restrictions or bans on antibiotic use. Other countries have placed restrictions or bans on the use of specific antibiotics in certain food-producing animals, regardless of the route of administration (in feed or injectable).

From 2015 to 2021, our revenue from shared-class antibiotics has declined at a compound annual growth rate (CAGR) of 1%, excluding the impact of foreign exchange rates. This was driven primarily by changing regulations in many markets, including the Veterinary Feed Directive, as well as changing market demand and our tiered approach to antibiotic stewardship, which included removing growth promotion from labels and requiring veterinary oversight in the U.S. and other markets. Globally, during 2021, our revenue from shared-class antibiotics increased approximately 36%, excluding the impact of foreign exchange rates, but represented 9% (3% from sales in the U.S. and 6% from international sales) of total revenue, down from 16% in 2015. The increase was driven by of the addition of Bayer Animal Health product revenue. From 2015 to 2021, our revenue from animal-only antibiotics increased at a CAGR of less than 1%, excluding the impact of foreign exchange rates. During 2021, our revenue from animal-only antibiotics increased approximately 18%, excluding the impact of foreign exchange rates, and represented 14% of total revenue, down from 23% in 2015. In 2021, 12% of our revenue from animal-only antibiotics resulted from the sale of ionophores. Ionophores are a special class of animal-only antimicrobials, and because of their animal-only designation, mode of action and spectrum of activity, their use has not to date been impacted by regulations or changing market demand in many international markets.

The impact of changes in regulations and market preferences regarding the use of antibiotics in farm animals could have a material adverse effect on our business, financial condition and results of operations. If there is an increased public perception that consumption of food derived from animals that utilize our products poses a risk to human health, there may be a further decline in the production of those food products and, in turn, demand for our products. In addition, antibiotic resistance concerns will likely result in additional restrictions or bans, expanded regulations or public pressure to further reduce the use of antibiotics in farm animals, increased demand for antibiotic-free protein, or changes in the market acceptance or regulatory treatment of ionophores, any of which could materially adversely affect our business, financial condition and results of operations.

In addition, our revenue has been impacted by changing trade dynamics with China and other markets that restrict the use of productivity products, such as those containing ractopamine, in farm animals. This has resulted in many U.S. food producers eliminating their use of ractopamine to gain access to those markets. Our farm animal products *Optaflexx™* and *Paylean™* contain ractopamine. If more producers decide to access such markets or additional markets restrict the use of ractopamine or other productivity products, our business, financial condition and results of operations could be materially adversely affected.

Generic 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 jurisdictions where such patents are obtained. The extent of protection afforded by our patents varies from jurisdiction to jurisdiction 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 jurisdiction. Some of our top products such as *Rumensin*, *Maxiban*, *Denagard* and *Tylan Premix* do not have patent protection. Other products are protected by patents that expire over the next several years. As the patents for a brand name product expire, competitors may begin to introduce generic or other alternatives, and as a result, we may face competition from lower-priced alternatives to many of our products. For example, we have experienced significant competitive headwinds from generic ractopamine in the U.S. In the third quarter of 2013, a large established animal health company received U.S. approval for generic ractopamine. U.S. revenue from *Optaflexx*, our ractopamine beef product, has declined at a compound annual growth rate of 18% from 2015 to 2021 as a result of generic competition and international regulatory restrictions. In the third quarter of 2019, an established animal health company received U.S. approval for generic monensin in cattle and goats for certain indications. U.S. revenue from *Rumensin*, our monensin product, declined at a compound annual growth rate of 3% from 2015 to 2021 partly due to competition and may continue to decline as a result of the generic competition. We may face similar competition in the future for existing products that do not benefit from exclusivity or for existing products with material patents expiring in the future. See "Item 1. Business — Intellectual Property."

Generic competitors are becoming more aggressive in terms of launching products before patent rights expire, and, because of attractive pricing, sales of generic products are an increasing percentage of overall animal health sales in certain regions. Although the impact of generic competition in the animal health industry to date has not typically mirrored that seen in human health, product pricing and the impact of generic competition in the future may more closely mirror human health as a result of changes in industry dynamics, such as channel expansion, consolidation, an increase in the availability and use of pet insurance and the potential for generic competition by established animal health businesses. If animal health customers increase their use of new or existing generic products, our business, financial condition and results of operations could be materially adversely affected.

We may not successfully implement our business strategies or achieve targeted cost efficiencies and gross margin improvements.

We are pursuing strategic initiatives that management considers critical to our long-term success, including, but not limited to: improving manufacturing processes, reducing our manufacturing footprint, achieving lean initiatives, consolidating our CMO network, strategically insourcing projects, pursuing cost savings opportunities through alternate sources of supply and improving the productivity of our sales force. Following the acquisition of Bayer Animal Health, we have announced restructuring programs which have included the elimination of positions across several countries, primarily in sales and marketing, research & development, manufacturing and quality, and back-office support. There are significant risks involved with the execution of these restructuring programs, including costly expenses related to severance, asset impairment and other charges as well as business disruption, loss of accumulated knowledge and procedural efficiency, failure to achieve some or all of the benefits of the restructuring programs, lawsuits arising from the restructuring programs, and the need for a significant amount of management and other employees' time and focus, which may divert attention from operating the business. We may pursue additional strategic initiatives in the future to improve gross margins and achieve our targeted cost efficiencies. We also have acquired or partnered with a number of smaller animal health businesses, and we intend to continue to do so in the future. There are significant risks involved with the execution of these initiatives, including significant business, economic and competitive uncertainties, many of which are outside of our control. Accordingly, we may not succeed in implementing these strategic initiatives. Realizing the anticipated benefits from these initiatives, if any benefits are achieved at all, may take several years. We may be unable to achieve our targeted cost efficiencies and gross margin improvements. Additionally, we may have insufficient access to capital to fund investments in strategic initiatives, or our business strategy may change from time to time, which could delay our ability to implement initiatives that we believe are important to our business.

Consolidation of our customers and distributors could negatively affect the pricing of our products.

Third-party distributors, veterinarians and farm animal 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, farm animal producers, particularly swine and poultry producers, and our distributors have seen recent 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, our customers 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 business, financial condition and results of operations.

An outbreak of infectious disease carried by farm animals could negatively affect the demand for, and sale and production of, our farm animal products.

Sales of our farm animal products could be materially adversely affected by a general outbreak of infectious disease, or an outbreak of disease carried by farm animals, which could lead to the widespread death or precautionary destruction of farm animals as well as the reduced consumption and demand for animal protein. In addition, outbreaks of disease carried by farm 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 farm animal 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 negatively impacted sales of our animal health products. The discovery of additional cases of any of these, or new, diseases may result in additional restrictions on animal protein, reduced herd or flock sizes, or reduced demand for animal protein, any of which may have a material adverse effect on our business, financial condition and results of operations. In addition, 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.

The COVID-19 pandemic has had, and is expected to continue to have, an adverse impact on our business, our future results of operations and our overall financial performance.

The COVID-19 pandemic has impacted and may further impact the U.S. and the broader economies of affected countries, including negatively impacting economic growth, the proper functioning of financial and capital markets, foreign currency exchange rates and interest rates. There continues to be uncertainty around its duration, ultimate impact and the timing of recovery. Therefore, the pandemic has led to extended disruptions, and could continue to result in further disruptions, of economic activity and the impact on our consolidated results of operations, financial position and cash flows could be material.

As a result of the adverse impact that the COVID-19 pandemic is having on our economy and the economies in the countries in which we operate, the pandemic has had, and may continue to have, an adverse effect on our supply chain as we experience disruptions or delays in shipments of certain materials or components of our products. Prolonged shortages or supply chain disruptions may result in higher shipping costs, lower production levels or R&D delays, which may have a material adverse effect on our business, financial condition, results of operations and/or cash flows.

Our customers, and therefore our business and revenues, are sensitive to negative changes in economic conditions. With respect to our farm animal business, our livestock customers have been and may continue to be challenged by processing plant shutdowns, travel bans, quarantines inhibiting consumption of protein and the transportation of livestock, and labor shortages, which, in turn, have led and may lead to a further decrease in demand for our customers' livestock. For example, an effort by dairy farmers to decrease milk production could negatively impact demand for *Rumensin*. Such challenges could not only lead to a decrease in demand for our products but could also significantly impact our customers' ability to pay for our products. COVID-19 also impacted our pet health business, as social distancing guidelines decreased veterinary visits and reduced veterinary practice spending in the middle of 2020; however, spending returned to normal levels in most regions by the end of the year. We expect the negative impacts of the COVID-19 pandemic on our revenue to continue until conditions impacting the economy and life in general improve.

The impact of the COVID-19 pandemic on the global financial markets may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity. Additionally, our suppliers and third-party distributors may face difficulties maintaining operations and normal liquidity in light of government-mandated restrictions. Further, the resulting global economic downturn may negatively impact the ability of certain of our customers to make payments on a timely basis, adversely impacting our cash flows from operations. While our liquidity has not been significantly impacted by delayed collections thus far, we do not yet know the full extent of the impact of the COVID-19 pandemic and its resulting economic impact, which could have a material adverse effect on our liquidity, capital resources, operations and business.

Our R&D, acquisition and licensing efforts may fail to generate new products or expand the use of our existing products.

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, including the acquisitions of Bayer Animal Health and KindredBio. 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 markets may not achieve similar success when introduced into other markets. Furthermore, the timing and cost of our R&D may increase, and our R&D may become less predictable as, among other things, 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.

As part of our development strategy, we often hire clinical research organizations to perform preclinical testing and clinical trials for drug candidates. Clinical trials and procedures are inherently uncertain and there can be no assurance that these trials or procedures will be enrolled or completed in a timely or cost-effective manner or result in a commercially viable product or indication. Failure to do so could have a material adverse effect on our prospects. Furthermore, unfavorable or inconsistent clinical data from current or future clinical trials or procedures conducted by us, our competitors or third parties, or perceptions regarding this clinical data, could adversely affect our ability to obtain necessary approvals and the market's view of our future prospects.

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, farm animal 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. Furthermore, the use of our products for indications other than those 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 business, financial condition and results of operations.

Unanticipated safety, quality or efficacy concerns or identified concerns associated with our products may harm our reputation and have an adverse impact on our performance.

Unanticipated safety, quality or efficacy concerns arise from time to time with respect to animal health products, whether or not scientifically or clinically supported, potentially 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.

For example, lawsuits seeking actual damages, injunctive relief, and/or restitution for allegedly deceptive marketing have been filed against us arising out of the use of *Seresto*, a non-prescription flea and tick collar for cats and dogs, based on reports alleging that the collar has caused injury and death to pets. Further, a U.S. House of Representatives' subcommittee chair requested that we produce certain documents and information related to the *Seresto* collar and further made a request to temporarily remove *Seresto* collars from the market. Similar actions relating to *Seresto* could be taken by regulatory agencies. If any such claims with respect to *Seresto* or our other products are resolved adversely to us, or if a regulatory agency determines that a recall of any of our products, including *Seresto*, is necessary, such action could cause harm to our reputation, reduce our product sales, result in monetary penalties and other costly remedies against us, and could therefore have a material adverse effect on our business, financial condition and results of operations.

In addition, we depend on positive perceptions of the safety, quality and efficacy of our products, and animal health products in general, by food producers, veterinarians and pet owners. Any concern as to the safety, quality or efficacy of our products, whether actual or perceived, may harm our reputation. These concerns, including those relating to *Seresto*, and the related harm to our reputation could materially adversely affect our business, financial condition and results of operations, regardless of whether such reports are accurate.

Our business results fluctuate due to seasonality and other factors and the extent of such fluctuations may be unpredictable.

Historically, our operating results have fluctuated during the year, and we expect these fluctuations to continue. For example, on average, approximately 70% and 60% of total annual revenue contribution from our higher-margin parasiticide products *Seresto* and *Advantage Family*, respectively, occurs in the first half of the year. This dynamic is reflective of the flea and tick season in the Northern Hemisphere and our growing pet health portfolio.

Other factors that may cause our operating results to fluctuate are:

- weather conditions and the availability of natural resources;
- increased or decreased inventory levels at our channel distributors;
- timing of customer orders and deliveries;
- competitive changes, such as price changes or new product introductions that we or our competitors may make;
- timing of marketing programs and events; and

- availability of veterinarians to use our products, as there are seasonal impacts, due to veterinarian vacations or training events that limit their ability to serve their customers that result in the use of our products.

For more detailed information on some of the above-listed factors that can cause fluctuations in our operating results, see risks described below under "Our business may be negatively affected by weather conditions and the availability of natural resources" and "Increased or decreased inventory levels at our channel distributors can lead to fluctuations in our revenues and variations in our payment terms extended to our distributors can impact our cash flows."

Accordingly, the fluctuations in our revenues due to seasonality and other factors, many of which are beyond our control, mean period-to-period comparisons of our historical results are not necessarily meaningful. Investors should not rely on such fluctuations as an indication of our future performance. To the extent that we experience the factors described above, our future operating results may not meet the expectations of securities analysts or investors, which may cause the market price of our common stock to decline.

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 products in a particular region are affected by weather conditions (including those that may be related to climate change), 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.

Farm animal 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 farm animal producers may purchase less of our products.

Further, heat waves may cause stress in animals and lead to increased vulnerability to disease, reduced fertility rates and reduced milk production. Droughts may threaten pasture and feed supplies by reducing the quality and amount of forage available to grazing livestock, while climate change may increase the prevalence of parasites and diseases that affect farm 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.

In addition, veterinary hospitals and practitioners depend on visits from, and access to, the animals under their care. Veterinarians' patient volume and ability to operate could be adversely affected if they experience prolonged snow, ice or other severe weather conditions, particularly in regions not accustomed to sustained inclement weather.

Modification of foreign trade policy may harm our farm animal product customers.

Changes in 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 results of operations. A number of our customers rely on duty reduction benefits provided by free trade agreements, such as the U.S.-Mexico-Canada-Agreement. However, trade partnerships and treaties can be modified by domestic and foreign governments, which could result in new or increased tariffs. Additionally, countries are becoming increasingly protectionist, both to protect local industries as well as to ensure domestic supply chain continuity for key products, such as medicine. Finally, as global security decreases, more countries will use sanctions and export controls as a method to deal with such insecurity, which could result in decreased markets for our products.

Our results of operations may be adversely affected by foreign currency exchange rate fluctuations.

Our results are reported in U.S. dollars. As a result, we are exposed to foreign currency exchange risk as the functional currency financial statements of non-U.S. subsidiaries are translated to U.S. dollars for reporting purposes. To the extent that revenue and expense transactions are not denominated in the functional currency, we are also subject to the risk of transaction losses. Given the volatility of exchange rates and despite the mitigating impact of foreign currency forward or option derivative contracts we enter into in order to reduce the effect of fluctuating currency exchange rates in future periods, there is no guarantee that we will be able to effectively manage currency transaction and/or translation risks, which could adversely affect our results of operations.

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

If any of our top products experience issues, such as disruptive innovations or the introduction of more effective competitive products, negative publicity, changes to veterinarian or customer preferences, loss of patent protection, material product liability litigation, new or unexpected side effects, manufacturing disruptions and/or regulatory proceedings, our revenue could be negatively impacted, perhaps significantly. Our top five products, *Seresto*, *Rumensin*, *Advantix*, *Advocate*, and *Interceptor Plus* contributed approximately 24% of our revenue in 2021. Any issues with these top products, particularly *Rumensin*, which contributed approximately 5% of our revenue in 2021 and is now subject to generic competition in the U.S., could have a material adverse effect on our business, financial condition and results of operations.

Customer exposure to rising costs and reduced customer income, as well as a lack of availability or significant increases in the cost of raw materials used in manufacturing our products, could have a material adverse effect on our profit margins and operating results.

Feed, fuel, transportation and other key costs for farm animal producers may continue to increase or animal protein prices or sales may decrease. Either of these trends could cause deterioration in the financial condition of our farm animal product customers, potentially inhibiting their ability to purchase our products or pay us for products delivered. Our farm animal product customers may offset rising costs by reducing spending on our products, including by switching to lower-cost alternatives. In addition, concerns about the financial resources of pet owners could cause veterinarians to alter their treatment recommendations in favor of lower-cost alternatives to our products, which could result in a decrease in sales of our pet health products, especially in developed countries where there are higher rates of pet ownership. Rising costs or reduced income for our customers could have a material adverse effect on our business, financial condition and results of operations.

We rely on third parties to source many of our raw materials and to manufacture products that we distribute. See "Item 1. Business — Manufacturing and Supply Chain." We have and may continue to experience cost increases in certain raw materials or other components required to manufacture our products due to increased shipping costs and other inflationary pressures. This may have a material adverse impact on our financial results if we cannot pass on such increases to our customers. Further, the unavailability or delivery delays of raw materials has affected and could continue to affect our ability to ship the related products timely, more severely impacting high-volume or high-margin products.

For our pet health products, increased use of alternative distribution channels, or changes within existing distribution channels, could negatively impact our market share, margins and distribution of our products.

In most markets, pet owners typically purchase their animal health products directly from veterinarians. However, pet owners increasingly have the option to purchase animal health products from sources other than veterinarians, such as online 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. Pet 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 pet health prescription products primarily through the veterinarian distribution channel, any significant decrease in visits to veterinarians by pet owners could reduce our market share for such products and materially adversely affect our business, financial condition and results of operations. In addition, pet 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 U.S., and may be proposed in the U.S. or abroad in the future, which could impact the distribution channels for our pet health 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 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 pet health 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 further increase our use of online retailers, “big-box” retail stores or other over-the-counter distribution channels to sell our pet health products. We may not be adequately prepared or able to distribute our pet health products if an increased portion of our sales occur through these channels. Also, we may realize lower margins on sales through these distribution channels than we do on sales through veterinarians. Any of these events could materially adversely affect our business, financial condition and results of operations.

In addition, if one or more of our pet health distributors discontinues or modifies their relationship with us, our business, financial condition and results of operations may be materially adversely affected. For example, in 2020, we completed the previously communicated channel inventory reduction, moving to inventory levels across the world and across species that represent the minimum necessary to allow our distributors to maintain strong service levels with their end customers.

Increased or decreased inventory levels at our channel distributors can lead to fluctuations in our revenues and variations in payment terms extended to our distributors can impact our cash flows.

In addition to selling our products directly to veterinarians, we sell to distributors who, in turn, sell our products to third parties. Inventory levels at our distributors may increase or decrease as a result of various factors, including end customer demand, new customer contracts, heightened and generic competition, required minimum inventory levels, our ability to renew distribution contracts with expected terms, our ability to implement commercial strategies, regulatory restrictions, unexpected customer behavior, proactive measures taken by us in response to shifting market dynamics, and procedures and environmental factors beyond our control, including weather conditions or an outbreak of infectious disease such as COVID-19 or diseases carried by farm animals such as African Swine Fever. These increases and decreases can lead to variations in our quarterly and annual revenues. In addition, like all companies that manufacture and sell products, we have policies that govern the payment terms that we extend to our customers. Due to consolidation amongst our distributors, as well as changes in the buying habits of end customers or the need for certain inventory levels at our distributors to avoid supply disruptions, from time to time, our distributors have requested exceptions to the payment term policies that we extend to them. Extensions of customer payment terms can impact our cash flows, liquidity and results of operations.

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

Under 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, 2021, we had recorded on our balance sheet goodwill of $6.2 billion and identifiable intangible assets of $5.6 billion. Identifiable intangible assets consist primarily of marketed products acquired or licensed from third parties, licensed platform technologies that have alternative future uses in R&D, manufacturing technologies, and customer relationships from business combinations. We also have indefinite-lived intangible assets, which consist of acquired in-process R&D projects from business combinations that are subject to impairment and non-cash impairment charges.

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 the consolidated statements of operations and write-downs recorded on our consolidated balance sheets could vary if our management’s conclusions change. Any impairment of goodwill or identifiable intangible assets could have a material adverse effect on our business, financial condition and results of operations.

Our R&D relies on evaluations of animals, which may become subject to bans, additional restrictive regulations or increased attention from activism movements.

As an animal health medicines and vaccines business, we are required to evaluate the effect of our existing and new products in animals in order to register such 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 new regulations applicable to animal testing. To the extent that the activities of such organizations and individuals are successful, our R&D, and by extension our business, financial condition and results of operations, could be materially adversely affected. In addition, negative publicity about us or our industry could harm our reputation. For example, farm animal 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 farm animal 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 farm animals 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.

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 sufficient quantities to our customers. We own and operate 20 internal manufacturing sites located in 12 countries. We also employ a network of approximately 140 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, and have in the past resulted 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;
- mislabeling;
- construction delays;
- equipment malfunctions;
- shortages of materials;
- labor problems;
- 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 materially adversely affect our business, financial condition and results of operations.

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 have invested and will continue to invest in improvements to our existing manufacturing facilities and in new manufacturing plants. These types of projects are subject to risks of delay or cost overruns inherent in any large construction project and require licensing by or approvals from various regulatory authorities. Significant cost overruns or delays in completing these projects could have an adverse effect on our financial condition or results of operations.

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

Our business, financial condition and results of operations could be materially adversely affected by unfavorable results in pending or future litigation, regulatory investigations, and other legal matters. These matters may include, among other things, allegations of violation of U.S. and foreign competition law, labor laws, securities laws and regulations, consumer protection laws and environmental laws and regulations, as well as claims or litigation relating to product liability, intellectual property, securities, breach of contract and tort. For example, shareholder class action lawsuits that were filed against us in 2020 allege, in part, that we and certain of our executives made materially false and/or misleading statements and/or failed to disclose certain facts about our supply chain, inventory, revenue, projections and our relationships with third party distributors and revenue attributable to those distributors. We intend to vigorously defend the claims made in these lawsuits; however, the ultimate resolution cannot be predicted, and the claims raised in these lawsuits may result in further legal matters or actions against us, including, but not limited to, government enforcement actions or additional private litigation. 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 U.S., attempts have been made to allow damages for emotional distress and pain and suffering in connection with the loss of, or injury to, a pet. If such attempts were successful, our exposure with respect to product liability claims could increase materially.

Also, on July 1, 2021, we received a subpoena from the SEC relating to our channel inventory and sales practices prior to mid-2020. We have been responding to requests for documents and information from the SEC and will continue to do so. We believe that our actions were appropriate. However, we cannot predict the outcome of any particular proceeding, or whether the SEC investigation will be resolved favorably or ultimately result in charges or material damages, fines or other penalties, enforcement actions, or civil or criminal proceedings against us or members of our senior management.

Litigation matters and regulatory investigations, 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 legal matters. An adverse outcome of litigation or legal matters could result in us being responsible for significant damages. Any of these negative effects resulting from litigation, regulatory investigations and other legal matters could materially adversely affect our business, financial condition and results of operations.

Our insurance policies may be insufficient to protect against all potential hazards or litigation claims.

We rely on a combination of insurance and self-insurance, and changes in predictions, assumptions, and interpretations could affect our operations. Insurance policies include limits and may be insufficient to protect against all potential hazards and risks or litigation claims. Our product liability insurance policy may not fully cover our potential liabilities. In addition, we may determine that we should increase our coverage, and this insurance may be prohibitively expensive to us or our collaborators or licensees and may not fully cover our potential liabilities.

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, sale of our products. In addition, our manufacturing facilities, including the manufacturing facilities operated by our CMOs, 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 business, financial condition and results of operations.

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, we may be subject to re-review and may lose our approvals. For example, pending claims have been asserted in a lawsuit against the FDA's approval of *Experior*™, which was one of our eight new product launches in 2021. Our failure to obtain approvals, delays in the approval process, or our failure to maintain approvals in any jurisdiction, may prevent us from selling products in that jurisdiction until approval or re-approval is obtained, if ever.

In the EU, the Veterinary Medicinal Products Regulation updated the rules related to the authorization and use of veterinary medicines effective January 28, 2022. The updated rules limit the use of antibiotics, tighten importation rules, and impose stricter pharmacovigilance standards. This regulation must still be implemented at the member state level and as such, additional requirements may be adopted by individual member states which would have the effect of increasing the compliance requirements for our business in the EU with resulting costs.

We may incur additional tax expense or become subject to additional tax exposure.

We are subject to income taxes in the U.S. and numerous other jurisdictions. Our future results of operations could be adversely affected by changes in the effective tax rate as a result of a change in the mix of earnings between U.S. and non-U.S. jurisdictions or among jurisdictions with differing statutory tax rates, changes in our overall profitability, changes in tax laws or treaties or in their application or interpretation, changes in tax rates, changes in generally accepted accounting principles, changes in the valuation of deferred tax assets and liabilities, the results of audits and examinations of previously filed tax returns and continuing assessments of our tax exposures. We are also subject to the examination of our tax returns and other tax matters by the Internal Revenue Service and other tax authorities and governmental bodies. We regularly assess the likelihood of an adverse outcome resulting from these examinations to determine the adequacy of our provision for taxes. There can be no assurance as to the outcome of these examinations. If our effective tax rates were to increase, particularly in the U.S. or other material foreign jurisdictions, or if the ultimate determination of our taxes owed is for an amount in excess of amounts previously accrued, our operating results, cash flows and financial condition could be adversely affected.

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. 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. With the acquisition of the Bayer Animal Health business, we have now expanded our business more into direct to retailer and e-commerce channels in order to meet the pet owners where they want to purchase, which may increase the risk of counterfeiting of our products. Public loss of confidence in the integrity of vaccines and/or pharmaceutical products as a result of counterfeiting, illegal compounding or theft could have a material adverse effect on our business, financial condition and results of operations.

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 for the investigation and remediation of contaminated land under the U.S. Comprehensive Environmental Response, Compensation and Liability Act of 1980, as amended, 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. We could be subject to liability for the investigation and remediation of legacy environmental contamination caused by historical industrial activity as sites that we own or on which we operate. 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, property damage and natural resource damages, resulting from the disposal or release of hazardous materials into the environment. Such liability could materially adversely affect our business, financial condition and results of operations.

Furthermore, regulatory agencies are showing increasing concern over the impact of animal health products and farm animal operations on the environment. This increased regulatory scrutiny has in the past and may in the future necessitate that additional time and resources be spent to address these concerns in both new and existing products.

Our 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, environmental damage or significant environmental, health and safety issues that might arise at a manufacturing or R&D facility. 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. It is possible 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 could materially adversely affect our business, financial condition and results of operations.

The actual or purported intellectual property rights of third parties may negatively affect our business.

A third party may sue us, or our distributors or licensors, or otherwise make a claim alleging infringement or other violation of such third-party's patents, trademarks, trade dress, copyrights, trade secrets, domain names or other intellectual property rights. If our distributors, licensors or we do not prevail in this type of litigation, we may be required to:

- pay monetary damages;
- obtain a license in order to continue manufacturing or marketing the affected products, which may not be available on commercially reasonable terms, or at all; or
- stop activities, including any commercial activities, relating to the affected products, which could include a recall of the affected products and/or a cessation of sales in the future.

The costs of defending an intellectual property claim could be substantial and could materially adversely affect our business, financial condition and results of operations, even if we successfully defend such claim. Moreover, even if we believe that we do not infringe a validly existing third-party patent, we may choose to license such patent, which would result in associated costs and obligations. We may also incur costs in connection with an obligation to indemnify a distributor, licensor or other third party.

The intellectual property positions of animal health medicines and vaccines businesses frequently involve complex legal and factual questions, and an issued patent does not guarantee us the right to practice the patented technology or develop, manufacture or commercialize the patented product. For example, while we generally enter into proprietary information agreements with our employees and third parties, which assign intellectual property rights to us, these agreements may not be honored or may not effectively assign intellectual property rights to us under the local laws of some countries or jurisdictions. We cannot be certain that a competitor or other third party does not have or will not obtain rights to intellectual property that may prevent us from manufacturing, developing or marketing certain of our products, regardless of whether we believe such intellectual property rights are valid and enforceable or we believe we would otherwise be able to develop a more commercially successful product, which may materially adversely affect our business, financial condition and results of operations.

If our intellectual property rights are challenged or circumvented, competitors may be able to take advantage of our R&D efforts or harm the value of our brands.

Our long-term success depends on our ability to market innovative, competitive products. We rely and expect to continue to rely on a combination of intellectual property, including patent, trademark, trade dress, copyright, trade secret and domain name protection, as well as confidentiality and license agreements with our employees and others, to protect our intellectual property and proprietary rights. If we fail to obtain and maintain adequate intellectual property protection, we may not be able to prevent third parties from using our proprietary technologies or from marketing products that are very similar or identical to ours.

Our currently pending or future patent applications may not result in issued patents, or be approved on a timely basis, if at all. Similarly, any term extensions that we seek may not be approved on a timely basis, if at all. In addition, our issued patents, or any patents that may issue in the future, may not contain claims sufficiently broad to protect us against third parties with similar technologies or products or provide us with any competitive advantage, including exclusivity in a particular product area.

The validity and scope of our patent claims also may vary between countries, as individual countries have their own patent laws. For example, some countries only permit the issuance of patents covering a novel chemical compound itself, and its first use, and thus further methods of use for the same compound may not be patentable. The validity, enforceability, scope and effective term of patents can be highly uncertain and often involve complex legal and factual questions and proceedings that vary based on the local law of the relevant jurisdiction. Our ability to enforce our patents also depends on the laws of individual countries and each country's practice with respect to enforcement of intellectual property rights. Patent protection must be obtained on a jurisdiction-by-jurisdiction basis, and we only pursue patent protection in countries where we think it makes commercial sense for the given product. In addition, if we are unable to maintain our existing license agreements or other agreements pursuant to which third parties grant us rights to intellectual property, including because such agreements terminate, our financial condition and results of operations could be materially adversely affected.

Patent law reform in the U.S. and other countries may also weaken our ability to enforce our patent rights or make such enforcement financially unattractive. The America Invents Act permits enhanced third-party actions for challenging patents and implements a first-to-invent system. These reforms could result in increased costs to protect our intellectual property or limit our ability to obtain and maintain patent protection for our products in these jurisdictions. Additionally, certain foreign governments have indicated that compulsory licenses to patents may be granted in the case of national emergencies, which could diminish or eliminate sales and profits from those regions and materially adversely affect our financial condition and results of operations.

Our trademarks and brands may provide us with a competitive advantage in the market as they may be known or trusted by consumers. In order to maintain the value of such brands, we must be able to enforce and defend our trademarks. We have pursued and will pursue the registration of trademarks and service marks in the U.S. and internationally; however, enforcing rights against those who knowingly or unknowingly dilute or infringe our brands can be difficult. Effective trademark, service mark, trade dress or related protections may not be available in every country in which our products and services are available. Enforcement is especially difficult in first-to-file countries where "trademark squatters" can prevent us from obtaining adequate protections for our brands. There can be no assurance that the steps we have taken and will take to protect our proprietary rights in our brands and trademarks will be adequate or that third parties will not infringe, dilute or misappropriate our brands, trademarks, trade dress or other similar proprietary rights.

Many of our products are based on or incorporate proprietary information. We actively seek to protect our proprietary information, including our trade secrets and proprietary know-how, by generally requiring our employees, consultants, other advisors and other third parties to execute proprietary information and confidentiality agreements upon the commencement of their employment, engagement or other relationship. Despite these efforts and precautions, we may be unable to prevent a third party from copying or otherwise obtaining and using our trade secrets or our other intellectual property without authorization and legal remedies may not adequately compensate us for the damages caused by such unauthorized use. Further, others may independently and lawfully develop substantially similar or identical products that circumvent our intellectual property by means of alternative designs or processes or otherwise.

Significant portions 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;
- changes in the value of foreign currencies relative to the U.S. dollar or high inflation;
- compliance with governmental controls;
- difficulties enforcing contractual and intellectual property rights;
- parallel trade in our products (importation of our products from EU countries where our products are sold at lower prices into EU countries where the products are sold at higher prices);
- compliance with a wide variety of laws and regulations, such as the U.S. Foreign Corrupt Practices Act (the FCPA) and similar non-U.S. laws and regulations;
- compliance with foreign labor laws;
- compliance with local, regional and global restrictions on banking and commercial activities in emerging markets;
- burdens to comply with multiple and potentially conflicting foreign laws and regulations, including those relating to environmental, health and safety requirements and those in emerging markets;
- 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 such as the recent crisis in Ukraine;

- 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 the Treasury and the EU, in relation to our products or the products of farmers and other customers;
- 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 in 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;
- continued uncertainty, potential instability and volatility due to the withdrawal of the United Kingdom from the European Union; 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, as well as restrictions and sanctions that may be imposed on one or more jurisdictions, including those arising from the recent crisis in Ukraine. 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 technologies. 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 damage to our reputation. In addition, variations in the pricing of our products between jurisdictions may result in the unauthorized 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 business, financial condition and results of operations.

Further, 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.

We depend on sophisticated information technology and infrastructure.

We are continuing to enhance a number of our business processes, including our financial reporting and supply chain processes and with respect to where and from whom we obtain information technology systems. We have made and will continue to make significant configuration, process and data changes within many of the information technology systems we use. If our information technology systems and processes are not sufficient to support our business and financial reporting functions, or if we fail to properly implement our new business processes, our financial reporting may be delayed or inaccurate and, as a result, our business, financial condition and results of operations may be materially adversely affected. Even if we are able to successfully configure and change our systems, all technology systems, even with implementation of security measures, are vulnerable to disability, failures or unauthorized access. If our information technology systems were to fail or be breached, this could materially adversely affect our reputation and our ability to perform critical business functions, and sensitive and confidential data could be compromised.

Breaches of our information technology systems or improper disclosure of confidential company or personal data, or a failure to comply with privacy laws, regulations and our contractual obligations concerning data privacy or the security of certain information could have a material adverse effect on our reputation and operations.

We rely on information technology systems to process, transmit and store electronic information in our day-to-day operations, including customer, employee and company data. The secure processing, maintenance and transmission of this information is critical to our operations. In addition, the legal environment surrounding information security, storage, use, processing, transmission, maintenance, disclosure and privacy is demanding with the frequent imposition of new and changing regulatory requirements.

We store, process, and transmit certain information with third parties, including the use of cloud technologies. Our information systems and those of our third-party vendors are subjected to computer viruses or other malicious codes, unauthorized access attempts, phishing and other cyber-attacks and are also vulnerable to an increasing threat of continually evolving cybersecurity risks and external hazards, as well as improper or inadvertent staff behavior. Any potential cyber breach could result in the unauthorized access, public disclosure, loss or theft of confidential data, or unauthorized access to, disruption of, or interference with our operations that rely on information systems. Such breach can also have negative consequences, such as increased costs for security measures or remediation costs, and diversion of management attention.

In the wake of the COVID-19 global pandemic, we are increasingly dependent on our information technology systems as our office workers, who are primarily working remotely, rely on third-party applications to perform their job duties and are processing information through our network via their home networks, which may be less secure. As such, our ability to effectively manage our business depends on the security, reliability and adequacy of our technology systems and data and the ability of our employees to follow our cyber security policies and protocols.

Any actual or perceived access, disclosure or other loss of information or any significant breakdown, intrusion, interruption, cyber-attack or corruption of customer, employee or company data or our failure to comply with federal, state, local and foreign privacy laws or contractual obligations with customers, vendors, payment processors and other third parties, could result in legal claims or proceedings, liability under laws or contracts that protect the privacy of personal information, regulatory penalties, disruption of our operations, and damage to our reputation, all of which could materially adversely affect our business, revenue and competitive position. While we will continue to implement additional protective measures to reduce the risk of and detect cyber-incidents, cyber-attacks are becoming more sophisticated and frequent, and the techniques used in such attacks change rapidly. Our protective measures may not protect us against attacks and such attacks could have a significant impact on our business and reputation.

Increased regulation or decreased governmental financial support relating to the raising, processing or consumption of farm animals could reduce demand for our farm animal products.

Companies in the farm animal sector are subject to extensive and increasingly stringent regulations. See "Item 1. Business — Regulatory" for further discussion. If farm animal producers are adversely affected by new regulations or changes to existing regulations, they may reduce herd or flock sizes or become less profitable and, as a result, they may reduce their use of our products, which may materially adversely affect our business, financial condition and results of operations. Also, many farm animal 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 farm animal products. More stringent regulation of the farm animal sector, including regarding the use of farm animal products, could have a material adverse effect on our business, financial condition and results of operations.

Our business could be materially 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 U.S. 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, higher ongoing labor costs or other labor problems in the future at our sites. We may also experience difficulty or delays in implementing changes to our workforce in certain markets.

Further, labor-related issues, including at our suppliers or CMOs, could cause a disruption of our operations, which could have a material adverse effect on our business, financial condition and results of operations, potentially resulting in cancelled orders by customers, unanticipated inventory accumulation or shortages and reduced revenue and net income.

A loss of key personnel or highly skilled employees could disrupt our operations.

Our future success depends partly on the continued service of our highly qualified and well-trained key research, engineering, sales, marketing, manufacturing, executive and administrative personnel. We face intense competition for these qualified personnel from our competitors and others, particularly for certain highly technical specialties in geographic areas where we continue to recruit. Due to this intense competition, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit or identify suitable replacement personnel. If we are unsuccessful in our recruitment and retention efforts, our business may be harmed. In addition, if we fail to effectively manage organizational and/or strategic changes, our financial condition, results of operations and reputation, as well as our ability to successfully attract, motivate and retain key employees, could be harmed.

We have underfunded pension plan liabilities. We will require current and future operating cash flow to fund these shortfalls, reducing the cash available for other uses.

We have certain defined benefit pension plans, predominantly in Germany and Switzerland, that our employees participate in that are either dedicated to our employees or where the plan assets and liabilities that relate to our employees were legally required to transfer to us at the time of our separation from Lilly. The funded status and net periodic pension cost for these plans is materially affected by the discount rate used to measure pension obligations, the longevity and actuarial profile of our workforce, the level of plan assets available to fund those obligations and the actual and expected long-term rate of return on plan assets. Significant changes in investment performance or a change in the portfolio mix of invested assets can result in corresponding increases and decreases in the valuation of plan assets or in a change in the expected rate of return on plan assets. As of December 31, 2021, for pension plans with projected benefit obligations in excess of plan assets, the projected benefit obligation was $455 million with plan assets of $200 million. Any changes in the discount rate could result in a significant increase or decrease in the valuation of pension obligations, affecting the reported funded status of our pension plans as well as the net periodic pension cost in the following years. Similarly, changes in the expected return on plan assets can result in significant changes in the net periodic pension cost in the following years. The need to make additional cash contributions will divert resources from our operations and may have a material adverse effect on our business, financial condition and results of operations.

Risks Related to Acquisitions and Divestitures

We may not be able to successfully complete favorable transactions or successfully integrate acquired businesses when we pursue acquisitions, divestitures, joint ventures or other significant transactions.

From time to time, we evaluate potential acquisitions, divestitures or joint ventures, such as the proposed carve-out of our microbiome R&D platform, that would further our strategic objectives. The completion of such transactions is often subject to conditions that may be outside our control, including obtaining the requisite approval of the stockholders of the target company and/or government approval pursuant to the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended. Accordingly, we may not be able to complete announced and signed transactions and therefore not realize the anticipated benefits therefrom.

After the closing of an acquisition, including the transaction with KindredBio, we are required to devote significant management attention and resources to integrating the portfolio and operations of the target company. Potential difficulties that we may encounter in the integration process, including as a result of distraction of our management, include the following:

- the inability to realize the anticipated value from various assets of the target company;
- the inability to combine the businesses of the acquired company with ours in a manner that permits us to achieve the cost savings or other synergies anticipated as a result of the transaction or to achieve such cost savings or other anticipated synergies in a timely manner, which could result in us not realizing some anticipated benefits of the transaction in the time frame anticipated, or at all;

- loss of key employees;
- potential unknown liabilities and unforeseen increased expenses, delays or unfavorable conditions in connection with the closing of the transaction and the subsequent integration; and
- performance shortfalls at our or the target company as a result of the diversion of management's attention from ongoing business activities as a result of completing the transaction and integrating the companies' operations.

In the case of our announcement regarding our intention to carve-out our microbiome R&D platform, the terms, timing and structure of any such separation of this platform, or whether the separation can be completed at all, remain uncertain, as is our ability to achieve any operational and strategic benefits from the separation. In the meantime, the uncertainty of announcing the separation initiative may adversely impact potential customers and suppliers related to the microbiome R&D platform.

Future acquisitions could also result in potentially dilutive issuances of equity securities, the incurrence of debt, contingent liabilities or amortization expenses related to intangible assets, and increased operating expenses, which could adversely affect our results of operations and financial condition. Furthermore, if we issue equity or debt securities to raise additional funds, our existing shareholders may experience significant dilution, and the new equity or debt securities may have rights, preferences and privileges senior to those of our existing stockholders. Furthermore, if we sell a substantial number of shares of common stock in the public markets, the availability of those shares for sale could adversely affect the market price of our common stock. Such sales, or the perception in the market that holders of a large number of shares intend to sell shares, could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity securities.

We may be unable to successfully integrate the Bayer Animal Health business and realize the anticipated benefits of the acquisition.

The successful integration of the Bayer Animal Health business and operations into those of our own and our ability to realize the expected synergies and benefits of the transaction is subject to a number of risks and uncertainties, many of which are outside of our control. We will also be required to devote significant management attention and resources to integrating business practices, cultures and operations of each business. The risks and uncertainties relating to integrating the two businesses and realizing the anticipated cost synergies include, among other things:

- the inability to achieve the anticipated revenue, earnings, accretion and other benefits due to the impact of the COVID-19 global health pandemic;
- the challenge of integrating complex organizations, systems, including the enterprise resource planning system upon which the Bayer Animal Health business is currently operating, operating procedures, compliance programs, technology, networks and other assets of the Bayer Animal Health business;
- the difficulties harmonizing differences in the business cultures of our company and the Bayer Animal Health business;
- the inability to combine successfully our respective businesses in a manner that permits us to achieve the cost savings, synergies and other anticipated benefits from the acquisition;
- the inability to minimize the diversion of management attention from ongoing business concerns during the process of integrating the Bayer Animal Health business into our business;
- the inability to resolve potential conflicts that may arise relating to customer, supplier and other important relationships of our business and the Bayer Animal Health business;
- the inability to transfer agreements relating to customers, suppliers and other important relationships of the Bayer Animal Health business;
- the challenge of managing the expanded operations of a significantly larger and more complex company and coordinating geographically separate organizations; and
- difficulties in fully exploring intellectual property licensed from Bayer in connection with the acquisition, given Bayer's rights as licensor of such intellectual property.

We have incurred substantial expenses to consummate and will continue to incur substantial expenses to integrate the acquisition but may not realize the anticipated cost synergies and other benefits to the extent expected, on the timeline expected, or at all. In addition, even if we are able to integrate the Bayer Animal Health business successfully, the anticipated benefits of the acquisition may not be realized fully, or at all, or may take longer to realize than expected. Moreover, competition in the animal health industry, including competition that has negatively impacted results in the pet health parasiticide market, may also cause us not to fully realize the anticipated benefits of the acquisition. Given the size and significance of the acquisition, we may encounter difficulties in the integration of the operations of the Bayer Animal Health business and may fail to realize the full benefits and synergies of the acquisition, which could adversely impact our business, results of operations and financial condition.

To ensure business continuity after the transfer of the Bayer Animal Health business, we entered into transitional services agreements and other long-term agreements with Bayer. Bayer's performance of its obligations under such long-term agreements is important to our transition of the Bayer Animal Health business. Our inability to resolve conflicts with Bayer that may arise under those long-term agreements could compromise our ability to successfully integrate the Bayer Animal Health business. We may also encounter difficulties in securing another vendor to provide us with those same services, which could adversely affect our business, financial condition or results of operations.

Risks Related to our Indebtedness

We have substantial indebtedness.

We have a significant amount of indebtedness, which could materially adversely affect our business, financial condition and results of operations. See "Item 8. Financial Statements and Supplementary Data — Note 9: Debt" to the consolidated financial statements for further discussion.

Our high level of debt could have important consequences, including:

- making it more difficult for us to satisfy our obligations with respect to our debt and any failure to comply with the obligations of any of our debt instruments, including restrictive covenants and borrowing conditions, could result in an event of default under the agreements governing other indebtedness;
- requiring us to dedicate a substantial portion of our cash flow from operations to the payment of interest and the repayment of our indebtedness, thereby reducing funds available to us for other purposes;
- limiting our ability to obtain additional financing to fund future working capital, capital expenditures, business development or other general corporate requirements, including dividends;
- increasing our vulnerability to general adverse economic and industry conditions;
- making us more highly leveraged than some of our competitors, which may place us at a competitive disadvantage;
- restricting us from making strategic acquisitions, engaging in development activities or exploiting business opportunities;
- causing us to make non-strategic divestitures;
- exposing us to the risk of increased interest rates as certain of our borrowings are and may in the future be at variable rates of interest;
- limiting our flexibility in planning for and reacting to changes in the animal health industry;
- impacting our effective tax rate; and
- increasing our cost of borrowing.

Despite our substantial indebtedness, we may still be able to incur significantly more debt, which could intensify the risks associated with our indebtedness.

We and our subsidiaries may be able to incur substantial indebtedness in the future, even following the incurrence of indebtedness in connection with the acquisition of Bayer Animal Health. Although the terms of the credit agreement governing our credit facilities contain restrictions on our and our subsidiaries' ability to incur additional indebtedness, these restrictions are subject to a number of important qualifications and exceptions, and the indebtedness incurred in compliance with these restrictions could be substantial. These restrictions do not prevent us from incurring other obligations that do not constitute indebtedness. In addition to our borrowings under our credit facilities, the covenants under the credit agreement governing our credit facilities are expected to, and the covenants under any other of our existing or future debt instruments could, allow us to incur a significant amount of additional indebtedness and, subject to certain limitations, such additional indebtedness could be secured. The more leveraged we become, the more we, and in turn our security holders, will be exposed to certain risks described above under "—We have substantial indebtedness."

We may not be able to generate sufficient cash to service all of our indebtedness and may be forced to take other actions to satisfy our obligations under our indebtedness, which may not be successful.

Our ability to make scheduled payments on or refinance our debt obligations depends on our financial condition and operating performance, which are subject to prevailing economic and competitive conditions and to certain financial, business, legislative, regulatory and other factors beyond our control. We may be unable to maintain a level of cash flows from operating activities sufficient to permit us to pay the principal and interest on our indebtedness.

If our cash flows and capital resources are insufficient to fund our debt service obligations, we could face substantial liquidity problems and could be forced to reduce or delay investments and capital expenditures, or to dispose of material assets or operations, alter our dividend policy, seek additional debt or equity capital or restructure or refinance our indebtedness. We may not be able to effect any such alternative measures on commercially reasonable terms or at all and, even if successful, those alternative actions may not allow us to meet our scheduled debt service obligations. The instruments that will govern our indebtedness may restrict our ability to dispose of assets and may restrict the use of proceeds from those dispositions and may also restrict our ability to raise debt or equity capital to be used to repay other indebtedness when it becomes due. We may not be able to consummate those dispositions or to obtain proceeds in an amount sufficient to meet any debt service obligations when due.

In addition, we conduct our operations through our subsidiaries. Accordingly, repayment of our indebtedness will depend on the generation of cash flow by our subsidiaries, including certain international subsidiaries, and their ability to make such cash available to us, by dividend, debt repayment or otherwise. Our subsidiaries may not have any obligation to pay amounts due on our indebtedness or to make funds available for that purpose. Our subsidiaries may not be able to, or may not be permitted to, make adequate distributions to enable us to make payments in respect of our indebtedness. Each subsidiary is a distinct legal entity and, under certain circumstances, legal, tax and contractual restrictions may limit our ability to obtain cash from our subsidiaries. In the event that we do not receive distributions from our subsidiaries, we may be unable to make required principal and interest payments on our indebtedness.

Our inability to generate sufficient cash flows to satisfy our debt obligations, or to refinance our indebtedness on commercially reasonable terms or at all, may materially adversely affect our business, financial condition and results of operations and our ability to satisfy our obligations under our indebtedness or pay dividends on our common stock.

Our debt agreements contain restrictions that will limit our flexibility in operating our business.

Our credit facilities contain, and any other existing or future indebtedness of ours would likely contain, a number of covenants that impose significant operating and financial restrictions on us, including restrictions on our and our subsidiaries' ability to, among other things:

- incur additional debt, guarantee indebtedness or issue certain preferred shares;

- pay dividends on or make distributions in respect of, or repurchase or redeem, our capital stock or make other restricted payments;
- prepay, redeem or repurchase certain debt;
- make loans or certain investments;
- sell certain assets;
- create liens on certain assets;
- consolidate, merge, sell or otherwise dispose of all or substantially all of our assets;
- enter into certain transactions with our affiliates;
- substantially alter the businesses we conduct;
- enter into agreements restricting our subsidiaries' ability to pay dividends; and
- designate our subsidiaries as unrestricted subsidiaries.

In addition, certain of our credit facilities require us to comply with a net total leverage ratio and a minimum fixed charge coverage ratio under certain circumstances.

As a result of these covenants, we are limited in the manner in which we conduct our business, and we may be unable to engage in favorable business activities or finance future operations or capital needs.

A failure to comply with the covenants under the indenture that governs the senior unsecured notes and credit facilities, or any of our other existing or future indebtedness could result in an event of default, which, if not cured or waived, could have a material adverse effect on our business, financial condition and results of operations. In the event of an event of default under our credit facilities, it is expected that the lenders:

- will not be required to lend any additional amounts to us;
- could elect to declare all borrowings outstanding, together with accrued and unpaid interest and fees, to be due and payable and terminate all commitments to extend further credit;
- could require us to apply all of our available cash to repay these borrowings; or
- could effectively prevent us from making debt service payments on the notes (due to a cash sweep feature).

Such actions by the lenders could cause cross defaults under our other indebtedness, including our senior unsecured notes. If we were unable to repay those amounts, the lenders under our credit facilities and any of our other existing or future secured indebtedness could proceed against the collateral granted to them to secure our credit facilities or such other indebtedness. We have pledged a significant portion of our assets as collateral under our credit facilities.

Changes in our credit rating could increase our interest expense and restrict our access to, and negatively impact the terms of, current or future financings or trade credit.

Credit rating agencies continually revise their ratings for the companies that they follow, including us. Credit rating agencies also evaluate our industry as a whole and may change their credit ratings for us based on their overall view of our industry. We cannot be sure that credit rating agencies will maintain their ratings on us and certain of our debt. As a result of the acquisition of Bayer Animal Health, our credit ratings were downgraded, resulting in increased borrowing costs. Because the ratings of certain of our senior unsecured notes have been downgraded, we are required to pay additional interest under the senior unsecured notes. Any further downgrades could result in requirements to pay additional interest under the senior unsecured notes. Moreover, any decision to downgrade our ratings could restrict our access to, and negatively impact the terms of, current or future financings and trade credit extended by our suppliers of raw materials or other vendors.

Changes in interest rates may adversely affect our earnings and/or cash flows.

Certain of our credit facilities bear interest at variable interest rates that use the London Inter-Bank Offered Rate (LIBOR) as a benchmark rate. On July 27, 2017, the United Kingdom's Financial Conduct Authority (FCA), which regulates LIBOR, announced that it intends to stop persuading or compelling banks to submit LIBOR quotations after 2021 (the FCA Announcement). The FCA Announcement indicates that the continuation of LIBOR on the current basis cannot and will not be assured after 2021, and LIBOR may cease to exist or otherwise be unsuitable for use as a benchmark.

In March 2021, ICE Benchmark Administration, the administrator of LIBOR, with the support of the U.S. Federal Reserve and the FCA, formally announced that LIBOR will cease to be published on June 30, 2023. The Alternative Reference Rates Committee in the U.S. has proposed that the Secured Overnight Financing Rate (SOFR) is the preferred alternative to U.S. LIBOR for use in derivatives and other financial contracts that are currently indexed to LIBOR; however, there are presently many variations of SOFR, and it is unknown whether these or any other alternative reference rate will attain market acceptance.

SOFR measures the cost of borrowing cash overnight, collateralized by U.S. Treasury securities, and is based on directly observable U.S. Treasury-backed repurchase transactions. Although our credit facilities provide for successor base rates, the discontinuance of LIBOR and the introduction of alternative reference rates, such as SOFR, could cause the interest rates calculated on our floating-rate debt and interest rate swaps to be materially different than expected.

Risks Related to Elanco Common Stock

We do not anticipate paying dividends on our common stock in the foreseeable future.

We do not anticipate paying any dividends in the foreseeable future on our common stock. We intend to retain all future earnings for the operation and expansion of our business and the repayment of outstanding debt. Certain of our credit facilities contain restrictive covenants that impose significant operating and financial restrictions on us, including restrictions on our ability to pay dividends and make other restricted payments. As a result, capital appreciation, if any, of our common stock may be our stockholders' major source of gain for the foreseeable future. While we may change this policy at some point in the future, we cannot assure you that we will make such a change.

The distributions we pay on our common stock may not qualify as dividends for U.S. federal income tax purposes, which could adversely affect the U.S. federal income tax consequences of owning our common stock.

Generally, any distributions that we make to a stockholder with respect to its shares of our common stock will constitute a dividend for U.S. federal income tax purposes to the extent of our current or accumulated earnings and profits as determined for U.S. federal income tax purposes. Furthermore, our ability to generate earnings and profits, as determined for U.S. federal income tax purposes, in any future year is subject to a number of variables that are uncertain and difficult to predict.

Generally, any distribution not constituting a dividend under the rules described above will be treated as first reducing the investor's adjusted basis in shares of our common stock and, to the extent that the distribution exceeds the adjusted basis in shares of our common stock, as gain from the sale or exchange of such shares, and if the investor is a domestic corporation, it will not be entitled to claim, with respect to such non-dividend distribution, a "dividends-received" deduction, which generally applies to dividends received from other domestic corporations.

Applicable laws and regulations, provisions of our amended and restated articles of incorporation and our amended and restated bylaws may discourage takeover attempts and business combinations that shareholders might consider in their best interests.

Applicable laws, provisions of our amended and restated articles of incorporation and our amended and restated bylaws may delay, deter, prevent or render more difficult a takeover attempt that our shareholders might consider in their best interests. For example, they may prevent our shareholders from receiving the benefit from any premium to the market price of our common stock offered by a bidder in a takeover context. Even in the absence of a takeover attempt, the existence of these provisions may adversely affect the prevailing market price of our common stock if they are viewed as discouraging takeover attempts in the future.

Our amended and restated articles of incorporation and our amended and restated bylaws contain provisions that are intended to encourage prospective acquirers to negotiate with our board of directors rather than to attempt a hostile takeover, which could deter coercive takeover practices and inadequate takeover bids. These provisions provide for:

- a board of directors divided into three classes with staggered terms;
- advance notice requirements regarding how our shareholders may present proposals or nominate directors for election at shareholder meetings;
- the right of our board of directors to issue one or more series of preferred stock with such powers, rights and preferences as the board of directors shall determine;
- only the board of directors to fill newly-created directorships or vacancies on our board of directors;
- limitations on the ability of shareholders to call special meetings of shareholders and require that all shareholder action be taken at a meeting rather than by written consent;
- a 66 2/3% shareholder vote requirement to amend our amended and restated articles of incorporation;
- the exclusive right of our board of directors to amend our amended and restated bylaws; and
- the requirement that a 66 2/3% vote is necessary to remove directors.

These limitations may adversely affect the prevailing market price and market for our common stock if they are viewed as limiting the liquidity of our stock or discouraging takeover attempts in the future.

We recently adopted a “proxy access” bylaw, which permits an eligible shareholder or group of shareholders to nominate, and have included in our proxy materials, director nominees constituting up to two individuals or 20% of our board of directors (whichever is greater), subject to the requirements and procedures in our bylaws; and we intend to put forward for shareholder approval at our 2022 annual meeting of shareholders a proposal to remove the 66 2/3% voting requirements in our amended and restated articles of incorporation and replace them with a majority standard. However, there can be no assurance that the requisite shareholder vote requirement for such proposal will be obtained, or that any such changes will reduce the risks described above.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

The address of our global headquarters is currently 2500 Innovation Way, Greenfield, IN 46140. We plan to relocate our global headquarters to a new office building in Indianapolis, Indiana, with occupancy expected in 2024.

Our global manufacturing network is comprised of 20 manufacturing sites. The largest manufacturing site in our network is located in Clinton, Indiana. In addition, our global manufacturing network is supplemented by approximately 140 CMOs. See "Item 1. Business — Manufacturing and Supply Chain."

We have R&D operations co-located with certain of our manufacturing sites to facilitate the efficient transfer of production processes from our laboratories to manufacturing. In addition, we maintain R&D operations at non-manufacturing locations in the U.S., Germany, Australia, Brazil, China, India, and Switzerland. Our R&D headquarters is currently our U.S. R&D site located in Greenfield, Indiana and will relocate to Indianapolis, Indiana when we relocate our global headquarters, expected in 2024. See "Item 1. Business — Research and Development."

We own or lease various additional properties for other business purposes, including office space, warehouses and logistics centers. We believe that our existing properties, as supplemented by CMOs, are adequate for our current requirements and our operations in the near future.

ITEM 3. LEGAL PROCEEDINGS

Information pertaining to certain legal proceedings is provided in Note 16: Commitments and Contingencies to the consolidated financial statements included under Item 8, " Financial Statements and Supplementary Data," and is incorporated by reference herein.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR THE REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

On September 20, 2018, our common stock began trading on the New York Stock Exchange under the symbol “ELAN.”

On January 30, 2020, our tangible equity units (TEUs) began trading on the New York Stock Exchange under the symbol “ELAT.”

Holders

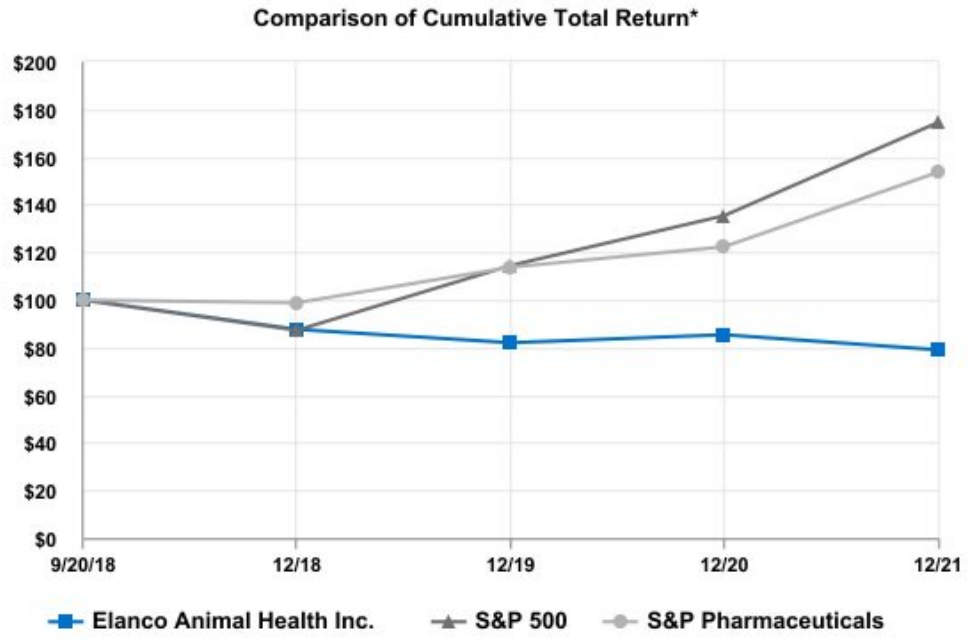
There were 275 holders of record of our common stock as of February 23, 2022. This does not include the number of stockholders who hold shares of our common stock through banks, brokers or other financial institutions.

Dividend Policy

We do not anticipate paying dividends on our common stock in the foreseeable future; however, we may change our dividend policy at any time.

Performance Graph

This graph compares the return on Elanco's common stock with that of the S&P 500 Stock Index and the S&P 500 Pharmaceuticals Index from September 20, 2018 (the first day our common stock was traded in conjunction with our initial public offering (IPO)) through December 31, 2021. The graph assumes that on September 20, 2018, the date that our common stock began trading on the New York Stock Exchange, a person invested $100 each in Elanco common stock, the S&P 500 Index, and the S&P 500 Pharmaceuticals Index. The graph measures total shareholder return, which takes into account both stock price and dividends. It assumes that dividends paid by a company are reinvested in that company's stock.



*$100 invested on September 20, 2018 in stock or index, including reinvestment of dividends. Fiscal years ended December 31.

	September 20, 2018	December 31, 2018	December 31, 2019	December 31, 2020	December 31, 2021
Elanco Animal Health Inc.	$ 100.00	$ 87.58	$ 81.81	$ 85.19	$ 78.83
S&P 500 Index	100.00	86.97	114.36	135.40	174.26
S&P 500 Pharmaceuticals Index	100.00	98.62	113.50	122.04	153.47

ITEM 6. (RESERVED)

Not applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF RESULTS OF OPERATIONS AND FINANCIAL CONDITION

Introduction

Management's discussion and analysis of financial condition and results of operations (MD&A) is intended to assist the reader in understanding and assessing significant changes and trends related to our results of operations and financial position. This discussion and analysis should be read in conjunction with the consolidated financial statements and accompanying footnotes in Item 8 of Part II of this Form 10-K. Certain statements in this Item 7 of Part II of this Form 10-K constitute forward-looking statements. Various risks and uncertainties, including those discussed in "Forward-Looking Statements" and Item 1A, "Risk Factors," may cause our actual results, financial position, and cash generated from operations to differ materially from these forward-looking statements. For results of operations discussions related to years ending December 31, 2020 and 2019, refer to Item 7 of Part II in our Annual Report on Form 10-K for the year ended December 31, 2020 filed with the Securities and Exchange Commission on March 1, 2021.

Overview

Elanco is a global animal health company that develops products for pets and farm animals in more than 90 countries. With a heritage dating back to 1954, we rigorously innovate to improve the health of animals and to benefit our customers while fostering an inclusive, cause-driven culture for our employees. We operate our business in a single segment directed at fulfilling our vision of enriching the lives of people through food, making protein more accessible and affordable, and through pet companionship, helping pets live longer, healthier lives.

On August 27, 2021, we acquired KindredBio, a biopharmaceutical company that develops innovative biologics focused on saving and improving the lives of pets. We had previously signed an agreement with KindredBio in the second quarter of 2021 to acquire exclusive global rights to KIND-030, a monoclonal antibody in development for the treatment and prevention of canine parvovirus. The acquisition of KindredBio further accelerates our opportunity for expansion in pet health, notably by expanding our research efforts in dermatology. See Note 5: Acquisitions and Divestitures to the consolidated financial statements for additional information on the acquisition. Subsequent to the acquisition date, our consolidated financial statements include the assets, liabilities, operating results and cash flows of KindredBio

On August 1, 2020, we completed the acquisition of Bayer Animal Health. The acquisition expanded our pet health product category, advancing our planned portfolio mix transformation and creating a better balance between our farm animal and pet health product categories. Our product portfolio and pipeline have been enhanced by the addition of Bayer Animal Health, which complements our commercial operations and international infrastructure. See Note 5: Acquisitions and Divestitures to the consolidated financial statements for additional information on the acquisition. Subsequent to the acquisition date, our consolidated financial statements include the assets, liabilities, operating results and cash flows of Bayer Animal Health.

We offer a diverse portfolio of approximately 200 brands that make us a trusted partner to pet owners, veterinarians and farm animal producers. Our products are generally sold worldwide to third-party distributors, independent retailers, and directly to farm animal producers and veterinarians. With the acquisition of Bayer Animal Health, we have expanded our presence in retail and e-commerce channels in order to meet pet owners where they want to purchase.

A summary of our 2021, 2020, and 2019 revenue and net income (loss) is as follows:

	Year Ended December 31,		
	2021	2020	2019
Revenue	$ 4,765	$ 3,273	$ 3,071
Net income (loss)	(472)	(560)	68

Increases or decreases in inventory levels at our channel distributors can positively or negatively impact our quarterly and annual revenue results, leading to variations in revenues. This can be a result of various factors, such as end customer demand, new customer contracts, heightened and generic competition, the need for certain inventory levels, our ability to renew distribution contracts with expected terms, our ability to implement commercial strategies, regulatory restrictions, unexpected customer behavior, proactive measures taken by us in response to shifting market dynamics, payment terms we extend, which are subject to internal policies, and procedures and environmental factors beyond our control, including weather conditions and the COVID-19 global pandemic.

Key Trends and Conditions Affecting Our Results of Operations

The animal health industry, which focuses on both pets and farm animals, is a growing industry that benefits billions of people worldwide.

We believe that factors influencing growth in demand for pet medicines and vaccines include:

- increased pet ownership globally;
- pets living longer; and
- increased pet spending as pets are viewed as members of the family by owners.

As demand for animal protein grows, farm animal health is becoming increasingly important. Factors influencing growth in demand for farm animal medicines and vaccines include:

- two in three people needing improved nutrition;
- increased global demand for protein, particularly poultry and aquaculture;
- natural resource constraints, such as scarcity of arable land, fresh water and increased competition for cultivated land, driving the need for more efficient food production;
- loss of productivity due to farm animal disease and death;
- increased focus on food safety and food security; and
- human population growth, increased standards of living, particularly in many emerging markets, and increased urbanization.

Growth in farm animal nutritional health products (enzymes, probiotics and prebiotics) is influenced, among other factors, by demand for antibiotic alternatives that can promote animal health and increase productivity.

Factors Affecting Our Results of Operations

COVID-19 Pandemic and Resulting Operating Environment

Our business has been impacted by the COVID-19 pandemic. We continue to monitor the global outbreak of COVID-19 and have worked with our customers, employees, suppliers and other stakeholders to mitigate the risks posed by its spread. The COVID-19 pandemic continues to impact the economy in the U.S. and globally, and has affected the operations of our company, vendors and suppliers, and supply of and demand for our products as follows:

Operations

As a result of the COVID-19 pandemic, governmental authorities implemented measures to try to contain the virus, such as travel bans and restrictions, limits on gatherings, quarantines, shelter-in-place orders, site closures and business shutdowns. These measures have affected the ability of our employees, vendors, and suppliers to perform their respective responsibilities and obligations relative to the conduct of our business. We have important manufacturing operations worldwide that have been impacted by the outbreak. Measures requiring business shutdowns generally exclude certain essential services, and those essential services commonly include critical infrastructure and the businesses that support that critical infrastructure. Because the animal health industry has been designated an essential business, our manufacturing and research facilities remain operational, while our employees in other company functions continue to primarily work remotely. These measures have impacted and may further impact our workforce and operations, as well as those of our customers, vendors and suppliers.

In late 2020 and early 2021, vaccines effective in combating COVID-19 were authorized for use by health agencies in certain countries and regions in which we operate (including the U.S., U.K., European Union, Canada and Mexico) and began to be administered. While the outbreak recently appeared to be trending downward, particularly as vaccination rates increased, new variants of COVID-19 continue to emerge, including the Delta variant and Omicron variant, spreading throughout the U.S. and globally, causing some countries and regions to reinstate travel bans and restrictions. In addition, the availability of COVID-19 vaccines, their continued effectiveness and the need for and availability of boosters are difficult to predict, and vaccination levels vary across jurisdictions. The pace and shape of the COVID-19 recovery as well as the impact and extent of COVID-19 variants or potential resurgences are not presently known. As a result, it is possible the COVID-19 pandemic, particularly in light of variant strains of the virus, could further impact our operations and the operations of our customers, suppliers and vendors as a result of quarantines, facility closures, illnesses, and travel and logistics restrictions.

Supply

The COVID-19 pandemic and related economic effects have disrupted the global supply chain across all modes of transportation, which in turn has resulted in less reliable transportation schedules and increased freight costs. This disruption, combined with increased demand for key raw materials (including those used in COVID-19 vaccine manufacturing), has also impacted our suppliers, resulting in shortages of raw materials or components required to manufacture our products. We continue to work closely with suppliers and freight partners to mitigate impacts to our operations and customers, including the addition of new transportation routes and targeted increases of certain safety stocks. Although we regularly monitor the financial health of companies in our supply chain, prolonged financial hardship on our suppliers and labor shortages could continue to disrupt our ability to obtain key raw materials, adversely affecting our operations. The global industry freight environment has experienced, and could continue to experience, lead time disruptions and increases in shipping costs, negatively impacting our profitability.

Demand

The COVID-19 pandemic has adversely impacted global economic conditions. In particular, the COVID-19 pandemic created significant uncertainty for our channel distribution partners with respect to end customer demand and working capital. Our third party distributors may face difficulties maintaining operations and normal liquidity in light of government-mandated restrictions. Due to liquidity and working capital pressure caused by the COVID-19 pandemic, our distributors continue to manage inventory more tightly. In response to this, along with a shift in tactics for demand generation with our distributors, we reduced channel inventory levels during the first half of 2020 as we tightened our approach across all facets of our distributor relationships. We estimate that this decreased our revenue by approximately $160 million in the first half of 2020. These actions have allowed us to improve working capital management, increase gross margin, implement new compensation structures with our distributors and enable greater control of overall stock levels. For our pet health business, demand in our direct to retailer and e-commerce channels could be negatively impacted by economic conditions as they fluctuate.

In our farm animal business, demand was negatively impacted by processing plant closures in 2020, resulting in a backlog of animals ready for processing, and weakened food service demand, which collectively put pressure on producer economics. Processing plants have adjusted operations and have cleared most of the backlog, and demand for certain protein categories continues to recover. While the impact was most significant for the U.S. livestock industry, particularly in the second and third quarters of 2020, the pressure has occurred globally and across species. As the pandemic continued throughout 2021, our business was affected by lower levels of demand in certain markets due to unfavorable macroeconomic conditions and reduced food service consumption as well as an overall reduction in the bird and animal populations due to herd reduction and disease. As a result, the industry has seen lowered prices and producer profitability across species, most notably in international poultry and aqua. While we anticipate that recovery of end consumer demand will continue to occur, particularly in the food service business, this recovery may be negatively impacted by ongoing labor shortages in the swine, poultry, dairy and beef industries or the effect of inflation on customer profitability. We also expect this recovery to be volatile and uncertain. In addition, demand may be impacted by potential future mitigation measures such as shutdowns if prolonged resurgences in COVID-19 and its variants occur globally.

We continue to monitor the impacts on our customers' liquidity and therefore our ability to collect on our accounts receivable. While our allowance on these receivables factors in expected credit losses, disruption and declines in the global economy could result in difficulties in our ability to collect, which we have not experienced on a material basis at this time. If significant issues with collections occur, material increases in our allowance for doubtful accounts may be required.

Our Acquisition of Bayer Animal Health and KindredBio

We have incurred and expect to continue to incur expenses in connection with our acquisitions of Bayer Animal Health and KindredBio, including fees for professional services such as legal, accounting, consulting, and other advisory fees and expenses. Expenses incurred in 2021 primarily related to integration activities. In addition, we have incurred and expect to continue to incur costs related to the build out of processes and systems to support finance and global supply and logistics and to expand administrative functions, including, but not limited to, information technology, facilities management, distribution, human resources, and manufacturing, to replace services previously provided by the former parent company of Bayer Animal Health. We anticipate that these additional costs will be partially offset by expected synergies

Product Development and New Product Launches

A key element of our targeted value creation strategy is to drive growth through portfolio development and product innovation. We continue to pursue the development of new chemical and biological molecules through our approach to innovation. Our future growth and success depend on both 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, and the expansion of the use of our existing products. We believe we are an industry leader in animal health R&D, with a track record of product innovation, business development and commercialization.

Competition

We face intense competition. Principal methods of competition vary depending on the particular region, species, product category, or individual product. Some of these methods include new product development, including generic alternatives to our products, quality, price, service and promotion. See "Item 1. Business — Competition."

Productivity

Our results during the periods presented have benefited from operational and productivity initiatives implemented following recent acquisitions and in response to changing market demand for antibiotics and other headwinds.

Prior to the acquisition of Bayer Animal Health, our acquisitions within the last six years added in the aggregate $1.4 billion in revenue, 4,600 full-time employees, 12 manufacturing and eight R&D sites. The acquisition of Bayer Animal Health on August 1, 2020 and KindredBio on August 27, 2021 added 3,950 full-time employees, 10 manufacturing sites, and five R&D sites (before company-wide restructuring activities initiated in 2020 and 2021). In addition, from 2015 to 2021, changing market demand for antibiotics and other headwinds, such as competition with generics and innovation, affected some of our highest gross margin products, resulting in a change to our product mix and driving operating margin lower. In response, we implemented a number of initiatives across the manufacturing, R&D and selling, general and administrative (SG&A) functions. Our manufacturing cost savings strategies included improving manufacturing processes and headcount through lean manufacturing (minimizing waste while maintaining productivity), closing three manufacturing sites, consolidating our CMO network, strategically insourcing certain projects, and pursuing cost savings opportunities through alternate sources of supply. Additional cost savings resulted from reducing the number of R&D sites from 16 to eight, SG&A savings from sales force consolidation, and reducing discretionary and other general and administrative (G&A) operating expense.

Foreign Exchange Rates

Significant portions of our revenue and costs are exposed to changes in foreign exchange rates. Our products are sold in more than 90 countries and, as a result, our revenue is influenced by changes in foreign exchange rates. For the years ended December 31, 2021 and 2020, approximately 51% and 49%, respectively, of our revenue was denominated in foreign currencies. As we operate in multiple foreign currencies, including the Euro, British pound, Swiss franc, Brazilian real, Australian dollar, Japanese yen, Canadian dollar, Chinese yuan, and other currencies, changes in those currencies relative to the U.S. dollar impact our revenue, cost of sales and expenses, and consequently, net income. These fluctuations may also affect the ability to buy and sell our products between markets impacted by significant exchange rate variances. Currency movements increased revenue by 1% during the year ended December 31, 2021. Currency movements decreased revenue by 1% and 2% during the years ended December 31, 2020 and 2019, respectively.

Components of Revenue and Costs and Expenses

Revenue

Our revenue is primarily derived from a diversified portfolio of products across species consisting of dogs and cats (collectively, pet health) and cattle, poultry, swine and aqua (collectively, farm animal). We market our products to veterinarians, pet owners, and farm animal producers, then sell directly or indirectly through third-party distributors, retailers, or e-commerce outlets. For additional information regarding our products, including descriptions of our product categories, see "Item 1. Business — Commercial Operations" and "Item 1. Business — Products."

Costs, Expenses and Other

Cost of sales consists primarily of cost of materials, facilities and other infrastructure used to manufacture our products, shipping and handling, inventory losses and expired products.

Marketing, selling and administrative expenses consist of, among other things, the costs of marketing, promotion and advertising and the costs of administration (business technology, facilities, legal, finance, human resources, business development, external affairs and procurement).

Amortization of intangible assets consists of the amortization expense for intangible assets that have been acquired through business combinations and other business development arrangements.

R&D expenses consist of project costs specific to new product R&D and product lifecycle management, overhead costs associated with R&D operations, regulatory, product registrations and investments that support local market clinical trials for approved indications. We manage overall R&D based on our strategic opportunities and do not disaggregate our R&D expenses incurred by nature or by product as we do not use or maintain such information in managing our business.

Asset impairment, restructuring and other special charges consist primarily of severance costs resulting from actions taken as part of our productivity initiatives and to reduce our costs; long-lived asset impairment charges and write-downs primarily related to product rationalizations, site closures, and the sale of manufacturing sites; transaction and integration costs from acquired businesses and other related expenses, primarily Bayer Animal Health; costs associated with the acquisition of KindredBio; and costs related to the build out of processes and systems to support finance and global supply and logistics, among others, as we stand our organization up as an independent company.

Interest expense, net of capitalized interest consists of interest incurred on our debt.

Other (income) expense, net consists primarily of various items including net (gains)/losses on asset disposals, realized and unrealized foreign exchange translation (gains)/losses, (gains)/losses on equity investments and loss or impairment on other investments.

Comparability of Historical Results

Our historical results of operations for the periods presented may not be comparable with prior periods or with our results of operations in the future, due to many factors, included but not limited to the factors identified in "Key Trends and Conditions Affecting Our Results of Operations."

Other Recent Acquisitions

Our financial results have been impacted by other recent acquisitions and integrations. For the periods presented, these include primarily the acquisitions and integrations of Aratana Therapeutics, Inc., which closed on July 18, 2019, and Prevtec Microbia Inc., which closed on July 31, 2019. For more information, see Note 5: Acquisitions and Divestitures to the consolidated financial statements.

Results of Operations

The following discussion and analysis of the consolidated statements of operations should be read along with the consolidated financial statements and the notes thereto included elsewhere in this report. For more information, see Note 2: Basis of Presentation to the consolidated financial statements.

	Year Ended December 31,			% Change	
(Dollars in millions)	**2021**	**2020**	**2019**	**21/20**	**20/19**
Revenue	$ 4,765	$ 3,273	$ 3,071	46%	7%
Costs, expenses and other:					
Cost of sales	2,134	1,667	1,470	28%	13%
% of revenue	45%	51%	48%		
Research and development	369	327	270	13%	21%
% of revenue	8%	10%	9%		
Marketing, selling and administrative	1,404	996	760	41%	31%
% of revenue	29%	30%	25%		
Amortization of intangible assets	556	360	200	54%	80%
% of revenue	12%	11%	7%		
Asset impairment, restructuring and other special charges	628	623	186	1%	235%
Interest expense, net of capitalized interest	236	150	79	57%	90%
Other (income) expense, net	5	(178)	28	NM	NM
Income (loss) before taxes	(567)	(672)	78	(16)%	NM
% of revenue	(12)%	(21)%	3%	NM	NM
Income tax expense (benefit)	(95)	(112)	10	(15)%	NM
Net income (loss)	$ (472)	$ (560)	$ 68	(16)%	NM

Certain amounts and percentages may reflect rounding adjustments.

NM - Not meaningful

Disaggregated Revenue

On a global basis, our revenue by product category for the years ended December 31 is summarized as follows:

	Revenue			% of Total Revenue			% Change	
(Dollars in millions)	2021	2020	2019	2021	2020	2019	21/20	20/19
Pet Health	$ 2,351	$ 1,358	$ 1,136	49 %	41 %	37 %	73%	20%
Farm Animal	2,332	1,835	1,855	49 %	56 %	60 %	27%	(1)%
Subtotal	4,683	3,193	2,991	98 %	98 %	97 %	47%	7%
Contract Manufacturing [(1)]	82	80	80	2 %	2 %	3 %	3%	0%
Total	$ 4,765	$ 3,273	$ 3,071	100 %	100 %	100 %	46%	7%

Note: Numbers may not add due to rounding

(1) Represents revenue from arrangements in which we manufacture products on behalf of a third party, including supply agreements associated with divestitures of products related to the acquisition of Bayer Animal Health.

On a global basis, the effect of price, foreign exchange rates and volumes on changes in revenue as compared to the prior year was as follows:

Full year 2021 (Dollars in millions)	Revenue	Price	FX Rate	Legacy Elanco Volume	Bayer Animal Health Volume	Total	CER*
Pet Health	$ 2,351	4%	1%	8%	60%	73%	72%
Farm Animal	2,332	—%	1%	4%	22%	27%	26%
Subtotal	4,683	2%	1%	6%	38%	47%	46%
Contract Manufacturing	82	—%	—%	(70)%	73%	3%	3%
Total	$ 4,765	2%	1%	4%	39%	46%	45%

Full year 2020 (Dollars in millions)	Revenue	Price	FX Rate	Legacy Elanco Volume	Bayer Animal Health Volume	Total	CER*
Pet Health	$ 1,358	5%	—%	(15)%	30%	20%	20%
Farm Animal	1,835	2%	(1)%	(14)%	12%	(1)%	—%
Subtotal	3,193	3%	(1)%	(14)%	19%	7%	8%
Contract Manufacturing	80	1%	(2)%	(32)%	34%	1%	3%
Total	$ 3,273	3%	(1)%	(15)%	20%	7%	8%

Note: Numbers may not add due to rounding

*Constant exchange rate (CER), a non-GAAP measure, is defined as revenue growth excluding the impact of foreign exchange. The calculation assumes the same foreign currency exchange rates that were in effect for the comparable prior-year period were used in translation of the current period results. We believe this metric provides a useful comparison to previous periods.

Revenue

Pet Health revenue increased by $993 million or 73%, partially driven by Bayer Animal Health product revenue of $1,194 million as compared to $339 million in the prior year. Legacy Elanco revenue increased as a result of a favorable comparison to the prior year, during which we reduced channel inventory levels with our distributors in the first half of 2020 and experienced reduced demand for veterinary products, primarily in U.S. vaccines and international markets, due to the COVID-19 pandemic. Growth in the legacy Elanco business primarily related to increases in volume and price and, to a lesser extent, the positive impact of foreign exchange rates. U.S. parasiticides and therapeutics led price growth, and higher volumes were attributable to newer generation parasiticides, pain products, and new products launched in 2021. These factors were partially offset by declines in older generation parasiticides and the impact of divestitures.

Farm Animal revenue increased by $497 million or 27%, mainly driven by Bayer Animal Health product revenue of $643 million as compared to $226 million in the prior year. Legacy Elanco revenue increased as a result of a favorable comparison to the prior year, which included lower levels of demand due to the COVID-19 pandemic's impact on global protein markets, as well as actions taken across brands to reduce channel inventory levels in the first half of 2020 due to the pandemic. Growth in the legacy Elanco business primarily related to increases in volume and a positive impact from foreign exchange rates. Revenue increases from volume growth in global cattle and U.S. swine, improvement in international poultry and aqua, and new products launched in 2021 were partially offset by generic competition, lower levels of demand in China's swine market due to pressured producer profitability, the impact from exiting certain operations in 2021, and an unfavorable comparison for U.S. cattle vaccines and implants, which benefited from a short-term competitor stock-out in the fourth quarter of 2020.

Contract Manufacturing revenue increased by $2 million to $82 million and represented 2% of total revenue. Contract Manufacturing revenue for the period includes $66 million resulting from the acquisition of Bayer Animal Health.

Cost of Sales

	Year Ended December 31,			% Change	
(Dollars in millions)	**2021**	**2020**	**2019**	**21/20**	**20/19**
Cost of sales	$ 2,134	$ 1,667	$ 1,470	28 %	13 %
% of revenue	45 %	51 %	48 %		

Cost of sales increased $467 million in 2021 as compared to 2020 primarily due to increased sales, partially offset by lower amortization of the inventory fair value adjustment associated with the Bayer Animal Health acquisition. Cost of sales as a percent of revenues decreased to 45% from 51%. This decrease was due to the inclusion of Bayer Animal Health products, which have higher margins, as well as continued improvements in manufacturing productivity, increases in price, and lower amortization of the inventory fair value adjustment.

Excluding the amortization of the inventory fair value adjustment associated with the Bayer Animal Health acquisition, cost of sales as a percent of revenue would have been 43% and 48% in 2021 and 2020, respectively.

Research and Development

	Year Ended December 31,			% Change	
(Dollars in millions)	**2021**	**2020**	**2019**	**21/20**	**20/19**
Research and development	$ 369	$ 327	$ 270	13 %	21 %
% of revenue	8 %	10 %	9 %		

R&D expenses increased $42 million to $369 million in 2021 as compared to 2020, primarily due to the inclusion of the Bayer Animal Health and KindredBio businesses. As a percent of revenue, research and development was 8% compared to 10% in the prior year. The decrease was primarily due to the rationalization of R&D projects, personnel and site operations in the current year following the acquisition of Bayer Animal Health as well as a higher revenue base.

Marketing, Selling and Administrative

(Dollars in millions)	Year Ended December 31, 2021	2020	2019	% Change 21/20	20/19
Marketing, selling and administrative	$ 1,404	$ 996	$ 760	41 %	31 %
% of revenue	29 %	30 %	25 %		

Marketing, selling and administrative expenses increased $408 million in 2021 compared to 2020, primarily as a result of the acquisition of Bayer Animal Health, increased promotional spend for direct-to-consumer and digital advertising, increased information technology spending, increased legal and administrative costs, and increased legacy Elanco compensation and benefits due to the addition of employees to perform activities that were previously covered by the TSAs with Lilly that were exited during the first half of 2021. These increases were partially offset by disciplined cost management across the business and realization of synergies.

Amortization of Intangible Assets

(Dollars in millions)	Year Ended December 31, 2021	2020	2019	% Change 21/20	20/19
Amortization of intangible assets	$ 556	$ 360	$ 200	54 %	80 %

Amortization of intangible assets increased $196 million to $556 million in 2021 as compared to 2020, primarily due to the inclusion of a full year of amortization of intangible assets recorded from the acquisition of Bayer Animal Health.

Asset Impairment, Restructuring and Other Special Charges

(Dollars in millions)	Year Ended December 31, 2021	2020	2019	% Change 21/20	20/19
Asset impairment, restructuring and other special charges	$ 628	$ 623	$ 186	1 %	235 %

For additional information regarding our asset impairment, restructuring and other special charges, see Note 6: Asset Impairment, Restructuring and Other Special Charges to the consolidated financial statements.

Asset impairment, restructuring and other special charges increased $5 million to $628 million in 2021 as compared to 2020, primarily due to a $273 million charge to write down assets at our Shawnee and Speke sites that were classified as held for sale to an amount equal to estimated fair value less costs to sell, a $26 million charge to establish a liability for future royalty and milestone payments relating to our canine parvovirus license agreement with KindredBio, and $66 million of impairment charges for intangible assets that were subject to product rationalization in the current year. The impact of these items was partially offset by a year over year decrease in overall acquisition related charges, which include transaction costs related to acquisitions, costs associated with the implementation of new systems, programs, and processes due to our separation from Lilly, and costs associated with the implementation of new systems, programs, and processes in connection with the integration of Bayer Animal Health. The increase as compared to prior year was also partially offset by a decrease in severance charges as compared to 2020, $29 million of pension curtailment gains and a $16 million reversal of severance accruals during the period due primarily to favorable negotiations.

Interest Expense, Net of Capitalized Interest

(Dollars in millions)	Year Ended December 31, 2021	2020	2019	% Change 21/20	20/19
Interest expense, net of capitalized interest	$ 236	$ 150	$ 79	57 %	90 %

Interest expense increased $86 million to $236 million in 2021, primarily due to interest associated with the Term Loan B entered into August 1, 2020 and used to finance the Bayer Animal Health acquisition and additional debt used to finance the KindredBio acquisition.

Other (Income) Expense, Net

(Dollars in millions)	Year Ended December 31, 2021	2020	2019	% Change 21/20	20/19
Other (income) expense, net	$ 5	$ (178)	$ 28	NM	NM

Other expense recorded during 2021 primarily consisted of mark-to-market adjustments on equity investments and foreign exchange losses, partially offset by gains on divestitures, certain components of net periodic benefit income, an up-front payment received in relation to an asset assignment agreement, a milestone earned in relation to an existing asset sale agreement, and up-front payments received, milestones earned, and equity issued to us in relation to a license agreement. Other income recorded during 2020 was primarily composed of gains recorded on the divestitures of certain products and a $46 million gain on the sale of land and buildings in New South Wales, Australia.

Income Tax Expense (Benefit)

(Dollars in millions)	Year Ended December 31, 2021	2020	2019	% Change 21/20	20/19
Income tax expense (benefit)	(95)	(112)	10	(15)%	NM
Effective tax rate	17 %	17 %	13 %		

Our historical income tax expense may not be indicative of our future expected tax rate. See “Comparability of Historical Results” for further discussion.

Income tax benefit decreased $17 million to $95 million in 2021, primarily due to a pre-tax loss partially offset by a non-cash charge of $62 million relating to the increase of the valuation allowance on U.S deferred tax assets. See Note 15: Income Taxes to our consolidated financial statements.

Liquidity and Capital Resources

Our primary sources of liquidity are cash on hand, cash flows from operations and funds available under our credit facilities. As a significant portion of our business is conducted internationally, we hold a significant portion of cash outside of the U.S. We monitor and adjust the amount of foreign cash based on projected cash flow requirements. Our ability to use foreign cash to fund cash flow requirements in the U.S. may be impacted by local regulations and, to a lesser extent, following U.S. tax reforms, the income taxes associated with transferring cash to the U.S. We currently intend to indefinitely reinvest foreign earnings for continued use in our foreign operations. See Note 15: Income Taxes to the consolidated financial statements for further discussion. As our structure evolves as a standalone company, we may change that strategy, particularly to the extent we identify tax efficient reinvestment alternatives for our foreign earnings or change our cash management strategy.

We believe our primary sources of liquidity are sufficient to fund our short-term and long-term existing and planned capital requirements, which include working capital obligations, funding existing marketed and pipeline products, capital expenditures, business development in our targeted areas, short-term and long-term debt obligations which include principal and interest payments as well as interest rate swaps, operating lease payments, purchase obligations, and costs associated with the integrations of Bayer Animal Health and KindredBio. In addition, we have the ability to access capital markets to obtain debt refinancing for longer-term funding, if required, to service our long-term debt obligations. Further, we believe we have sufficient cash flow and liquidity to remain in compliance with our debt covenants.

Our ability to meet future funding requirements may be impacted by macroeconomic, business and financial volatility. As markets change, we will continue to monitor our liquidity position. However, a challenging economic environment or an economic downturn may impact our liquidity or ability to obtain future financing. See "Item 1A. Risk Factors - We may not be able to generate sufficient cash to service all of our indebtedness and may be forced to take other actions to satisfy our obligations under our indebtedness, which may not be successful."

Cash Flows

The following table provides a summary of cash flows from operating, investing and financing activities for the periods presented:

(Dollars in millions)	Year Ended December 31,			$ Change	
Net cash provided by (used for):	2021	2020	2019	21/20	20/19
Operating activities	$ 483	$ (41)	$ 224	$ 524	$ (265)
Investing activities	(530)	(4,779)	(235)	4,249	(4,544)
Financing activities	210	4,954	(305)	(4,744)	5,259
Effect of exchange rate changes on cash and cash equivalents	(31)	27	(17)	(58)	44
Net increase (decrease) in cash, cash equivalents and restricted cash	$ 132	$ 161	$ (333)	$ (29)	$ 494

Operating Activities

Our cash flow from operating activities increased by $524 million from cash used for operating activities of $41 million for the year ended December 31, 2020 to cash provided by operating activities of $483 million for the year ended December 31, 2021. The increase is primarily attributable to a decrease in net loss year over year as well as a favorable impact on cash from the exclusion of non-cash items included in net loss during 2021 as compared to 2020. The impact of these items was partially offset by a decrease in cash due to changes in operating assets and liabilities, particularly accounts payable and other liabilities, as compared to the prior year. Cash provided by operating activities during 2021 as compared to 2020 reflects the impact of the acquisition of Bayer Animal Health on our results for a full year, a favorable comparison to the prior year due to the channel inventory reduction in the first half of 2020, and the overall recovery observed in the current year after the COVID-19 pandemic impacted the global economy for much of 2020. In the past, we have extended our payment terms for distributors on occasion. Although we presently have no plans to do so in the future, it is possible that we will need to extend payment terms in certain situations as a result of the COVID-19 pandemic, competitive pressures and the need for certain inventory levels at our channel distributors to avoid supply disruptions. If so, such extensions of customer payment terms could result in additional uses of our cash flow.

Investing Activities

Our cash flow used for investing activities decreased $4,249 million to $530 million for the year ended December 31, 2021 compared to $4,779 million for the year ended December 31, 2020. The decrease was primarily driven by lower cash paid for acquisitions as well as a decrease in purchases of software, partially offset by a decrease in proceeds from product divestitures. During 2021, cash paid for acquisitions was comprised of $444 million of cash consideration paid to acquire KindredBio, partially offset by cash acquired from KindredBio and the impact of the finalization of the working capital adjustment related to the acquisition of Bayer Animal Health. Cash used for investing activities during 2020 was composed of $5,170 million of cash consideration paid to acquire Bayer Animal Health, partially offset by cash acquired from Bayer Animal Health and proceeds from product divestitures and the settlement of net investment hedges.

Financing Activities

Our cash provided by financing activities decreased $4,744 million to $210 million for the year ended December 31, 2021 compared to $4,954 million for the year ended December 31, 2020. Cash provided by financing activities during 2021 primarily reflected proceeds from our borrowings under our new debt financing arrangement with Farm Credit, proceeds from our revolving credit facility, and $64 million of funding received from the developer in connection with the construction of our new corporate headquarters in Indianapolis, Indiana, partially offset by the repayment of indebtedness outstanding under our Senior Notes and revolving credit facility. Cash provided by financing activities during 2020 reflected proceeds from our borrowings under the Term Loan B and revolving credit facility and issuances of common stock and TEUs to finance the acquisition of Bayer Animal Health during the period, partially offset by the repayment of indebtedness outstanding under our credit facilities.

Capital Expenditures and Software Purchases

Capital expenditures were $126 million during 2021, a decrease of $9 million compared to 2020. Purchases of software were $33 million during 2021, a decrease of $143 million compared to 2020. We expect 2022 capital expenditures and software purchases to be approximately $155 million to $185 million.

Description of Indebtedness

For a complete description of our debt and available credit facilities as of December 31, 2021, see Note 9: Debt to the consolidated financial statements.

Contractual Obligations

Our contractual obligations and commitments as of December 31, 2021 are primarily comprised of long-term debt obligations, operating leases, and purchase obligations. Our long-term debt obligations are comprised of our expected principal and interest obligations and our interest rate swaps. Purchase obligations consist of open purchase orders as of December 31, 2021 and contractual payment obligations with significant vendors which are noncancelable and are not contingent. These obligations are primarily short-term in nature. See Note 13: Leases to the consolidated financial statements for further discussion regarding the contractual obligations related to our new corporate headquarters in Indianapolis, Indiana.

Critical Accounting Policies and Estimates

The preparation of financial statements in accordance with U.S. GAAP requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses. Certain of our accounting policies are considered critical because these policies are the most important to the depiction of our financial statements and require significant, difficult or complex judgments by us, often requiring the use of estimates about the effects of matters that are inherently uncertain. Actual results that differ from our estimates could have an unfavorable effect on our financial position and results of operations. We apply estimation methodologies consistently from year to year. The following is a summary of accounting policies that we consider critical to the consolidated financial statements.

Revenue Recognition

Our gross product revenue is subject to deductions that are generally estimated and recorded in the same period that the revenue is recognized and that primarily represent revenue incentives (rebates and discounts) and sales returns. For example:

- for revenue incentives, we use our historical experience with similar incentives programs and current sales data and estimates of inventory levels at our channel distributors to evaluate the impact of such programs on revenue and continually monitor the impact of this experience and adjust as necessary; and
- for sales returns, we consider items such as: local returns policies and practices; returns as a percentage of revenue; an understanding of the reasons for past returns; estimated shelf life by product; and estimate of the amount of time between shipment and return to estimate the impact of sales returns.

If any of our ratios, factors, assessments, experiences or judgments are not indicative or accurate predictors of our future experience, our results could be materially affected.

Although the amounts recorded for these revenue deductions are dependent on estimates and assumptions, historically our adjustments to actual results have not been material. The sensitivity of our estimates can vary by program, type of customer and geographic location. Amounts recorded for revenue deductions can result from a complex series of judgments about future events and uncertainties and can rely on estimates and assumptions.

See Note 3: Summary of Significant Accounting Policies and Note 4: Revenue to the consolidated financial statements for further discussion regarding our revenue recognition policy and quantitative information regarding our rebate programs, respectively.

Acquisitions and Fair Value

We account for the assets acquired and liabilities assumed in an acquisition based on their respective fair values as of the acquisition date. The excess of the purchase price over the fair value of the acquired net assets, where applicable, is recorded as goodwill.

The judgments made in determining estimated fair values assigned to assets acquired and liabilities assumed in a business combination, as well as estimated asset lives, can materially affect our consolidated results of operations. The fair values of intangible assets are determined using information available at the acquisition date based on expectations and assumptions that are deemed reasonable by management. These fair value estimates require significant judgment with respect to future revenues and EBIT margins, use of working capital, the selection of appropriate discount rates, product mix, income tax rates and other assumptions and estimates. Such estimates and assumptions are determined based upon our business plans and when applicable, market participants' views of us and other similar companies. Depending on the facts and circumstances, we may deem it necessary to engage an independent valuation expert to assist in valuing significant assets and liabilities.

Impairment of Indefinite-Lived and Long-Lived Assets

We review the carrying value of long-lived assets (both intangible and tangible) for potential impairment on a periodic basis and whenever events or changes in circumstances indicate the carrying value of an asset (or asset group) may not be recoverable. We identify impairment by comparing the projected undiscounted cash flows to be generated by the asset (or asset group) to its carrying value. If an impairment is identified, a loss is recorded equal to the excess of the asset's net book value over its fair value utilizing a discounted cash flow analysis, and the cost basis is adjusted.

Goodwill and indefinite-lived intangible assets are reviewed for impairment at least annually and when certain impairment indicators are present. When required, a comparison of fair value to the carrying amount of assets is performed to determine the amount of any impairment.

The estimated cash flows and fair values used in our impairment reviews require significant judgment with respect to future volume; use of working capital; foreign currency exchange rates; the selection of appropriate discount rates; product mix; income tax rates and other assumptions and estimates. Such estimates and assumptions are determined based upon our business plans and when applicable, market participants' views of us and other similar companies. We make these judgments based on our historical experience, relevant market size, historical pricing of similar products and expected industry trends. These assumptions are subject to change in future periods because of, among other things, additional information, financial information based on further historical experience, changes in competition, our investment decisions, volatility in foreign currency exchange rates, and results of research and development. A change in these assumptions or the use of alternative estimates and assumptions could have a significant impact on the estimated fair values of the assets and may result in an impairment of the existing assets in a future period.

During the years ended December 31, 2021, 2020 and 2019, we recorded asset impairments of $66 million, $17 million and $16 million, respectively. For more information related to our impairment charges, see Note 6: Asset Impairment, Restructuring and Other Special Charges to the consolidated financial statements.

Deferred Tax Asset Valuation Allowances

We maintain valuation allowances unless it is more likely than not that all of the deferred tax asset will be realized. Changes in valuation allowances are included in our tax provision in the period of change. In determining whether a valuation allowance is warranted, we evaluate factors such as prior earnings history, expected future earnings, carryback and carryforward periods, amount and availability of taxable temporary differences, and tax strategies that could potentially enhance the likelihood of realization of a deferred tax asset. The realizability assessments made at a given balance sheet date are subject to change in the future, particularly if earnings of a subsidiary are significantly higher or lower than expected, or if we take operational or tax planning actions that could impact the future taxable earnings of a subsidiary. A change in these assumptions may result in an increase or decrease in the realizability of our existing deferred tax assets, and therefore a change in the valuation allowance, in future periods. Concluding that a valuation allowance is not required is difficult when there is significant negative evidence which is objective and verifiable, such as cumulative losses in recent years. We prepare a three-year cumulative pre-tax book income or loss analysis adjusted for certain permanent book to tax differences as a measure of our cumulative results in recent years. In the U.S. and certain foreign jurisdictions, our analysis indicates that we have cumulative three-year historical pre-tax book losses on this basis. This is considered significant negative evidence which is objective and verifiable and therefore, difficult to overcome. However, the three-year cumulative pre-tax book loss position is not solely determinative and accordingly, we consider all other available positive and negative evidence in our analysis. In making such judgments, significant weight is given to evidence that can be objectively verified.

As of December 31, 2021 and 2020, we had valuation allowances of $162 million and $94 million, respectively. In recent years we have incurred pre-tax book losses in the U.S. primarily as a result of transaction, restructuring, integration and other costs as well as the negative impacts of the COVID-19 pandemic. As a result, we have concluded that it is “more likely than not” that we will not be able to utilize a portion of the U.S. deferred tax assets and have recorded valuation allowances of $162 million and $75 million, respectively, against these deferred tax assets. Under current tax laws, the valuation allowance will not limit our ability to utilize U.S. deferred tax assets provided we can generate sufficient future taxable income in the U.S. We anticipate that we will continue to record a valuation allowance against the losses until such time as we are able to determine it is “more likely than not” that the deferred tax asset will be realized.

Recently Issued Accounting Pronouncements

For discussion of our new accounting standards, see Note 3: Summary of Significant Accounting Policies - Implementation of New Financial Accounting Pronouncements to the consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Foreign Exchange Risk

We operate on a global basis and are exposed to the risk that our earnings, cash flows and equity could be adversely impacted by fluctuations in foreign exchange rates. We are primarily exposed to foreign exchange risk with respect to net assets denominated in the Euro, British pound, Swiss franc, Brazilian real, Australian dollar, Japanese yen, Canadian dollar, and Chinese yuan.

We face foreign currency exchange exposures when we enter into transactions arising from subsidiary trade and loan payables and receivables denominated in foreign currencies and purchases of local subsidiaries due to local regulations as a result of the acquisition of Bayer Animal Health. We also face currency exposure that arises from translating the results of our global operations to the U.S. dollar at exchange rates that have fluctuated from the beginning of the period. We may enter into foreign currency forward or option derivative contracts to reduce the effect of fluctuating currency exchange rates in future periods.

We estimate that a hypothetical 10% adverse movement in all foreign currency exchange rates related to the translation of the results of our foreign operations would decrease our net income by approximately $4 million for the year ended December 31, 2021.

We generally identify hyperinflationary markets as those markets whose cumulative inflation rate over a three-year period exceeds 100%. We have concluded that our Argentina subsidiary is operating in a hyperinflationary market. As a result, beginning in the second quarter of 2018, the functional currency of our Argentina subsidiary changed from the local currency to the U.S. dollar. During the year ended December 31, 2021, revenue generated in Argentina represented less than 1% of our consolidated revenue. Assets held in Argentina as of December 31, 2021 represented less than 1% of our consolidated assets. While the hyperinflationary conditions did not have a material impact on our business during the year ended December 31, 2021, in the future, we may incur larger currency devaluations, which could have a material adverse impact on our results of operations.

Interest Risk

Our variable-rate debt is exposed to interest rate fluctuations based on LIBOR. As of December 31, 2021, we held certain interest rate swap agreements with a notional value of $3,800 million that have the economic effect of modifying our variable-interest so that a portion of the variable-rate interest payable becomes fixed. During the year ended December 31, 2021, we recorded a gain of $86 million, net of taxes on these interest rate swaps in other comprehensive income (loss). The gain is primarily attributable to an increase in the U.S. Treasury yield curve during the first half of 2021. See Note 10: Financial Instruments and Fair Value to the consolidated financial statements for further information.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Elanco Animal Health Incorporated

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Elanco Animal Health Incorporated (the Company) as of December 31, 2021 and 2020, the related consolidated statements of operations, comprehensive income (loss), equity and cash flows for each of the three years in the period ended December 31, 2021, and the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company’s internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated February 28, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the account or disclosures to which they relate.

Sales rebates and discounts

Description of the matter

At December 31, 2021, the Company's sales rebates and discounts liability totaled $316 million. As explained in Notes 3 and 4 to the consolidated financial statements, the Company estimates a sales rebates and discounts liability for direct customers and other indirect customers in the distribution chain under the terms of their contracts using the expected value approach. The sales rebates and discounts are recorded as a deduction to revenue at the time the Company recognizes a sale to a customer.

Auditing the sales rebates and discounts liability is complex because of the level of subjectivity involved in management's assumptions used in the measurement process and the volume of rebate programs offered. For example, the estimate of the sales rebate and discount liability is based on historical experience with similar incentive programs, current sales data and estimates of inventory levels at the channel distributors.

How we addressed the matter in our audit

We tested the Company's internal controls over the sales rebates and discounts liability process. This included testing controls over management's review of the significant assumptions in the estimation of sales rebates and discounts, including rebate rates by product category, sales in to and out of the distribution channel, and channel inventory levels.

To test the Company's sales rebates and discounts liability, our audit procedures included, among others, evaluating the assumptions discussed above and testing the completeness and accuracy of the underlying data used in management's expected value analysis. For example, we compared the significant assumptions to third-party reports used by the Company to estimate indirect sales volumes during the period and we confirmed product remaining in the distribution channel at period end. In addition, we inspected the underlying direct and indirect customer rebate programs and compared the rebate percentages used in the Company's analyses with the program percentages. Additionally, we assessed the historical accuracy of management's sales rebates and discounts estimates by comparing the prior period sales rebates and discounts liability to the amount of actual payments made in subsequent periods. We also performed independent calculations of the rebate accruals and a sensitivity analysis of certain significant assumptions to evaluate the change in the sales rebates and discounts liability resulting from changes in the assumptions.

Acquisition of KindredBio

Description of the matter

During 2021, the Company completed its acquisition of KindredBio for total consideration of $444 million, as disclosed in Note 5 to the consolidated financial statements. The acquisition was accounted for as a business combination. Auditing the Company's accounting for its acquisition of KindredBio was complex due to the significant estimation uncertainty in determining the fair value of identified intangible assets, which principally consisted of in-process research and development (IPR&D) of $334 million. The Company used the income approach valuation technique to estimate the fair value of the IPR&D intangible assets. This valuation technique provides an estimate of the fair value of an asset based on market participant expectations of the cash flows an asset would generate over its remaining estimated economic life. The significant assumptions used to estimate the value of these intangible assets included estimated net cash flows that form the basis of the forecasted results (e.g., revenue and EBIT margins).

How we addressed the matter in our audit

We tested the Company's controls over its accounting for acquisitions. This included testing controls over the recognition and measurement of consideration transferred and related intangible assets, including the valuation models and underlying assumptions discussed above used to develop such estimates.

To test the estimated fair value of the IPR&D intangible assets, our audit procedures included, among others, obtaining an understanding of management’s approach to evaluate the reasonableness of the significant assumptions discussed above. Specifically, we evaluated the reasonableness of the projected revenue and EBIT margin assumptions used within the valuation as compared against industry and market trends and identified contrary evidence. Additionally, we performed sensitivity analyses of the significant assumptions to evaluate the changes in the fair value of the intangible assets resulting from changes in the assumptions. We involved our valuation specialists to assist in our evaluation of the methodology used by the Company and certain assumptions included in the fair value estimates. Lastly, we evaluated the appropriateness of the Company’s related disclosures.

/s/ Ernst & Young LLP

We have served as the Company’s auditor since 2017.

Indianapolis, Indiana
February 28, 2022

Elanco Animal Health Incorporated
Consolidated Statements of Operations
(in millions, except per-share data)

	Year Ended December 31,		
	2021	2020	2019
Revenue	$ 4,765	$ 3,273	$ 3,071
Costs, expenses and other:			
Cost of sales	2,134	1,667	1,470
Research and development	369	327	270
Marketing, selling and administrative	1,404	996	760
Amortization of intangible assets	556	360	200
Asset impairment, restructuring and other special charges	628	623	186
Interest expense, net of capitalized interest	236	150	79
Other (income) expense, net	5	(178)	28
	5,332	3,945	2,993
Income (loss) before income taxes	(567)	(672)	78
Income tax expense (benefit)	(95)	(112)	10
Net income (loss)	$ (472)	$ (560)	$ 68
Earnings (loss) per share:			
Basic	$ (0.97)	$ (1.27)	$ 0.18
Diluted	$ (0.97)	$ (1.27)	$ 0.18
Weighted average shares outstanding:			
Basic	487.2	441.4	369.0
Diluted	487.2	441.4	370.3

See notes to consolidated financial statements.

Elanco Animal Health Incorporated
Consolidated Statements of Comprehensive Income (Loss)
(in millions)

	Year Ended December 31,		
	2021	2020	2019
Net income (loss)	$ (472)	$ (560)	$ 68
Other comprehensive income (loss):			
Unrealized gain (loss) on derivatives for cash flow hedges, net of taxes	86	(61)	—
Foreign currency translation	(613)	558	20
Defined benefit pension and retiree health benefit plans, net of taxes	15	(21)	29
Other comprehensive income (loss), net of taxes	(512)	476	49
Comprehensive income (loss)	$ (984)	$ (84)	$ 117

See notes to consolidated financial statements.

Elanco Animal Health Incorporated
Consolidated Balance Sheets
(in millions, except share data)

	December 31, 2021	December 31, 2020
Assets		
Current Assets		
Cash and cash equivalents	$ 638	$ 495
Accounts receivable, net of allowances of $12 (2021) and $9 (2020)	833	872
Other receivables	195	205
Inventories	1,373	1,578
Prepaid expenses and other	237	256
Restricted cash	—	11
Total current assets	3,276	3,417
Noncurrent Assets		
Goodwill	6,172	6,225
Other intangibles, net	5,587	6,387
Other noncurrent assets	387	348
Property and equipment, net	1,061	1,316
Total assets	$ 16,483	$ 17,693
Liabilities and Equity		
Current Liabilities		
Accounts payable	$ 418	$ 501
Employee compensation	185	144
Sales rebates and discounts	316	295
Current portion of long-term debt	294	555
Other current liabilities	430	582
Total current liabilities	1,643	2,077
Noncurrent Liabilities		
Long-term debt	6,025	5,572
Accrued retirement benefits	271	346
Deferred taxes	745	900
Other noncurrent liabilities	261	322
Total liabilities	8,945	9,217
Commitments and Contingencies		
Equity		
Preferred stock, 1,000,000,000 shares authorized, no par value; none issued	—	—
Common stock, 5,000,000,000 shares authorized, no par value; 473,119,786 and 471,921,116 shares issued and outstanding as of December 31, 2021 and 2020, respectively	—	—
Additional paid-in capital	8,696	8,650
Accumulated deficit	(949)	(477)
Accumulated other comprehensive income (loss)	(209)	303
Total equity	7,538	8,476
Total liabilities and equity	$ 16,483	$ 17,693

See notes to consolidated financial statements.

Elanco Animal Health Incorporated
Consolidated Statements of Equity
(in millions)

	Common Stock				Accumulated Other Comprehensive Income (Loss)				
	Shares	Amount	Additional Paid-in Capital	Retained Earnings (Accumulated Deficit)	Cash Flow Hedge	Foreign Currency Translation	Defined Benefit Pension and Retiree Health Benefit Plans	Total	Total Equity
December 31, 2018	365.6	$ —	$ 5,403	$ 16	$ —	$ (218)	$ (4)	$ (222)	$ 5,197
Net income	—	—	—	68	—	—	—	—	68
Other comprehensive income, net of tax	—	—	—	—	—	20	29	49	49
Separation activities [1]	—	—	(51)	—	—	—	—	—	(51)
Stock-based compensation	—	—	41	—	—	—	—	—	41
Issuance of stock under employee stock plans, net	0.1	—	—	—	—	—	—	—	—
Issuances of stock in connection with Aratana acquisition:									
Issuance to Aratana shareholders for acquisition	7.2	—	238	—	—	—	—	—	238
Accelerated vesting of equity awards	0.1	—	3	—	—	—	—	—	3
Other	—	—	2	—	—	—	—	—	2
December 31, 2019	373.0	—	5,636	84	—	(198)	25	(173)	5,547
Net loss	—	—	—	(560)	—	—	—	—	(560)
Adoption of Accounting Standards Update (ASU) 2016-13	—	—	—	(1)	—	—	—	—	(1)
Other comprehensive income (loss), net of tax	—	—	—	—	(61)	558	(21)	476	476
Separation activities [1]	—	—	38	—	—	—	—	—	38
Stock-based compensation	—	—	48	—	—	—	—	—	48
Issuance of stock under employee stock plans, net	1.0	—	(15)	—	—	—	—		(15)
Issuance of common stock and tangible equity units, net of issuance costs	25.0	—	1,220	—	—	—	—	—	1,220
Issuance of stock to Bayer for acquisition, net of issuance costs	72.9	—	1,723	—	—	—	—	—	1,723
December 31, 2020	471.9	—	8,650	(477)	(61)	360	4	303	8,476
Net loss	—	—	—	(472)	—	—	—	—	(472)
Other comprehensive income (loss), net of taxes	—	—	—	—	86	(613)	15	(512)	(512)
Stock-based compensation	—	—	66	—	—	—	—	—	66
Issuance of stock under employee stock plans, net	1.2	—	(20)	—	—	—	—	—	(20)
December 31, 2021	473.1	$ —	$ 8,696	$ (949)	$ 25	$ (253)	$ 19	$ (209)	$ 7,538

(1) Represent amounts associated with transactions between us and Lilly, related primarily to the completion of the local country asset purchases, the finalization of assets and liabilities associated with the legal separation from Lilly, centralized cash management, and resulting impacts on deferred tax assets, that occurred subsequent to our initial public offering.

See notes to consolidated financial statements.

Elanco Animal Health Incorporated
Consolidated Statements of Cash Flows
(in millions)

	Year Ended December 31,		
	2021	2020	2019
Cash Flows from Operating Activities			
Net income (loss)	$ (472)	$ (560)	$ 68
Adjustments to reconcile net income (loss) to cash flows from operating activities:			
Depreciation and amortization	716	517	314
Deferred income tax benefit	(154)	(125)	—
Stock-based compensation expense	66	48	49
Asset impairment and write-down charges	339	25	33
Loss (gain) on sale of assets	4	(51)	—
Loss (gain) on divestitures	1	(170)	—
Inventory fair value step-up amortization	64	90	1
Other non-cash operating activities, net	6	20	(13)
Other changes in operating assets and liabilities, net of acquisitions and divestitures:			
Receivables	(25)	14	(172)
Inventories	27	(95)	(34)
Other assets	22	(123)	7
Accounts payable and other liabilities	(120)	369	(29)
Other changes in operating assets and liabilities	9	—	—
Net Cash Provided by (Used for) Operating Activities	483	(41)	224
Cash Flows from Investing Activities			
Purchases of property and equipment	(126)	(135)	(140)
Disposals of property and equipment	17	72	—
Purchases of software	(33)	(176)	(57)
Purchases of intangible assets	(38)	—	—
Cash paid for acquisitions, net of cash acquired	(342)	(5,001)	(33)
Divestiture proceeds	—	435	—
Other investing activities, net	(8)	26	(5)
Net Cash Used for Investing Activities	(530)	(4,779)	(235)
Cash Flows from Financing Activities			
Proceeds from issuance of long-term debt	500	4,804	—
Proceeds from revolving credit facility	500	—	—
Repayments of long-term borrowings	(573)	(952)	(121)
Repayments of revolving credit facility	(250)	—	—
Proceeds from issuance of common stock and tangible equity units	—	1,220	—
Debt issuance costs	(2)	(102)	—
Consideration paid to Lilly in connection with the separation	—	—	(192)
Funding related to construction of corporate headquarters	64	—	—
Other financing activities, net	(29)	(16)	8
Net Cash Provided by (Used for) Financing Activities	210	4,954	(305)
Effect of exchange rate changes on cash and cash equivalents	(31)	27	(17)
Net increase (decrease) in cash, cash equivalents and restricted cash	132	161	(333)
Cash, cash equivalents and restricted cash at January 1	506	345	678
Cash, cash equivalents and restricted cash at December 31	$ 638	$ 506	$ 345

See notes to consolidated financial statements.

Elanco Animal Health Incorporated
Notes to Consolidated Financial Statements
(Tables present dollars and shares in millions, except per-share and per-unit data)

Note 1. Background

Elanco is a global animal health company that innovates, develops, manufactures and markets products for pets and farm animals. We offer a portfolio of approximately 200 brands to pet owners, veterinarians and farm animal producers in more than 90 countries. Our products are generally sold worldwide directly to wholesalers, distributors, and independent retailers. Certain products are also sold directly to farm animal producers and veterinarians. We have a diversified business of products across species consisting of: dogs and cats (collectively, pet health) and cattle, poultry, swine and aqua (collectively, farm animal).

Elanco was incorporated in Indiana on September 18, 2018, and prior to that was a business unit of Lilly.

On August 1, 2020 and August 27, 2021, we completed the acquisitions of Bayer Animal Health and KindredBio, respectively. See Note 5: Acquisitions and Divestitures for additional information.

Note 2. Basis of Presentation

We have prepared the accompanying consolidated financial statements in accordance with accounting principles generally accepted in the United States (GAAP). In our opinion, the financial statements reflect all adjustments (including those that are normal and recurring) that are necessary for fair presentation of the results of operations for the periods shown. All intercompany balances and transactions have been eliminated.

In preparing financial statements in conformity with GAAP, we must make estimates and assumptions that affect the reported amounts of assets, liabilities, revenue, expenses, and related disclosures at the date of the financial statements and during the reporting period. Actual results could differ from those estimates. We issued our financial statements by filing with the Securities and Exchange Commission and have evaluated subsequent events up to the time of the filing.

Note 3. Summary of Significant Accounting Policies

Revenue

We recognize revenue primarily from product sales to customers. Revenue from sales of products is recognized at the point where the customer obtains control of the goods and we satisfy our performance obligation, which generally is at the time we ship the product to the customer. Payment terms differ by jurisdiction and customer, but payment terms in most of our major jurisdictions typically range from 30 to 120 days from date of shipment. Revenue for our product sales has not been adjusted for the effects of a financing component as we expect, at contract inception, that the period between when we transfer control of the product and when we receive payment will be one year or less. Any exceptions are either not material or we collect interest for payments made after the due date. For contract manufacturing organization (CMO) arrangements, we recognize revenue over time or at a point in time depending on our evaluation of when the customer obtains control of the promised goods or service. Revenue is recognized over time when we are creating or enhancing an asset that the customer controls. In this instance revenue is recognized as the asset is created or enhanced or our performance does not create an asset with an alternative use and we have an enforceable right to payment for performance completed.

Provisions for rebates and discounts, as well as returns are established in the same period the related sales are recognized. We generally ship product shortly after orders are received; therefore, we generally only have a few days of orders received but not yet shipped at the end of any reporting period. Shipping and handling activities are considered to be fulfillment activities and are not considered to be a separate performance obligation. We exclude from the measurement of the transaction price all taxes assessed by a governmental authority that are imposed on our sales of product and collected from a customer.

Significant judgments must be made in determining the transaction price for sales of products related to anticipated rebates, discounts and returns. The following describe the most significant of these judgments:

Sales Rebates and Discounts - Background and Uncertainties

- Many of our products are sold to wholesale distributors. We initially invoice our customers contractual list prices. Contracts with direct and indirect customers may provide for various rebates and discounts that may differ in each contract. As a consequence, to determine the appropriate transaction price for our product sales at the time we recognize a sale to a direct customer, we must estimate any rebates or discounts that ultimately will be due to the direct customer and other customers in the distribution chain under the terms of our contracts. Judgments are required in making these estimates.
- The rebate and discount amounts are recorded as a deduction to arrive at our net product sales. We estimate these accruals using an expected value approach.
- In determining the appropriate accrual amount, we consider our historical experience with similar incentives programs and current sales data and estimates of inventory levels at our channel distributors to evaluate the impact of such programs on revenue and continually monitor the impact of this experience and adjust as necessary. Although we accrue a liability for rebates related to these programs at the time the sale is recorded, the rebate related to that sale is typically paid up to six months after the rebate or incentive period expires. Because of this time lag, in any particular period rebate adjustments may incorporate revisions of accruals for several periods.

Sales Returns - Background and Uncertainties

- We estimate a reserve for future product returns related to product sales using an expected value approach. This estimate is based on several factors, including: local returns policies and practices; returns as a percentage of revenue; an understanding of the reasons for past returns; estimated shelf life by product; and estimate of the amount of time between shipment and return. Adjustments to the returns reserve have been and may in the future be required based on revised estimates to our assumptions, which would have an impact on our consolidated results of operations. We record the return amounts as a deduction to arrive at our net product sales.

Research and Development Expenses and Acquired In-Process Research and Development

Research and development expenses include the following:

- Research and development costs, which are expensed as incurred;
- Milestone payment obligations incurred prior to regulatory approval of the product, which are accrued when the event requiring payment of the milestone occurs; and
- Acquired in-process research and development (IPR&D) expense, which includes the initial costs of IPR&D projects, acquired directly in a transaction other than a business combination, that do not have an alternative future use.

Advertising Expenses

Costs associated with advertising are generally expensed as incurred and are included in marketing, selling and administrative expenses in the consolidated statements of operations. The costs of TV, radio, and other electronic media and publications are expensed when the related advertising occurs. Advertising and promotion expenses totaled approximately $248 million in 2021. Expenses increased significantly in 2021 as compared to prior years due to the 2020 acquisition of Bayer Animal Health.

Foreign Currency Translation

Operations in our subsidiaries outside the U.S. are recorded in the functional currency of each subsidiary which is determined by a review of the environment where each subsidiary primarily generates and expends cash. The results of operations for our subsidiaries outside the U.S., where the U.S. dollar is not the functional currency, are translated from functional currencies into U.S. dollars using the weighted average currency rate for the period. Assets and liabilities are translated using the period end exchange rates. The U.S. dollar effects that arise from translating the net assets of these subsidiaries are recorded in other comprehensive income (loss).

Other Significant Accounting Policies

Our other significant accounting policies are described in the remaining appropriate notes to the consolidated financial statements.

Implementation of New Financial Accounting Pronouncements

The following table provides a brief description of an accounting standard that was effective January 1, 2021 and was adopted on that date:

Standard	Description	Effect on the financial statements or other significant matters
Accounting Standards Update (ASU) 2019-12, *Simplifying the Accounting for Income Taxes*	The amendments in this update include simplifications related to accounting for income taxes including removing certain exceptions related to the approach for intraperiod tax allocation and the recognition of deferred tax liabilities for outside basis differences. The standard also clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill.	The adoption of this guidance did not have a material impact on our consolidated financial statements.

The following table provides brief descriptions of the accounting standards applicable to us that have not yet been adopted:

Standard	Description	Effective Date	Effect on the financial statements or other significant matters
ASU 2020-04, Reference rate reform (Topic 848) - *Facilitation of the Effects of Reference Rate Reform on Financial Reporting*; ASU 2021-01, *Reference Rate Reform* (Topic 848): *Scope*	ASU 2020-04 provides optional expedients and exceptions for applying GAAP to contracts, hedging relationships, and other transactions affected by reference rate reform if certain criteria are met. ASU 2021-01 clarifies the scope of Topic 848 so that derivatives affected by the discounting transition are explicitly eligible for certain optional expedients and exceptions.	These standards were effective as of March 12, 2020 through December 31, 2022 and adoption is permitted at any time during the period on a prospective basis.	We are currently in the process of evaluating the impact of the London Interbank Offered Rate (LIBOR) on our existing contracts and may elect optional expedients in future periods as reference rate reform activities occur. We do not expect that these updates will have a material impact on our consolidated financial statements.
ASU 2021-10, *Government Assistance* (Topic 832)	The amendments in this update require annual disclosure of transactions with governments that are accounted for by applying a grant or contribution model. The new pronouncement requires entities to provide information about the nature, terms and conditions associated with the transactions and the financial statement line items affected.	We adopted this standard on January 1, 2022.	The adoption of this guidance did not have a material impact on our consolidated financial statements.

Note 4. Revenue

Our sales rebates and discounts are based on specific agreements. The most significant of our sales rebate and discount programs in terms of accrual and payment amounts, percentage of our products that are sold via these programs, and level of judgment required in estimating the appropriate transaction price, relate to our programs in the U.S., France and the U.K. As of December 31, 2021 and 2020, the aggregate liability for sales rebates and discounts for these countries represented approximately 75% and 73%, respectively, of our total liability.

The following table summarizes the activity in our global sales rebates liability:

	Year Ended December 31,	
	2021	2020
Beginning balance	$ 295	$ 211
Reduction of revenue	671	471
Payments	(650)	(461)
Additions related to the Bayer Animal Health acquisition	—	74
Ending balance	$ 316	$ 295

Adjustments to revenue recognized as a result of changes in estimates for the judgments described above during the years ended December 31, 2021, 2020, and 2019 for product shipped in previous periods were not material.

Actual global product returns were approximately 1% of net revenue for the years ended December 31, 2021, 2020, and 2019.

Disaggregation of Revenue

In the first quarter of 2021, management revisited how it analyzes revenue, both internally and externally, and determined that disaggregation by major product line provides a more meaningful view of our results. Accordingly, we updated our disaggregated revenue presentation from the previous five categories (i.e., pet health disease prevention, pet health therapeutics, farm animal future protein & health, farm animal ruminants & swine, and contract manufacturing) to the following:

	2021	2020	2019
Pet Health	$ 2,351	$ 1,358	$ 1,136
Farm Animal	2,332	1,835	1,855
Contract Manufacturing [1]	82	80	80
Revenue	$ 4,765	$ 3,273	$ 3,071

(1) Represents revenue from arrangements in which we manufacture products on behalf of a third party, including supply agreements associated with divestitures of products related to the acquisition of Bayer Animal Health.

Note 5. Acquisitions and Divestitures

During 2021 and 2020, we completed the acquisitions of KindredBio and Bayer Animal Health, respectively. During 2019, we completed the acquisitions of all outstanding shares of Aratana Therapeutics, Inc. (Aratana) and Prevtec Microbia Inc. (Prevtec). These transactions were accounted for as business combinations under the acquisition method of accounting. The acquisition method requires, among other things, that assets acquired and liabilities assumed in a business combination be recognized at their fair values as of the acquisition date. The determination of estimated fair value requires management to make significant estimates and assumptions. The excess of the purchase price over the fair value of the acquired net assets, where applicable, has been recorded as goodwill. The results of operations of these acquisitions are included in the consolidated financial statements from the dates of acquisition.

KindredBio Acquisition

On August 27, 2021, we acquired KindredBio, a publicly traded biopharmaceutical company that develops innovative biologics focused on saving and improving the lives of pets. The acquisition further accelerates our pet health expansion, particularly by expanding our presence in dermatology. In connection with the merger agreement, we acquired all outstanding stock of KindredBio for $9.25 per share, or an aggregate cash purchase consideration of $444 million. We utilized our revolving credit facility and cash on hand to finance the acquisition. Refer to Note 9: Debt for further details.

On May 5, 2021, we signed an agreement with KindredBio to acquire exclusive global rights to KIND-030, a monoclonal antibody that is being developed for the treatment and prevention of canine parvovirus. We calculated the fair value of the liability associated with that agreement using an income approach leveraging the estimated sales royalty, sales milestone and technical milestone payments avoided, and settled the $26 million liability upon the closing of our acquisition of KindredBio. Refer to Note 6: Asset Impairment, Restructuring and Other Special Charges for further discussion.

We incurred transaction costs in connection with the KindredBio acquisition of $6 million during the year ended December 31, 2021. Transaction costs were primarily associated with legal and other professional services related to the acquisition and are reflected within asset impairment, restructuring and other special charges in the consolidated statements of operations.

Revenue and loss from KindredBio included in the consolidated statements of operations since the date of acquisition were immaterial.

The following table summarizes the preliminary amounts recognized for assets acquired and liabilities assumed as of the acquisition date:

Estimated Fair Value at August 27, 2021		
Cash and cash equivalents	$	31
Other net working capital		9
Property and equipment		33
Intangible assets, primarily acquired in-process research and development (IPR&D)		334
Deferred income taxes, net		(22)
Total identifiable net assets		385
Goodwill		33
Settlement of liability related to previous license agreement		26
Total consideration transferred	$	444

The accounting for this acquisition is substantially complete, with the exception of the finalization of the valuation of intangible assets, tax-related amounts and minor working capital adjustments. The measurement period adjustments recorded during 2021, which were made to reflect the facts and circumstances in existence as of the acquisition date, primarily related to the finalization of our fair value assessment of property and equipment, revised cash flow assumptions for acquired IPR&D, and minor tax and working capital adjustments. The net impact of these adjustments was an increase of $3 million to goodwill. Finalization of the valuation during the measurement period could result in a change in the amounts recorded for the acquisition date fair value. The completion of the valuation will occur no later than one year from the acquisition date.

Property and equipment is mostly comprised of land, buildings, equipment (including laboratory equipment, furniture and fixtures, and computer equipment), and construction in progress. The estimated fair value of real and personal property was determined using the sales comparison data valuation technique, to the extent that market data for similar assets was available. When market pricing data was not available for a given asset or asset class, the direct replacement cost method was used.

The estimated fair values of acquired IPR&D were determined using the income approach, which is a valuation technique that provides an estimate of the fair value of an asset based on market participant expectations of the cash flows an asset would generate over its remaining useful life. Some of the significant assumptions inherent in the development of these asset valuations include the estimated net cash flows for each year for each asset (including revenues, cost of sales, R&D expenses, marketing, selling and administrative expenses, and contributory asset charges), the appropriate discount rate necessary to measure the risk inherent in each future cash flow stream, the life cycle of each asset, the potential regulatory and commercial success risk, and competitive trends impacting the asset and each cash flow stream, as well as other factors.

The goodwill recognized from this acquisition is primarily attributable to KindredBio's assembled workforce and expected synergies. The majority of goodwill associated with this acquisition is not deductible for tax purposes.

Bayer Animal Health Acquisition

On August 1, 2020, we completed the acquisition of Bayer Animal Health. The acquisition has expanded our pet health product category, advancing our planned portfolio mix transformation and creating a better balance between our farm animal and pet health product categories. Our product portfolio and pipeline have been enhanced by the addition of Bayer Animal Health, which complements our commercial operations and international infrastructure while expanding our direct to retailer/e-commerce presence.

Total consideration transferred to Bayer and its subsidiaries for the acquisition is summarized as follows:

Cash consideration [1]	$	5,054
Fair value of Elanco common stock [2]		1,724
Fair value of total consideration transferred	$	6,778

(1) Includes initial cash consideration of $5,170 million less working capital and tax adjustments of $116 million.

(2) Represents the acquisition date fair value of 73 million shares of Elanco common stock at $23.64 per share. Per the terms of the stock and asset purchase agreement, the number of shares was based on approximately $2.3 billion divided by the 20-day volume-weighted average stock price as of the last day of trading before the closing of the acquisition (but subject to a 7.5% symmetrical collar centered on the baseline share number of approximately $2.3 billion divided by an initial share price of $33.60).

We recognized transaction costs related to the acquisition of Bayer Animal Health of $3 million, $267 million, and $43 million for the years ended December 31, 2021, 2020, and 2019 respectively. These costs were primarily associated with legal and professional services related to the acquisition and are reflected within asset impairment, restructuring and other special charges in the consolidated statements of operations.

The amount of revenue attributable to Bayer Animal Health included in the consolidated statements of operations since the date of acquisition for the years ended December 31, 2021 and 2020 is $1,903 million and $592 million, respectively. Based on our current operational structure, we have not recorded standalone costs for Bayer Animal Health after the date of the acquisition. As a result, we are unable to accurately determine earnings or loss attributable to Bayer Animal Health since the date of acquisition.

The following table summarizes the fair value of assets acquired and liabilities assumed as of the acquisition date:

Estimated Fair Value at August 1, 2020		
Cash and cash equivalents	$	169
Accounts receivable		10
Inventories		487
Prepaid expenses and other current assets		60
Property and equipment		315
Intangible assets:		
Acquired in-process research and development		65
Marketed products		3,740
Assets held for sale		138
Accounts payable and accrued liabilities		(237)
Accrued retirement benefits		(220)
Other noncurrent assets and liabilities - net		(878)
Total identifiable net assets		3,649
Goodwill		3,129
Total consideration transferred	$	6,778

The valuation of assets acquired and liabilities assumed was finalized during the second quarter of 2021. The measurement period adjustments recorded during 2021, which were made to reflect the facts and circumstances in existence as of the acquisition date, primarily related to the finalization of our fair value assessment of property and equipment located at the Shawnee, Kansas site (Shawnee), revised cash flow assumptions for marketed products, adjustments related to changes in inventory balances and gross margin assumptions, tax adjustments, and minor working capital adjustments. These adjustments resulted in a decrease to marketed products intangible assets of $210 million, a decrease to property and equipment of $32 million, a net increase to working capital accounts and other non-current assets and liabilities of $26 million, and an increase to goodwill of $207 million.

Inventories comprised of $311 million, $81 million, and $95 million in finished products, work in process, and raw materials, respectively. The estimate of fair value of finished products was determined based on net realizable value adjusted for the costs to complete the sales process, a reasonable profit allowance from the sales process, and estimated holding costs. The estimate of fair value of work in process was determined based on net realizable value adjusted for costs to complete the manufacturing process, costs of the sales process, a reasonable profit allowance for the remaining manufacturing and sales process effort, and an estimate of holding costs. The fair value of raw materials was determined to approximate book value. The net fair value step-up adjustment to inventories of $152 million has been amortized to cost of sales as the inventory is sold to customers. As of December 31, 2021, the fair value step-up adjustment has been fully amortized.

Property and equipment is mostly composed of land, buildings, equipment (including machinery, furniture and fixtures, and computer equipment), and construction in progress. The estimated fair value of real property was determined using the sales comparison data valuation technique and personal property was determined using the direct replacement cost method. The estimated fair value of property and equipment located at the Shawnee, Kansas site was determined using the income approach.

Intangible assets relate to $65 million of IPR&D and $3,740 million of marketed products. The acquired definite-lived intangible assets are being amortized over a weighted-average estimated useful life of approximately 10 years on a straight-line basis. The estimated fair values of identifiable intangible assets were determined using the income approach. Some of the significant assumptions inherent in the development of these asset valuations include the estimated net cash flows for each year for each asset or product (including revenues, cost of sales, R&D expenses, marketing, selling and administrative expenses, and contributory asset charges), the appropriate discount rate necessary to measure the risk inherent in each future cash flow stream, the life cycle of each asset, the potential regulatory and commercial success risk, and competitive trends impacting the asset and each cash flow stream, as well as other factors.

Assets held for sale include $133 million of intangible assets, consisting of marketed products and IPR&D, and $5 million of inventory related to the divestitures of *Drontal*™, *Profender*™ and other products. See the *Divestitures* section below for further details.

Accrued retirement benefits primarily relate to certain Bayer Animal Health international subsidiaries that have underfunded defined benefit pension plans. We have recorded the fair value of these plans using assumptions and accounting policies similar to those disclosed in Note 18: Retirement Benefits. Upon acquisition, the excess of projected benefit obligation over the fair value of plan assets was recognized as a liability and previously existing deferred actuarial gains and losses and unrecognized service costs or benefits were eliminated.

The goodwill recognized from this acquisition represents the value of additional growth platforms and an expanded revenue base as well as anticipated operational synergies and cost savings from the creation of a single combined global organization. The majority of goodwill associated with this acquisition is not deductible for tax purposes.

2019 Acquisitions

Aratana Therapeutics, Inc.

On July 18, 2019, we acquired Aratana, a pet therapeutics company focused on innovative therapies for dogs and cats, for stock and cash-based contingent value rights. Aratana is the creator of the canine osteoarthritis medicine, *Galliprant*, the rights to which we acquired in 2016. The acquisition enhances our presence in the areas of appetite stimulants in dogs, pain relief in dogs and cats, and treatments of other conditions in the U.S. and internationally. In connection with the acquisition, we issued approximately 7 million shares with a value of $238 million to Aratana shareholders, based on our stock price on the last trading day immediately prior to the closing date. The purchase consideration also included up to $12 million in contingent value rights, which represent the rights of Aratana shareholders to receive a contingent payment of $0.25 per share in cash upon the achievement of a specified milestone as outlined in the merger agreement. We calculated an immaterial fair value for the contingent value rights using the Monte Carlo simulation model. See Note 10: Financial Instruments and Fair Value for further discussion.

Contingent consideration liabilities that we previously recorded for future royalty and milestone payments in relation to the 2016 acquisition of rights to *Galliprant* were settled upon the closing of our acquisition of Aratana. The liabilities were valued at $85 million as of the acquisition date using the Monte Carlo simulation model. The resulting $8 million loss upon settlement was recorded in other (income) expense, net in the consolidated statements of operations for the year ended December 31, 2019.

The following table summarizes the amounts recognized for assets acquired and liabilities assumed as of the acquisition date:

Estimated Fair Value at July 18, 2019		
Cash and cash equivalents	$	26
Inventories		10
Acquired in-process research and development		32
Marketed products [1]		37
Other intangible assets [1]		13
Other assets and liabilities - net		4
Total identifiable net assets		122
Goodwill [2]		31
Settlement of existing contingent consideration liabilities		85
Total consideration transferred	$	238

(1) These intangible assets, which are being amortized on a straight-line basis over their estimated useful lives, are expected to have a weighted average useful life of approximately 13 years.

(2) The goodwill recognized from this acquisition is attributable primarily to expected synergies from combining the operations of Aratana with our legacy business. The majority of goodwill associated with this acquisition is not deductible for tax purposes.

The accounting for this acquisition is complete. A $20 million measurement period adjustment was recorded primarily to establish a deferred tax liability for the preexisting *Galliprant* contingent consideration liability during the year ended December 31, 2020.

We issued 0.1 million shares and recorded $4 million of stock-based compensation expense for the vesting of Aratana equity awards that was accelerated upon the closing of the acquisition during 2019.

Prevtec Microbia Inc.

On July 31, 2019, we acquired Prevtec in a cash transaction for approximately $60 million, inclusive of certain post-closing adjustments. Prevtec is a Canadian biotechnology company specializing in the development of vaccines intended to help prevent bacterial diseases in farm animals. The acquisition allows us to expand on our previous distribution arrangement for *Coliprotec*™ and is consistent with our efforts to explore innovative antibiotic alternatives.

The purchase consideration included up to $16 million in additional cash consideration, contingent upon the achievement of specific sales milestones by December 31, 2021. We recorded a $5 million liability on the consolidated balance sheet as of the acquisition date based on the fair value of the contingent consideration as calculated using the Monte Carlo simulation model. See Note 10: Financial Instruments and Fair Value for further discussion.

A previously existing $1 million receivable owed from Prevtec to Elanco Animal Health UK Limited was settled upon the closing of our acquisition of Prevtec. The resulting immaterial gain upon settlement was recorded in other (income) expense, net in the consolidated statements of operations for the year ended December 31, 2019.

The following table summarizes the amounts recognized for assets acquired and liabilities assumed as of the acquisition date:

Estimated Fair Value at July 31, 2019		
Cash and cash equivalents	$	1
Acquired in-process research and development		3
Marketed products[(1)]		59
Other intangible assets		1
Other assets and liabilities - net		(9)
Total identifiable net assets		55
Goodwill [(2)]		10
Total consideration transferred	$	65

(1) These intangible assets, which are being amortized on a straight-line basis over their estimated useful lives, are expected to have a weighted average useful life of 10 years.

(2) The goodwill recognized from this acquisition is attributable primarily to expected synergies from combining the operations of Prevtec with our legacy business and future unidentified projects and products. The goodwill associated with this acquisition is not deductible for tax purposes.

The accounting for this acquisition is complete. An immaterial measurement period adjustment to deferred taxes was recorded during the year ended December 31, 2020.

Pro forma financial information (unaudited)

The following table presents the estimated unaudited pro forma combined results of Elanco, Bayer Animal Health and Aratana for the years ended December 31, 2020 and 2019 as if the acquisitions had occurred on January 1, 2019:

	Year Ended December 31,	
	2020	2019
Revenue	$ 4,441	$ 4,691
Loss before income taxes	(675)	(160)

The supplemental pro forma financial information has been prepared using the acquisition method of accounting and is based on the historical financial information of Elanco, Bayer Animal Health and Aratana. The supplemental pro forma financial information does not necessarily represent what the combined companies' revenue or results of operations would have been had the acquisitions been completed on January 1, 2019, nor is it intended to be a projection of future operating results of the combined company. It also does not reflect any operating efficiencies or potential cost savings that might be achieved from synergies of combining Elanco, Bayer Animal Health and Aratana.

The unaudited supplemental pro forma financial information reflects primarily pro forma adjustments related to divestitures, fair value estimates for intangibles, property and equipment, and inventory, and interest expense and amortization of debt issuance costs for the debt issuance to finance the acquisition of Bayer Animal Health. The unaudited supplemental pro forma financial information includes transaction charges associated with the acquisition. There are no material, nonrecurring pro forma adjustments directly attributable to the acquisition included in the reported pro forma revenue and loss before income taxes.

Divestitures

Shawnee and Speke divestitures

In the second quarter of 2021, as part of our strategy to optimize our manufacturing footprint, we announced an agreement with TriRx Pharmaceuticals (TriRx) to sell our manufacturing sites in Shawnee and Speke, U.K. (Speke), including the planned transfer of approximately 600 employees. In connection with these arrangements, we also entered into long-term manufacturing and supply agreements, under which TriRx will manufacture existing Elanco products at both sites upon the closing of the transactions. During the year ended December 31, 2021, we recorded a $273 million pre-tax charge to reduce the carrying value of the disposal groups to an amount equal to fair value less costs to sell in asset impairment, restructuring, and other special charges in the consolidated statements of operations. Our fair value less costs to sell assessment includes the fair value of the favorable manufacturing and supply agreements, estimated using a combined income and market approach which incorporated Level 3 inputs. On August 1, 2021, we completed the sale of our Shawnee site and expect to receive gross cash proceeds of $51 million over a period of three years based on the terms of the agreement, beginning in the second half of 2022. We completed the sale of our Speke site on February 1, 2022; therefore, the related assets are classified as held for sale as of December 31, 2021. See Note 6: Asset Impairment, Restructuring and Other Special Charges for further information.

Elanco and Bayer Animal Health product divestitures

In connection with advancing our efforts to secure the necessary regulatory clearances for our acquisition of Bayer Animal Health, we signed agreements in 2020 to divest the rights to manufacture and commercialize certain legacy Elanco products. In 2020, we signed agreements to divest the worldwide rights to *Osurnia*™ and *Vecoxan*™ and the U.S. rights to *Capstar*™. In July 2020, we completed these sales, along with certain other immaterial divestitures. The transactions were accounted for as asset divestitures.

In 2020, we also signed an agreement to divest the worldwide rights to the legacy Elanco products *Itrafungol*™ and *Clomicalm*™ in connection with the required disposal of an early-stage IPR&D asset. We also made a payment during the year ended December 31, 2021 and accrued for future amounts we are required to pay to the buyer of the IPR&D asset to help fund their development costs for a set period of time. The divestiture closed during 2021. There were no proceeds received from the disposition of these assets and the resulting immaterial impact was recorded in other (income) expense, net in the consolidated statements of operations. The related assets met the assets held for sale criteria as of December 31, 2020.

To allow the Bayer Animal Health acquisition to close on a timely basis, we signed agreements to divest the rights to the legacy Bayer Animal Health products *Drontal* and *Profender* within the U.K. and European Economic Area as well as other IPR&D. We completed the transactions, which were accounted for as asset divestitures, in August 2020. *Drontal*, *Profender*, and the IPR&D rights were acquired as part of the Bayer Animal Health acquisition. The related assets were classified as held for sale on the balance sheet as of the acquisition date and measured at fair value at the time of the acquisition; therefore, no gains were recognized on the sales. During the year ended December 31, 2020, a loss of $7 million was recorded on the sale of IPR&D as recognition of the potential income from the divestiture was constrained by revenue accounting standards.

There were additional marketed and pipeline products that we were required to dispose of in order to comply with regulatory requirements. These divestitures did not have a material effect on our operations, cash flows or financial position.

During the year ended December 30, 2020, we received gross cash proceeds of $435 million and recognized pre-tax gains of $156 million (net of transaction costs of $13 million) relating to the product divestitures described above. Pre-tax gains were included in other (income) expense, net in the consolidated statements of operations.

Assets Held For Sale

Assets and liabilities considered held for sale in connection with the above divestitures were included in the respective line items on the consolidated balance sheet as follows:

	December 31, 2021	December 31, 2020
Inventories	$ 31	$ 2
Other intangibles, net	—	4
Property and equipment, net	50	—
Deferred tax asset	—	1
Total assets held for sale	$ 81	$ 7

Other intangibles, net classified as held for sale primarily consisted of marketed products.

Microbiome R&D platform carve-out

On October 5, 2021, we announced our intention to carve out our microbiome R&D platform, aiming to create a privately funded, independent, biopharmaceutical company focused on developing solutions for animal and human health. We are exploring structures with both strategic and financial sponsors, and may retain a minority stake in this new entity. The potential carve-out is expected to be executed in the first half of 2022 and the assets to be transferred are not expected to be material. We determined that the disposal of the related net assets does not qualify for reporting as a discontinued operation because it does not represent a strategic shift that has or will have a major effect on our operations and financial results.

Note 6. Asset Impairment, Restructuring and Other Special Charges

In recent years, we have incurred substantial costs associated with restructuring programs and cost-reduction initiatives designed to achieve a flexible and competitive cost structure. As discussed further below, restructuring activities primarily include charges associated with facility rationalization and workforce reductions. In connection with our recent acquisitions, including the acquisition of Bayer Animal Health, we have also incurred costs associated with executing transactions and integrating acquired operations, which may include expenditures for banking, legal, accounting, and other similar services. In addition, we have incurred costs to stand up our organization as an independent company. All operating functions can be impacted by these actions; therefore, non-cash expenses associated with our tangible and intangible assets can be incurred as a result of revised fair value projections and/or determinations to no longer utilize certain assets in the business on an ongoing basis.

For finite-lived intangible assets and other long-lived assets, whenever impairment indicators are present, we calculate the undiscounted value of projected cash flows associated with the asset, or group of assets, and compare it to the carrying amount. If the carrying amount is greater, we record an impairment loss for the excess of book value over fair value. Determinations of fair value can result from a complex series of judgments and rely on estimates and assumptions. See Note 2: Basis of Presentation and Note 3: Summary of Significant Accounting Policies for discussion regarding estimates and assumptions.

2021 Restructuring Programs

In 2021, we announced two separate restructuring programs to improve operating efficiencies.

The actions proposed in January 2021 focused on streamlining processes and delivering increased efficiency in functional areas, while improving the productivity of our investments in innovation. As part of the restructuring plan, we closed our R&D sites in Manukau, New Zealand and Cuxhaven, Germany. We have also reduced duplication and optimized structures in U.S. operations, marketing, manufacturing and quality central functions, and administrative areas. The restructuring resulted in the elimination of approximately 315 positions around the world. Activities related to this initiative resulted in net charges of $43 million during the year ended December 31, 2021, primarily consisting of severance costs and other cash charges. Restructuring charges under this program were substantially complete at the end of 2021.

The program announced in November 2021 includes initiatives to consolidate certain international commercial operations into one organization, integrate our centralized global marketing organization into country level commercial organizations, transform and simplify our R&D organizational structure, and other organizational adjustments. In connection with the proposed restructuring, we expect to eliminate approximately 380 positions. Activities related to this initiative resulted in charges of approximately $86 million in the fourth quarter of 2021, consisting of severance costs. Restructuring charges under this program were substantially complete at the end of 2021; however, we may continue to make adjustments to our severance accruals to reflect changes in estimates resulting from ongoing negotiations.

2020 Restructuring Program

In September 2020, following the closing of the Bayer Animal Health acquisition, we implemented a restructuring program designed to reduce duplication, drive efficiency and optimize our footprint in key geographies. As part of the restructuring plan, we have eliminated approximately 900 positions across 40 countries, primarily in the commercial and marketing functions, but also in R&D, manufacturing and quality, and back-office support functions. During the years ended December 30, 2021 and 2020 we recorded favorable adjustments of $15 million and charges of $162 million, respectively. The favorable adjustments reflect adjustments to severance accruals resulting from favorable negotiations and certain restructured employees filling open positions. Charges in 2020 primarily related to severance and asset write-down expenses. Restructuring charges under this program were substantially complete at the end of 2021.

Components of asset impairment, restructuring and other special charges for the years ended December 31 are as follows:

	2021	2020	2019
Restructuring charges (credits):			
Severance and other costs [1]	$ 110	$ 155	$ 8
Facility exit costs (credits) [1]	—	(3)	—
Acquisition related charges:			
Transaction and integration costs [2]	162	424	145
Non-cash and other items:			
Asset impairment [3]	66	17	16
Asset write-down [4]	278	19	17
Gain on sale of fixed assets	—	(4)	—
Net periodic benefit cost (credits) (Note 18)	(29)	—	—
Settlements and other [5]	41	15	—
Total expense	$ 628	$ 623	$ 186

(1) 2021 charges mainly represent employee termination costs for restructuring programs announced and initiated in January 2021 and November 2021. These costs were partially offset by the reversal of severance accruals associated with the January 2021 and September 2020 programs during the period. See below for further details. 2020 restructuring charges mainly represent employee termination costs for cost-reduction and productivity initiatives related to a restructuring program initiated following the acquisition of Bayer Animal Health, partially offset by a favorable true-up of a lease termination related to a previous restructuring program. 2019 charges primarily relate to employee termination costs from exiting R&D operations in Prince Edward Island, Canada, ceasing certain manufacturing operations in Wusi, China, and streamlining operations in Speke, England.

(2) Transaction costs represent external costs directly related to acquiring businesses and primarily include expenditures for banking, legal, accounting and other similar services. Integration costs represent internal and external incremental costs directly related to integrating acquired businesses, including the acquisitions of KindredBio and Bayer Animal Health (e.g., expenditures for consulting, system and process integration, and product transfers), as well as independent company stand-up costs related to the implementation of new systems, programs, and processes.

(3) Represents the impact of adjustments to fair value of property and equipment, IPR&D assets, and marketed products that were subject to product rationalization. See Note 11: Goodwill and Intangibles for further information.

(4) Represents the impact of changes in the estimated useful lives of assets involved in restructuring actions. 2021 also includes adjustments recorded to write down the Shawnee and Speke assets classified as held for sale as of June 30, 2021 to an amount equal to estimated fair value less costs to sell. See Note 5: Acquisitions and Divestitures for further discussion.

(5) 2021 includes a charge associated with the settlement of a liability for future royalty and milestone payments triggered in connection with our acquisition of KindredBio as discussed further in Note 5: Acquisitions and Divestitures, accounting and advisory fees related to the sale of our manufacturing site in Shawnee, and $10 million of litigation settlements, partially offset by a gain recorded on the divestiture of an early-stage IPR&D asset acquired as part of the Bayer Animal Health acquisition. 2020 charges relate to a non-recurring litigation settlement for a matter that originated prior to our separation from Lilly and a one-time expense associated with our agreement to build a new corporate headquarters.

The following table summarizes the activity in our reserves established in connection with restructuring activities:

	Exit costs	Severance	Total
Balance at December 31, 2019	$ 5	$ 16	$ 21
Charges	1	156	157
Reserve adjustment	(3)	(1)	(4)
Cash paid	(3)	(41)	(44)
Balance at December 31, 2020	—	130	130
Charges	—	126	126
Reserve adjustment	—	(16)	(16)
Cash paid	—	(114)	(114)
Balance at December 31, 2021	$ —	$ 126	$ 126

These reserves are included in other current and noncurrent liabilities on the consolidated balance sheets. Substantially all of the reserves are expected to be paid in the next 15 months primarily due to certain country negotiations and regulations. We believe that the reserves are adequate.

Note 7. Inventories

We state all inventories at the lower of cost or net realizable value. We use the last-in, first-out (LIFO) method for a portion of our inventories located in the continental U.S. Other inventories are valued by the first-in, first-out (FIFO) method or the weighted average cost method.

Inventories at December 31 consisted of the following:

	2021	2020
Finished products	$ 598	$ 772
Work in process	565	625
Raw materials and supplies	256	210
Total	1,419	1,607
Decrease to LIFO cost	(46)	(29)
Inventories	$ 1,373	$ 1,578

Inventories valued under the LIFO method comprised $243 million and $234 million of total inventories at December 31, 2021 and 2020, respectively.

Note 8. Equity

Common Stock Offering

On January 22, 2020, we entered into an underwriting agreement in which we agreed to sell approximately 23 million shares of our common stock at a public offering price of $32.00 per share. In connection with the offering, we granted the underwriters an option to purchase up to an additional 2 million shares, which was exercised in full on January 23, 2020. As a result, we issued and sold a total of approximately 25 million shares of our common stock for $768 million, after issuance costs.

Tangible Equity Unit (TEU) Offering

On January 22, 2020, we also completed our offering of 11 million, 5.00% TEUs. Total proceeds, net of issuance costs, were $528 million. Each TEU, which has a stated amount of $50, is comprised of a prepaid stock purchase contract (prepaid stock) and a senior amortizing note due February 1, 2023. Subsequent to issuance, each TEU may be legally separated into the two components. The prepaid stock is considered a freestanding financial instrument, indexed to Elanco common stock, and meets the conditions for equity classification.

The value allocated to the prepaid stock is reflected net of issuance costs in additional paid-in capital. The value allocated to the senior amortizing notes is reflected in long-term debt on the consolidated balance sheet, with payments expected in the next twelve months reflected in current portion of long-term debt. Issuance costs related to the amortizing notes are reflected as a reduction of the carrying amount and will be amortized through the maturity date using the effective interest rate method.

The proceeds from the issuance were allocated to equity and debt based on the relative fair value of the respective components of each TEU as follows:

	Equity Component	Debt Component	Total
Fair value per unit	$ 42.80	$ 7.20	$ 50.00
Gross proceeds	$ 471	$ 79	$ 550
Less: Issuance costs	19	3	22
Net proceeds	$ 452	$ 76	$ 528

The senior amortizing notes have an aggregate principal amount of $79 million and bear interest at 2.75% per year. On each February 1, May 1, August 1, and November 1 until the maturity date, we will pay equal quarterly cash installments of $0.6250 per each amortizing note with an initial principal amount of $7.2007 (except for the first installment payment of $0.6528 per amortizing note paid on May 1, 2020). Each installment constitutes a payment of interest and partial payment of principal, and in the aggregate will be equivalent to 5.00% per year with respect to the $50 stated amount per TEU.

Unless settled early at the holder's or our election, each prepaid stock purchase contract will automatically settle on February 1, 2023 (the mandatory settlement date) for a number of shares of common stock per contract based on the average of the volume-weighted average trading prices during the 20 consecutive trading day period beginning on, and including the 21st scheduled trading day immediately preceding February 1, 2023 (applicable market value) with reference to the following settlement rates:

Applicable Market Value	Common Stock Issued
Equal to or greater than $38.40	1.3021 shares (minimum settlement rate)
Less than $38.40, but greater than $32.00	$50 divided by applicable market value
Less than or equal to $32.00	1.5625 (maximum settlement rate)

The prepaid stock purchase contracts are mandatorily convertible into a minimum of 14 million shares or a maximum of 17 million shares of our common stock on the mandatory settlement date (unless redeemed by us or settled earlier at the unit holder's option). The 14 million minimum shares are included in the calculation of basic weighted average shares outstanding. The difference between the minimum and maximum shares represents potentially dilutive securities, which are included in the calculation of diluted weighted average shares outstanding on a pro rata basis to the extent that the average applicable market value is higher than $32.00 but is less than $38.40 during the period.

Note 9. Debt

Long-term debt as of December 31 consisted of the following:

	2021	2020
Incremental Term Facility	$ 499	$ —
Term Loan B	4,118	4,164
Revolving Credit Facility	250	—
3.912% Senior Notes due 2021	—	500
4.272% Senior Notes due 2023	750	750
4.900% Senior Notes due 2028	750	750
TEU Amortizing Notes	34	60
Other obligations	—	1
Unamortized debt issuance costs	(82)	(98)
	6,319	6,127
Less current portion of long-term debt	294	555
Total long-term debt	$ 6,025	$ 5,572

Maturities on long-term debt consisted of the following:

As of and for the years ending December 31	
2022	$ 308
2023	805
2024	48
2025	135
2026	48
2027 and thereafter	5,057
Total obligations and commitments	6,401
Unamortized debt issuance costs	(82)
Total debt	$ 6,319

Cash payments for interest during the years ended December 31 were as follows:

	2021	2020	2019
Interest paid	$ 221	$ 131	$ 104

Farm Credit Agreement

On August 12, 2021, we entered into a new debt financing arrangement with Farm Credit Mid-America, PCA (Farm Credit) for a $500 million credit facility, consisting of a senior secured term loan (Incremental Term Facility) to retire our existing Senior Notes due August 27, 2021. The Incremental Term Facility bears interest at a floating rate of LIBOR plus 175 basis points and is payable in quarterly installments of principal and interest with a final balloon payment due on August 12, 2028. The terms of the Incremental Term Facility, including pledged collateral and financial maintenance covenants, are generally consistent with the terms of our existing term loan B credit facility (Term Loan B) and revolving credit facility.

Bayer Animal Health Related Financing

In connection with the acquisition of Bayer Animal Health, on August 1, 2020, we borrowed $4,275 million under a Term Loan B facility. The Term Loan B bears interest at a floating rate of LIBOR plus 175 basis points and is payable in quarterly installments through August 1, 2027. In January 2022, we paid $70 million of the outstanding balance on our Term Loan B.

Simultaneously, we entered into a revolving credit facility providing up to $750 million (with incremental capacity available if certain conditions are met) and maturing over a five-year term. The revolving credit facility bears interest at LIBOR plus an applicable margin ranging between 1.50% and 2.25% per annum based on our corporate family rating or corporate credit rating. During 2021, we drew down $500 million on the revolving credit facility for working capital needs and to partially fund the acquisition of KindredBio. We subsequently repaid $250 million during the year ended December 31, 2021. In 2020, we drew down and subsequently repaid $450 million on the revolving credit facility to fund local country asset purchases in connection with our acquisition of Bayer Animal Health subsidiaries. In February 2022, we paid $163 million of the outstanding balance on our revolving credit facility.

These senior secured first lien credit facilities are secured by a significant portion of our assets. They include two financial maintenance covenants which are solely for the benefit of lenders under the revolving credit facility. There are no financial maintenance covenants for the benefit of the Term Loan B facility. The lenders under the Term Loan B facility have no enforcement rights with respect to the financial maintenance covenants for the revolving credit facility.

The first financial maintenance covenant for the revolving credit facility requires us to maintain a net total leverage ratio level (which is not subject to step-downs) as of the end of each quarter. The required level of this covenant is based on closing date pro forma net leverage and pro forma adjusted earnings before interest, taxes, depreciation and amortization (EBITDA) not exceeding 7.71 to 1.00 of our pro forma adjusted EBITDA for the four fiscal quarters ended December 31, 2021.

The second financial maintenance covenant for the revolving credit facility requires us to maintain a ratio of pro forma adjusted EBITDA to cash interest expense of no less than 2.00 to 1.00, tested as of the end of each fiscal quarter. We were in compliance with all covenants under the credit facility as of December 31, 2021.

Senior Notes

In August 2018, we issued $2 billion of senior notes (Senior Notes). The Senior Notes comprised of $500 million of 3.912% Senior Notes due August 27, 2021, which were fully repaid as part of the Farm Credit refinancing, $750 million of 4.272% Senior Notes due August 28, 2023, and $750 million of 4.900% Senior Notes due August 28, 2028. The interest rate payable on each series of Senior Notes is subject to adjustment if Moody's Investor Services, Inc. or Standard & Poor's Financial Services LLC downgrades, or subsequently upgrades, its ratings on the respective series of Senior Notes.

The indenture that governs the Senior Notes contains covenants that limit our, and certain of our subsidiaries' ability, to incur liens or engage in sale-leaseback transactions. The indenture also contains restrictions on our ability to consolidate, merge or sell substantially all of our assets, in addition, to other customary terms. We were in compliance with all such covenants under the indenture governing the Senior Notes as of December 31, 2021.

TEU Amortizing Notes

On January 22, 2020, we issued $550 million in TEUs. We offered 11 million, 5.00% TEUs at the stated amount of $50 per unit, comprised of prepaid stock purchase contracts and a senior amortizing note due February 1, 2023 (the mandatory settlement date). Total cash of $528 million was received, comprised of $452 million of prepaid stock purchase contracts and $76 million of senior amortizing notes, net of issuance costs. We paid $28 million representing partial payment of principal and interest on the TEU amortizing notes during the year ended December 31, 2021. See Note 8: Equity for further information.

Debt Extinguishment

On January 31, 2020, we repaid indebtedness outstanding under our existing term loan facility. We paid $372 million in cash, composed of $371 million of principal and $1 million of accrued interest, resulting in a debt extinguishment loss of $1 million (recognized in interest expense, net of capitalized interest in the consolidated statements of operations for the year ended December 31, 2020), primarily related to the write-off of deferred debt issuance costs.

On September 25, 2020, we made a repayment of principal of $100 million on the indebtedness outstanding under our Term Loan B facility. The repayment was accounted for as a partial debt extinguishment and resulted in a debt extinguishment loss of $2 million (recognized in interest expense, net of capitalized interest in the consolidated statements of operations for the year ended December 31, 2020), primarily related to the write-off of deferred debt issuance costs.

Note 10. Financial Instruments and Fair Value

Financial instruments that are potentially subject to credit risk consist principally of trade receivables. We evaluate the creditworthiness of our customers on a regular basis, monitor economic conditions, and calculate allowances for estimated credit losses on our trade receivables on a quarterly basis using an expected credit loss model. We assess whether collectability is probable at the time of sale and on an ongoing basis. Collateral is generally not required. The risk associated with this concentration is mitigated by our ongoing credit-review procedures.

A large portion of our cash is held by a few major financial institutions. We monitor the exposure with these institutions and do not expect any of these institutions to fail to meet their obligations. All highly liquid investments with a maturity of three months or less from the date of purchase are considered to be cash equivalents. The cost of these investments approximates fair value. We also consider the carrying value of restricted cash balances to be representative of its fair value.

We had investments without readily determinable fair values and equity method investments included in other noncurrent assets on the consolidated balance sheets totaling $22 million and $24 million as of December 31, 2021 and 2020, respectively. We recorded a net unrealized loss of $10 million and a net unrealized gain of $11 million in other (income) expense, net in the consolidated statements of operations for the years ended December 31, 2021 and 2020, respectively. Unrealized net losses in 2019 were immaterial.

The following table summarizes the fair value information at December 31, 2021 and 2020 for foreign exchange contract assets (liabilities), investments, contingent consideration liabilities, and cash flow hedge assets (liabilities) measured at fair value on a recurring basis in the respective balance sheet line items, as well as long-term debt (including TEU amortizing notes) for which fair value is disclosed on a recurring basis:

		Fair Value Measurements Using			
Financial statement line item	Carrying Amount	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value
December 31, 2021					
Prepaid expenses and other - foreign exchange contracts not designated as hedging instruments	$ 19	$ —	$ 19	$ —	$ 19
Other noncurrent assets - investments	13	13	—	—	13
Other noncurrent assets - forward-starting interest rate contracts designated as cash flow hedges	8	—	8	—	8
Other current liabilities - foreign exchange contracts not designated as hedging instruments	(20)	—	(20)	—	(20)
Long-term debt, including current portion	(6,401)	—	(6,518)	—	(6,518)
December 31, 2020					
Prepaid expenses and other - foreign exchange contracts not designated as hedging instruments	$ 36	$ —	$ 36	$ —	$ 36
Other noncurrent assets - investments	9	9	—	—	9
Other current liabilities - foreign exchange contracts not designated as hedging instruments	(36)	—	(36)	—	(36)
Other noncurrent liabilities- contingent consideration	(1)	—	—	(1)	(1)
Other noncurrent liabilities - forward-starting interest rate contracts designated as cash flow hedges	(76)	—	(76)	—	(76)
Long-term debt, including current portion	(6,225)	—	(6,420)	—	(6,420)

We determine our Level 2 fair value measurements based on a market approach using quoted market values or significant other observable inputs for identical or comparable assets or liabilities.

Contingent consideration liabilities as of December 31, 2020 related to the acquisitions of Aratana and Prevtec during 2019. For Aratana, we were contracted to pay up to $12 million in contingent value rights dependent on the achievement of a specified milestone by December 31, 2021 as outlined in the merger agreement. For Prevtec, based on the terms of the purchase agreement, we were contracted to pay $16 million contingent upon the achievement of specific *Coliprotec* sales milestones by December 31, 2021. The fair value of both contingent consideration liabilities was estimated using the Monte Carlo simulation model and Level 3 inputs including historical revenue, discount rate, asset volatility, and revenue volatility. The milestones for Aratana and Prevtec were not achieved, and therefore, our remaining liability was written off during the year ended December 31, 2021. The resulting gain of $1 million was recognized in other (income) expense, net in the consolidated statements of operations. During the year ended December 31, 2020, primarily as a result of a decrease in forecasted revenues related to *Coliprotec*, we decreased the fair value of the contingent consideration liability associated with the Prevtec acquisition by $4 million and recognized the gain in other (income) expense, net in the consolidated statements of operations. See Note 5: Acquisitions and Divestitures for further discussion.

Derivative Instruments and Hedging Activities

We are exposed to market risks, such as changes in foreign currency exchange rates and interest rates. To manage the volatility related to these exposures, we have entered into various derivative transactions. We formally assess, designate and document, as a hedge of an underlying exposure, each qualifying derivative instrument that will be accounted for as an accounting hedge at inception. Additionally, we assess, both at inception and at least quarterly thereafter, whether the financial instruments used in the hedging transaction are effective at offsetting changes in either the fair values or cash flows of the underlying exposures. Derivative cash flows, with the exception of net investment hedges, are principally classified in the operating activities section of the consolidated statements of cash flows, consistent with the underlying hedged item. Cash flows related to net investment hedges are classified in the investing activities section of the consolidated statements of cash flows.

Derivatives Not Designated as Hedges

We may enter into foreign exchange forward or option contracts to reduce the effect of fluctuating currency exchange rates. These derivative financial instruments primarily offset exposures in the Euro, British pound, Swiss franc (CHF), Brazilian real, Australian dollar, Japanese yen, Canadian dollar, and Chinese yuan. Foreign currency derivatives used for hedging are put in place using the same or like currencies and duration as the underlying exposures and are recorded at fair value with the gain or loss recognized in other (income) expense, net in the consolidated statements of operations. Forward contracts generally have maturities not exceeding 12 months. At December 31, 2021 and December 31, 2020, we had outstanding foreign exchange contracts with aggregate notional amounts of $1,212 million and $1,391 million, respectively.

The amount of net losses on derivative instruments not designated as hedging instruments, recorded in other (income) expense, net were as follows:

	For the Year Ended December 31,		
	2021	2020	2019
Foreign exchange forward contracts [1]	$ (35)	$ (4)	$ (5)

(1) These amounts were substantially offset in other (income) expense, net by the effect of changing exchange rates on the underlying foreign currency exposures.

Derivatives Designated as Hedges

In October 2018, as a means of mitigating the impact of currency fluctuations on our operations in Switzerland, we entered into a five-year cross-currency fixed interest rate swap with a 750 million CHF notional amount, which was designated as a net investment hedge against CHF denominated assets (the fair value of which was estimated based on quoted market values of similar hedges and was classified as Level 2). During the year ended December 31, 2020, we fully liquidated our cross currency interest rate swaps for a cash benefit of $35 million (including $2 million in interest). Notwithstanding settlement, gains and losses within accumulated other comprehensive income (loss) will remain in accumulated other comprehensive income (loss) until either the sale or substantial liquidation of the hedged subsidiary.

Gains on the net investment hedge, recognized within interest expense, net of capitalized interest, were as follows:

	For the Year Ended December 31,		
	2021	2020	2019
Cross-currency interest rate swap contracts	$ —	$ 6	$ 25

Over the life of the derivative, gains or losses due to spot rate fluctuations were recorded in cumulative translation adjustment in other comprehensive income (loss). The amounts of net gains on interest rate swap contracts, recorded, net of tax, in other comprehensive income (loss), were as follows:

	For the Year Ended December 31,		
	2021	2020	2019
Cross-currency interest rate swap contracts	$ —	$ 24	$ 8

We are subject to interest rate risk with regard to our existing floating-rate debt, and we utilize interest rate swap contracts to mitigate the variability in cash flows by effectively converting the floating-rate debt into fixed-rate debt. We recognize any differences between the variable interest rate payments and the fixed interest rate settlements with the swap counterparties as an adjustment to interest expense, net of capitalized interest over the life of the swaps. We have designated these swaps as cash flow hedges and record them at fair value on the consolidated balance sheets. Changes in the fair value of the hedges are recognized in other comprehensive income (loss). Fair value is estimated based on quoted market values of similar hedges and is classified as Level 2.

In March 2020, as a means of mitigating interest rate risk associated with the Term Loan B issuance, we executed forward-starting interest rate swaps with a $4.1 billion notional amount, which were designated as cash flow hedges and had maturity dates ranging between 2022 and 2025. In October 2021, six of the existing interest rate swap positions with maturities in 2025 and an aggregate notional value of $2.1 billion were terminated and replaced with 24 new interest rate swaps. The new swaps have maturities ranging between 2022 and 2025 with an aggregate notional amount of $2.1 billion. The new interest rate swaps qualified as effective cash flow hedges at inception and are recorded at fair value. An immaterial amount of cash was exchanged between Elanco and the counterparties; therefore, the transactions did not significantly impact the consolidated statements of cash flows. The amount of unrealized gains recorded in accumulated other comprehensive income (loss) related to the terminated interest rate swaps at the time of termination was $2 million. This amount will be amortized to interest expense over the remaining term of the original interest rate swaps.

The amounts of net gains (losses) on cash flow hedges, recorded, net of tax, in other comprehensive income (loss), were as follows:

	For the Year Ended December 31,		
	2021	2020	2019
Forward-starting interest rate swaps, net of tax benefit of $0, $15, and $0, respectively	$ 86	$ (61)	$ —

There was no tax effect for the year ended December 31, 2021 after the application of the U.S. valuation allowance. See Note 15: Income Taxes for further discussion. Over the next 12 months we expect to recognize charges of $2 million in interest expense, net of capitalized interest due to swap settlements. During the years ended December 31, 2021 and 2020, we recognized $28 million and $7 million, respectively, of net losses into interest expense.

Note 11. Goodwill and Intangibles

Goodwill

Goodwill was $6.2 billion as of December 31, 2021 and 2020. Goodwill results from excess consideration in a business combination over the fair value of identifiable net assets acquired. Goodwill is not amortized but is reviewed for impairment at least annually and when impairment indicators are present. Goodwill may be impaired if the carrying amount of a reporting unit exceeds the fair value of that reporting unit, calculated as based on discounted cash flows. An impairment charge would be recorded for the excess, if any, of the reporting unit's carrying amount over its fair value, but not to exceed the total amount of goodwill allocated to the reporting unit. The estimated fair value is based on a number of assumptions, including current market capitalization as corroboration of fair value. See Note 5: Acquisitions and Divestitures for further discussion of goodwill resulting from recent business combinations and changes in the carrying amount of goodwill.

The following table summarizes the changes in the carrying amount of goodwill during the period:

Balance as of December 31, 2020	$	6,225
Bayer Animal Health measurement period adjustments		207
Additions related to the KindredBio acquisition		33
Goodwill associated with Shawnee, Speke and other divestitures		(64)
Foreign currency translation adjustments		(229)
Balance as of December 31, 2021	$	6,172

No impairments occurred with respect to the carrying value of goodwill for the years ended December 31, 2021, 2020 and 2019.

Other Intangibles

The components of intangible assets other than goodwill as of December 31 were as follows:

	2021			2020		
Description	**Carrying Amount, Gross**	**Accumulated Amortization**	**Carrying Amount, Net**	**Carrying Amount, Gross**	**Accumulated Amortization**	**Carrying Amount, Net**
Finite-lived intangible assets:						
Marketed products	$ 6,828	$ (1,837)	$ 4,991	$ 7,394	$ (1,342)	$ 6,052
Software	285	(77)	208	346	(108)	238
Other	47	(28)	19	62	(40)	22
Total finite-lived intangible assets	7,160	(1,942)	5,218	7,802	(1,490)	6,312
Indefinite-lived intangible assets:						
Acquired in-process research and development	369	—	369	75	—	75
Other intangibles	$ 7,529	$ (1,942)	$ 5,587	$ 7,877	$ (1,490)	$ 6,387

Marketed products consist of the amortized cost of the rights to assets acquired in business combinations and approved for marketing in a significant global jurisdiction. Also included in this category are post-approval milestone payments from transactions other than a business combination.

Software consists of certain costs incurred in connection with obtaining or developing internal-use software, including payroll and payroll-related costs for employees directly associated with the internal-use software projects and direct costs of external resources. These costs include software classified as "in process" until the project is substantially complete and the software is ready for its intended purpose, at which point the costs are amortized on a straight-line basis over the estimated useful life. Depreciation expense includes $52 million in 2021, $35 million in 2020, and $20 million in 2019 for amortization of software.

Other finite-lived intangibles consist primarily of the amortized cost of licensed platform technologies that have alternative future uses in research and development, manufacturing technologies and customer relationships from business combinations. Acquired IPR&D consists of the related costs capitalized, adjusted for subsequent impairments, if any. The costs of acquired IPR&D projects acquired directly in a transaction other than a business combination are capitalized if the projects have an alternative future use; otherwise, they are expensed immediately. The fair values of acquired IPR&D projects acquired in business combinations are capitalized as other intangible assets.

Several methods may be used to determine the estimated fair value of marketed products, IPR&D, and other finite-lived intangibles acquired in a business combination. We utilize the "income method" for these intangibles. This method is a Level 3 fair value measurement and applies a probability weighting that considers the risk of development and commercialization to the estimated future net cash flows that are derived from projected revenues and estimated costs. These projections are based on factors such as relevant market size, patent protection, historical pricing of similar products and expected industry trends. The estimated future net cash flows are then discounted to the present value using an appropriate discount rate. This analysis is performed for each group of assets independently. The acquired IPR&D assets are treated as indefinite-lived intangible assets until completion or abandonment of the projects, at which time the assets are tested for impairment and amortized over the remaining useful life or written off, as appropriate.

During 2021, we added approximately $334 million of IPR&D as a result of the KindredBio acquisition. During 2020, after considering measurement period adjustments, we added approximately $65 million of IPR&D and $3,740 million of marketed products as a result of the Bayer Animal Health acquisition. See Note 5: Acquisitions and Divestitures for further discussion of intangible assets acquired in recent business combinations.

Indefinite-lived intangible assets are reviewed for impairment at least annually and when impairment indicators are present. The fair value of the indefinite lived intangible assets (acquired IPR&D) is estimated using the same assumptions as used for goodwill and by applying a probability weighting that reflects the risk of development and commercialization to the estimated future net cash flows that are derived from projected revenues and estimated costs. Finite-lived intangible assets are reviewed for impairment when an indicator of impairment is present. We compare the carrying amounts of the assets with the estimated undiscounted future cash flows. In the event the carrying amount exceeds the undiscounted cash flows, an impairment charge is recorded for the amount by which the carrying amount of the asset exceeds the estimated fair value, which is determined based on discounted future cash flows.

Impairment charges related to our other intangibles were as follows:

	2021	2020	2019
Asset impairment, restructuring and other special charges	$ 66	$ 17	$ 11

During 2021, we recorded impairment charges comprised of $55 million for acquired IPR&D and $11 million for marketed products. The impairments to acquired IPR&D primarily related to adjustments to the fair value of IPR&D assets that were subject to product rationalization, including a decision by management to terminate a project and fully impair the related asset associated with a farm animal parasiticide. The decision was prompted by unfavorable efficacy results observed during the year. The impairments of marketed products related to a full impairment based on a reassessment of competitive viability and project priority for an approved asset and an adjustment to the fair value of a mature brand that is subject to near-term product rationalization.

During 2020, we recorded impairment charges comprised of $9 million for acquired IPR&D and $8 million for marketed products. The impairment to acquired IPR&D related to reassessments of geographic viability and project priority, which was partially prompted by the addition of the Bayer Animal Health IPR&D pipeline. The impairment of marketed products related to adjustments made to record assets classified as held for sale at the lower of their carrying amounts or fair values less costs to sell.

During 2019, we recorded impairment charges of $11 million for indefinite-lived intangible assets, primarily related to product rationalization.

Intangible assets with finite lives are capitalized and are amortized over their estimated useful lives, ranging from 3 to 20 years. As of December 31, 2021, the remaining weighted-average amortization periods for finite-lived intangible assets are as follows:

	Weighted Average Life (Years)
Marketed products	10
Software	6
Other	7

The estimated amortization expense for each of the next five years associated with our finite-lived intangible assets as of December 31, 2021 is as follows:

	2022	2023	2024	2025	2026
Estimated amortization expense	$ 559	$ 559	$ 555	$ 537	$ 534

Note 12. Property and Equipment

Property and equipment is stated on the basis of cost. Provisions for depreciation of buildings and equipment are computed generally by the straight-line method at rates based on their estimated useful lives (12 to 50 years for buildings and 3 to 25 years for equipment). We review the carrying value of long-lived assets for potential impairment on a periodic basis and whenever events or changes in circumstances indicate the carrying value of an asset may not be recoverable. Impairment is determined by comparing projected undiscounted cash flows to be generated by the asset to its carrying value. If an impairment is identified, a loss is recorded equal to the excess of the asset's net book value over its fair value utilizing a discounted cash flow analysis, and the cost basis is adjusted.

At December 31, property and equipment consisted of the following:

	2021	2020
Land	$ 42	$ 46
Buildings	549	756
Equipment	1,354	1,360
Construction in progress	157	191
Finance lease asset	—	1
	2,102	2,354
Less accumulated depreciation	(1,041)	(1,038)
Property and equipment, net	$ 1,061	$ 1,316

The following provides property and equipment, less accumulated depreciation by geographic area:

	2021	2020
United States	$ 557	$ 673
Germany	211	221
United Kingdom	65	194
France	54	59
Other foreign countries	174	169
Property and equipment, net	$ 1,061	$ 1,316

Depreciation expense related to property and equipment was as follows:

	2021	2020	2019
Depreciation expense	$ 108	$ 122	$ 94

Note 13. Leases

We determine if an arrangement is a lease at inception. We have operating leases for corporate offices, research and development facilities, vehicles, and equipment. We generally have remaining lease terms ranging from one to 15 years, some of which have options to extend or terminate the leases. Finance leases are included in property and equipment, current portion of long-term debt, and long-term debt on the consolidated balance sheets. Finance leases are not material to the consolidated statements of operations, consolidated balance sheets, or consolidated statements of cash flows. Operating leases are included in noncurrent assets, other current liabilities, and other noncurrent liabilities on the consolidated balance sheets.

Right-of-use assets included in noncurrent assets represent our right to use an underlying asset for the lease term and lease liabilities represent our obligation to make lease payments arising from the lease. Right-of-use assets and operating lease liabilities are recognized at commencement date based on the present value of lease payments over the lease term. As most of our leases do not provide an implicit rate, we use our incremental borrowing rate based on the information available at commencement date in determining the present value of lease payments. We use the implicit rate if it is readily determinable. The right-of-use asset also includes any lease payments made and excludes lease incentives. Our lease terms may include options to extend or terminate the lease when it is reasonably certain and there is a significant economic incentive to exercise that option.

Operating lease expense for right-of-use assets is recognized on a straight-line basis over the lease term. Variable lease payments, which represent lease payments that vary due to changes in facts or circumstances occurring after the commencement date other than the passage of time, are expensed in the period in which the obligation for these payments was incurred.

We elected not to apply the recognition requirements of ASC 842, *Leases*, to short-term leases, which are deemed to be leases with a lease term of 12 months or less. Instead, we recognize lease payments in the consolidated statements of operations on a straight-line basis over the lease term and variable payments in the period in which the obligation for these payments was incurred. We elected this policy for all classes of underlying assets. We elected not to apply the practical expedient related to the separation of lease and non-lease components or the practical expedient which allows entities to use hindsight when determining lease term.

The impact of operating leases to the consolidated financial statements for the years ended December 31, was as follows:

	2021	2020	2019
Lease cost			
Operating lease cost	$ 43	$ 38	$ 26
Short-term lease cost	1	1	1
Variable lease cost	4	3	2
Total lease cost	$ 48	$ 42	$ 29
Other information			
Operating cash outflows from operating leases	$ 40	$ 36	$ 24
Right-of-use assets obtained in exchange for new operating lease liabilities (1)	36	138	20
Weighted-average remaining lease term - operating leases	7 years	8 years	5 years
Weighted-average discount rate - operating leases	3.8 %	3.8 %	3.6 %

(1) 2020 includes approximately $16 million of right-of-use assets acquired in the Bayer Animal Health acquisition.

Supplemental balance sheet information related to our operating leases is as follows:

Asset/Liability	Balance Sheet Classification	December 31, 2021	December 31, 2020
Right-of-use assets	Other noncurrent assets	$ 161	$ 187
Current operating lease liabilities	Other current liabilities	34	37
Non-current operating lease liabilities	Other noncurrent liabilities	127	151

As of December 31, 2021, the annual minimum lease payments of our operating lease liabilities were as follows:

2022	$ 41
2023	32
2024	24
2025	19
2026	15
2027 and thereafter	59
Total lease payments	190
Less imputed interest	(29)
Total	$ 161

Lease contracts that have been executed but have not yet commenced are excluded from the tables above. As of December 31, 2021, we have an additional lease commitment that has not yet commenced for our new corporate headquarters in Indianapolis, Indiana. Total minimum lease payments are estimated to be approximately $310 million over a term of 25 years, excluding extensions. Final lease payments may vary depending on the actual cost of certain construction activities. Lease commencement is expected in 2024.

Australia Sale-Leaseback

On June 26, 2020, our wholly-owned subsidiary, Elanco Australasia PTY LTD, sold land and an R&D facility located in New South Wales, Australia, for aggregate proceeds of $55 million, and leased the property back for an initial term of 15 years through a sale-leaseback transaction. Under the terms of the purchase and sale agreement, we determined that control of the assets was relinquished to the buyer-lessor. Therefore, we recognized a pre-tax gain on the sale of $46 million in other (income) expense, net in the consolidated statements of operations during the year ended December 31, 2020. Operating lease right-of-use assets and liabilities include the present value of $28 million for the associated lease payments, which are presented in other noncurrent assets and other noncurrent liabilities and other current liabilities on the consolidated balance sheet.

Note 14. Stock-Based Compensation

The 2018 Elanco Stock Plan (Plan) provides long-term incentives to attract, motivate and retain employees and non-employee directors. The types of stock-based awards available include, but are not limited to, restricted stock units (RSUs), performance-based awards (PAs), and stock options. Our practices and policies specify that stock-based compensation awards are approved by the Compensation Committee of the Board of Directors. The total number of shares authorized for stock-based compensation awards under the plan was 11 million. As of December 31, 2021, the aggregate number of remaining shares available for future grant was approximately 9 million.

Stock-Based Compensation Expense

We measure compensation expense for stock-based awards based on grant date fair value and the estimated number of awards that are expected to vest. For purposes of measuring stock-based compensation expense, we consider whether an adjustment to the observable market price is necessary to reflect material nonpublic information that is known to us at the time the award is granted. No adjustments were deemed necessary for the years ended December 31, 2021, 2020, or 2019. Forfeitures are estimated based on historical experience at the time of grant and are revised in subsequent periods if actual forfeitures differ from those estimates.

Components of stock-based compensation expense and related tax benefit for the years ended December 31 were as follows:

	2021	2020	2019
Total stock-based compensation expense [1]	$ 66	$ 48	$ 41
Related tax benefit	(11)	(8)	(10)

(1) Substantially all of our stock-based compensation expense relates to RSUs and PAs.

Restricted Stock Units

RSUs are granted to certain employees and are settled in shares of our common stock. RSU shares are accounted for at fair value based upon the closing stock price on the date of the grant. The corresponding expense is amortized over the vesting period, typically three years. The number of shares ultimately issued for the RSU program remains constant with the exception of forfeitures.

RSUs granted to employees for the years ended December 31 were as follows:

(Units in millions)	2021	2020	2019
Granted units	1.1	1.3	2.9
Weighted-average fair value	$ 33.57	$ 27.44	$ 31.22

Changes in the nonvested portion of RSUs for 2021 are summarized below:

(Shares in millions)	Shares	Weighted-Average Grant Date Fair Value
Nonvested units at January 1, 2021	2.4	$ 28.90
Granted	1.1	33.57
Vested	(0.9)	29.84
Forfeited	(0.4)	30.58
Nonvested units at December 31, 2021	2.2	30.87

The fair market value of RSUs vesting in 2021, 2020, and 2019 was $30 million, $33 million, and $23 million, respectively.

As of December 31, 2021 the total remaining unrecognized stock-based compensation expense related to nonvested RSUs was $26 million, which is expected to be amortized over a weighted-average remaining requisite service period of 17 months.

Performance-Based Awards

PAs, which are granted to eligible officers and management, represent the right to receive a share of our common stock and are subject to forfeiture until restrictions lapse (including continued employment through the end of the vesting period and achievement of certain pre-established metrics). Payouts can vary depending on achievement. PA shares are accounted for at fair value based upon the closing stock price on the date of grant and fully vest at the end of the measurement period. Stock-based compensation expense for PAs is recognized only if it is deemed probable that the performance condition will be achieved.

PA activity during the year ended December 31, 2021 is summarized below:

(Shares in millions)	Shares	Weighted-Average Grant Date Fair Value
Nonvested awards at January 1, 2021	1.2	$ 26.63
Granted	0.6	32.70
Vested	(0.7)	30.96
Forfeited	(0.1)	29.66
Nonvested awards at December 31, 2021	1.0	30.53

The fair market value of PAs vesting in 2021 and 2020 was $22 million and $2 million, respectively. No PAs vested in 2019.

As of December 31, 2021, the total remaining unrecognized stock-based compensation expense related to nonvested PAs was $17 million, which is expected to be amortized over a weighted-average remaining requisite service period of 12 months.

Note 15. Income Taxes

Our income tax provision for the years ended December 31, 2021 and 2020 includes income tax costs and benefits such as valuation allowances, uncertain tax positions, audit settlements, and other items.

We are included in Lilly's U.S. tax examinations by the Internal Revenue Service through the full separation date of March 11, 2019. Pursuant to the tax matters agreement we executed with Lilly in connection with the IPO, the potential liabilities or potential refunds attributable to pre-IPO periods in which Elanco was included in a Lilly consolidated or combined tax return remain with Lilly. The U.S. examination of tax years 2016 through 2018 began in the fourth quarter of 2019 and remains ongoing; therefore, the resolution of this audit period will likely extend beyond the next 12 months.

Effective January 1, 2022, the Tax Cuts and Jobs Act of 2017 requires the capitalization of research and development costs for tax purposes, which can then be amortized over five years and 15 years for domestic and foreign costs, respectively. Congress has proposed tax legislation to delay the effective date of this change to 2025, but it is uncertain whether the proposed delay will ultimately be enacted into law. Management is currently evaluating the potential impact on our cash flows from operations.

Deferred taxes are recognized for the future tax effects of temporary differences between financial and income tax reporting based on enacted tax laws and rates. We recognize the tax benefit from an uncertain tax position only if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon ultimate resolution.

Following is the composition of income (loss) before income tax expense (benefit):

	2021	2020	2019
Federal	$ (341)	$ (495)	$ 55
Foreign	(226)	(177)	23
Income (loss) before income taxes	$ (567)	$ (672)	$ 78

Following is the composition of income tax expense (benefit):

	2021	2020	2019
Current:			
Federal	$ —	$ (36)	$ (5)
Foreign	58	56	13
State	1	(7)	2
Total current tax expense	59	13	10
Deferred:			
Federal	(9)	(8)	15
Foreign	(144)	(125)	(8)
State	(1)	8	(7)
Total deferred tax expense (benefit)	(154)	(125)	—
Income tax expense (benefit)	$ (95)	$ (112)	$ 10

Significant components of our deferred tax assets and liabilities as of December 31 are as follows:

	2021	2020
Deferred tax assets:		
Compensation and benefits	$ 58	$ 69
Accruals and reserves	57	89
Tax credit carryovers	53	34
Tax loss carryovers	291	168
Inventories	18	18
Restructuring and other reserves	31	33
Operating lease liabilities	42	48
Other	71	25
Total gross deferred tax assets	621	484
Valuation allowances	(162)	(94)
Total deferred tax assets	459	390
Deferred tax liabilities:		
Right-of-use assets	(42)	(48)
Intangibles	(976)	(1,044)
Property and equipment	(80)	(115)
Other	—	—
Total deferred tax liabilities	(1,098)	(1,207)
Deferred tax liabilities - net	$ (639)	$ (817)

The deferred tax assets and related valuation allowance amounts for net operating losses and tax credits shown above have been adjusted for differences between financial reporting and tax return filings.

At December 31, 2021, we have tax credit carryovers of $53 million available to reduce future income taxes. The amount is comprised of foreign, U.S. federal and state credits. The foreign credits total $7 million and if unused, will begin to expire in 2036. The U.S. federal credits total $32 million and if unused, will begin to expire in 2030. The state credits total $14 million and if unused, will begin to expire in 2022. The U.S. federal credits are subject to a partial valuation allowance and state credits are subject to a full valuation allowance.

At December 31, 2021, we have net operating loss carryovers and other carryovers for foreign, U.S. federal and state income tax purposes of $291 million. $91 million will expire between 2022 and 2042, and $200 million of the carryovers have an indefinite carryforward period. Net operating losses and other carryovers for foreign, U.S. federal and state income tax purposes are subject to full and partial valuation allowances.

The movements in the valuation allowance are as follows:

	2021	2020
January 1	$ (94)	$ (32)
Increase	(74)	(75)
Release	6	13
December 31	$ (162)	$ (94)

The increase in the valuation allowance during 2021 is primarily attributable to the realizability of U.S. federal and state deferred tax assets as a result of U.S. pre-tax losses.

Deferred taxes are not provided on the unremitted earnings of subsidiaries outside of the U.S. because it is expected that these earnings will be reinvested indefinitely. For the amount considered to be indefinitely reinvested, it is not practicable to determine the amount of the related deferred income tax liability due to the complexities in the tax laws and assumptions we would be required to make. Deferred taxes, including U.S. or foreign withholding taxes, would be provided when we no longer consider our subsidiary earnings to be permanently invested, such as in situations where our subsidiaries plan to make future dividend distributions.

In accordance with the 2017 Tax Act, we treat taxes due on future Global Intangible Low-Taxed Income (GILTI) inclusions in U.S. taxable income as a current period expense when incurred.

Cash payments of income taxes were as follows:

	2021	2020	2019
Cash payments of income taxes	$ 151	$ 97	$ 43

The following is a reconciliation of the income tax expense (benefit) applying the U.S. federal statutory rate to income before income taxes to reported income tax expense:

	2021	2020	2019
Income tax expense (benefit) at the U.S. federal statutory tax rate	$ (119)	$ (141)	$ 16
Add (deduct):			
Taxation of international operations	(16)	(15)	21
State taxes	(8)	(10)	3
Income tax credits	(14)	(24)	(10)
Non-deductible employee compensation	4	1	4
Other permanent adjustments	(2)	18	(4)
Change in uncertain tax positions	(2)	(7)	(15)
Change in valuation allowance	62	66	(5)
Income tax expense (benefit)	$ (95)	$ (112)	$ 10

A reconciliation of the beginning and ending amount of gross unrecognized tax benefits is as follows:

	2021	2020	2019
Beginning balance at January 1	$ 3	$ 8	$ 15
Adjustments related to the separation from Lilly	—	—	(2)
Adjusted beginning balance at January 1	3	8	13
Additions based on tax positions related to the current year	—	—	1
Changes for tax positions of prior years	(1)	(2)	(1)
Additions related to acquisition	4	—	—
Settlements	—	(3)	(5)
Ending balance at December 31	$ 6	$ 3	$ 8

The total amount of unrecognized tax benefits that, if recognized, would affect tax expense was $6 million and $3 million at December 31, 2021 and 2020, respectively. Adjustments related to the separation from Lilly represent unrecognized tax benefits assumed by Lilly and have no impact on income tax expense in the consolidated financial statements. Additions related to acquisition represent unrecognized tax benefits related to the KindredBio acquisition that were recorded on the opening balance sheet.

We file income tax returns in the U.S. federal jurisdiction and various state, local and non-U.S. jurisdictions. Prior to our full separation from Lilly, certain of these income tax returns were filed on a consolidated or combined basis with Lilly.

We recognize both accrued interest and penalties related to unrecognized tax benefits in income tax expense (benefit). We recognized income tax expense (benefit) related to interest and penalties as follows:

	2021	2020	2019
Income tax benefit	$ (1)	$ (2)	$ (11)

At December 31, 2021 and 2020, our accruals for the payment of interest and penalties totaled $1 million.

Note 16. Commitments and Contingencies

Legal Matters

On May 20, 2020, a shareholder class action lawsuit captioned *Hunter v. Elanco Animal Health Inc., et al.* was filed in the United States District Court for the Southern District of Indiana (the Court) against Elanco and certain executives. On September 3, 2020, the Court appointed a lead plaintiff, and on November 9, 2020, the lead plaintiff filed an amended complaint adding additional claims against Elanco, certain executives, and other individuals. The lawsuit alleges, in part, that Elanco and certain of its executives made materially false and/or misleading statements and/or failed to disclose certain facts about Elanco's supply chain, inventory, revenue and projections. The lawsuit seeks unspecified monetary damages and purports to represent purchasers of Elanco securities between September 30, 2018 and May 6, 2020, and purchasers of Elanco common stock issued in connection with Elanco's acquisition of Aratana. We filed a motion to dismiss on January 13, 2021. The timing of the Court's decision is uncertain. We believe the claims made in the case are meritless, and we intend to vigorously defend our position. The process of resolving these matters is inherently uncertain and may develop over an extended period of time; therefore, at this time, the ultimate resolution cannot be predicted.

On October 16, 2020, a shareholder class action lawsuit captioned *Safron Capital Corporation v. Elanco Animal Health Inc., et al.* was filed in the Marion Superior Court of Indiana against Elanco, certain executives, and other individuals. On December 23, 2020, the plaintiffs filed an amended complaint adding an additional plaintiff. The lawsuit alleges, in part, that Elanco and certain of its executives made materially false and/or misleading statements and/or failed to disclose certain facts about Elanco's relationships with third party distributors and revenue attributable to those distributors within the registration statement on Form S-3 dated January 21, 2020 and accompanying prospectus filed in connection with Elanco's public offering which closed on or about January 27, 2020. The lawsuit seeks unspecified monetary damages and purports to represent purchasers of Elanco common stock or 5.00% TEUs issued in connection with the public offering. This case is currently stayed in deference to *Hunter v. Elanco Animal Health Inc.*

Claims seeking actual damages, injunctive relief, and/or restitution for allegedly deceptive marketing have been made against Elanco Animal Health Inc. and Bayer HealthCare LLC, along with other Elanco and Bayer entities, arising out of the use of *Seresto*, a non-prescription flea and tick collar for cats and dogs. During 2021, putative class action lawsuits were filed in state and federal courts in the U.S. alleging that the *Seresto* collars contain pesticides and other ingredients that can cause serious injury and death to cats and/or dogs wearing the product. The cases mention the existence of incident reports involving humans, but no plaintiff has claimed personal harm from the product. One plaintiff filed a petition before the Judicial Panel on Multidistrict Litigation (JPML). The hearing on the JPML petition took place on July 29, 2021, and a decision was reached to consolidate and transfer all pending lawsuits to the federal court in the Northern District of Illinois. We continue to receive information with respect to potential litigation costs, and we will be taking appropriate steps to defend these class action lawsuits.

Further, a U.S. House of Representative subcommittee chair requested that Elanco produce certain documents and information related to the *Seresto* collar and further made a request to temporarily recall *Seresto* collars from the market. We are continuing to cooperate with the subcommittee and have produced information pursuant to the request.

Seresto is a pesticide registered with the Environmental Protection Agency (EPA). A non-profit organization submitted a petition to the EPA requesting that the agency take action to cancel *Seresto's* pesticide registration and suspend the registration pending cancellation. The EPA is considering this petition and asked for public comment. We submitted a comment to the EPA supporting the safety profile of *Seresto*. All data and scientific evaluation used during the product registration process and through pharmacovigilance review supports the product's positive safety profile and efficacy. Therefore, we believe no removal, recall, or cancellation of the pesticide registration is warranted, nor has it been suggested by any regulatory agency. We continue to stand behind the safety profile for *Seresto,* and it remains available to consumers globally.

We are party to various other legal actions in the normal course of business. In determining whether a pending matter is significant for financial reporting and disclosure purposes, we consider both quantitative and qualitative factors in order to assess materiality. We accrue for liability claims to the extent that it is probable we will incur a loss and we can formulate a reasonable estimate of the costs. As of December 31, 2021 and 2020, we had no material liabilities established related to litigation as there were no significant claims which were probable and estimable. We are not currently subject to a significant claim other than the lawsuits noted above.

Regulatory Matters

On July 1, 2021, we received a subpoena from the SEC relating to our channel inventory and sales practices prior to mid-2020. We have cooperated in providing documents and information to the SEC and will continue to do so. Management believes that its actions were appropriate.

Note 17. Geographic Information

We operate as a single operating segment engaged in the development, manufacturing, marketing and sales of animal health products worldwide for both pets and farm animals. Consistent with our operational structure, our President and Chief Executive Officer (CEO), as the chief operating decision maker, makes resource allocation and business process decisions globally across our consolidated business. Strategic decisions are managed globally with global functional leaders responsible for determining significant costs/investments and with regional leaders responsible for overseeing the execution of the global strategy. Our global research and development organization is responsible for development of new products. Our manufacturing organization is responsible for the manufacturing and supply of products and for the optimization of our supply chain. Regional leaders are responsible for the distribution and sale of our products and for local direct costs. The business is also supported by global corporate staff functions. Managing and allocating resources at the global corporate level enables our CEO to assess the overall level of resources available and how to best deploy these resources across functions, product types, regional commercial organizations and research and development projects in line with our overarching long-term corporate-wide strategic goals, rather than on a product or geographic basis. Consistent with this decision-making process, our CEO uses consolidated, single-segment financial information for purposes of evaluating performance, allocating resources, setting incentive compensation targets, as well as forecasting future period financial results.

Our products include *AviPro, Baytril, Cydectin, Catosal, Denagard, Maxiban, Rumensin*, *Pulmotil*, and other products for livestock and poultry, as well as *Advantage, Advantix, Advocate* (collectively referred to as the *Advantage Family), Credelio, Duramune*, *Galliprant, Interceptor Plus, Seresto, Trifexis*, and other products for pets.

We have a single customer that accounted for 10%, 11% and 13% of revenue for the years ended December 31, 2021, 2020 and 2019, respectively. The product sales resulted in accounts receivable with this customer of $74 million and $87 million as of December 31, 2021 and 2020, respectively.

We are exposed to the risk of changes in social, political and economic conditions inherent in foreign operations and our results of operations and the value of our foreign assets are affected by fluctuations in foreign currency exchange rates.

Selected geographic area information was as follows:

	2021	2020	2019
United States	$ 2,124	$ 1,475	$ 1,525
International	2,641	1,798	1,546
Revenue	$ 4,765	$ 3,273	$ 3,071

Note 18. Retirement Benefits

Pension Plans

There are certain defined benefit pension plans that our employees participate in that are either dedicated to our employees or where the plan assets and liabilities that relate to our employees were legally required to transfer to Elanco at the time of our separation from Lilly. Our plans in Switzerland and Germany represent approximately 92% of our global benefit obligation. We use a measurement date of December 31 to develop the change in benefit obligation, change in plan assets, funded status and amounts recognized in the consolidated balance sheets at December 31 for our defined benefit pension plans, which were as follows:

	2021	2020
Change in benefit obligation:		
Benefit obligation at beginning of year	$ 560	$ 224
Service cost	18	14
Interest cost	2	2
Additions related to the Bayer Animal Health acquisition	—	265
Actuarial loss (gain)	(25)	18
Benefits paid	(4)	(8)
Curtailment gain	(19)	—
Settlements	(38)	(1)
Foreign currency exchange rate changes and other adjustments	(32)	46
Benefit obligation at end of year	462	560
Change in plan assets:		
Fair value of plan assets at beginning of year	234	149
Actual return on plan assets	13	5
Employer contribution	12	9
Additions related to the Bayer Animal Health acquisition	—	61
Benefits paid	(4)	(8)
Settlements	(38)	(1)
Foreign currency exchange rate changes and other adjustments	(10)	19
Fair value of plan assets at end of year	207	234
Funded status	(255)	(326)
Unrecognized net actuarial loss	13	67
Unrecognized prior service cost	(34)	(73)
Net amount recognized	$ (276)	$ (332)
Amounts recognized in the consolidated balance sheet consisted of:		
Other current liabilities	$ (1)	$ (2)
Accrued retirement benefits	(254)	(324)
Accumulated other comprehensive income before income taxes	(21)	(6)
Net amount recognized	$ (276)	$ (332)

The unrecognized net actuarial loss and unrecognized prior service cost for these pension plans have not yet been recognized in net periodic pension costs and are included in accumulated other comprehensive income (loss) at December 31, 2021.

Pension plan amendment

In September 2019, we signed agreements under which certain defined pension benefits in Switzerland transferred from the previous Lilly pension fund as of December 31, 2019 to a new Elanco pension fund effective January 1, 2020. This resulted in a plan amendment during the period. The plan amendment decreased our pension benefit obligation by approximately $21 million, consisting primarily of a decrease in prior service costs of approximately $75 million, partially offset by a loss of approximately $54 million driven by changes in certain assumptions. The net impact to accumulated other comprehensive income was a gain of approximately $21 million, which will be amortized over the average remaining service period of employees expected to receive benefits under the plans.

We do not expect any plan assets to be returned to us in 2022.

The following represents our weighted-average assumptions related to these pension plans as of December 31:

(Percentages)	2021	2020	2019
Discount rate for benefit obligation	1.1 %	0.6 %	0.6 %
Discount rate for net benefit costs	0.6	0.6	1.4
Rate of compensation increase for benefit obligation	2.7	3.1	2.3
Rate of compensation increase for net benefit costs	3.1	2.3	2.2
Expected return on plan assets for net benefit costs	2.9	3.2	4.0

The assumptions above are used to estimate our pension benefit obligations at year-end, which are reviewed on at least an annual basis. We revise these assumptions based on a yearly evaluation of long-term trends and market conditions that may impact the cost of providing retirement benefits.

The weighted-average discount rates for our defined benefit plans are set by benchmarking against investment grade corporate bonds where available, including, when there is sufficient data, a yield curve approach. For countries that lack a sufficient corporate bond market, a government bond index is used to establish the discount rate. Overall, the yield curves used to measure the benefit obligations as of December 31, 2021 resulted in higher discount rates as compared to the prior year.

In evaluating the expected rate of return, we consider many factors, with a primary analysis of current and projected market conditions; asset returns and asset allocations; and the views of leading financial advisers and economists. We may also review our historical assumptions compared with actual results, as well as the assumptions and trend rates utilized by similar plans, where applicable.

The following benefit payments, which reflect expected future service, as appropriate, are expected to be paid as follows:

	2022	2023	2024	2025	2026	2027-2031
Benefit payments	$ 12	$ 13	$ 13	$ 14	$ 15	$ 84

Amounts relating to these pension plans with projected benefit obligations in excess of plan assets were as follows at December 31:

	2021	2020
Projected benefit obligation	$ 455	$ 545
Fair value of plan assets	200	220

Amounts relating to these defined benefit pension plans with accumulated benefit obligations in excess of plan assets were as follows at December 31:

	2021	2020
Accumulated benefit obligation	$ 441	$ 521
Fair value of plan assets	200	220

The total accumulated benefit obligation for these defined benefit pension plans was $446 million and $534 million at December 31, 2021 and 2020, respectively.

Net pension expense (benefit) related to these plans included the following components:

	2021	2020	2019
Service cost	$ 18	$ 14	$ 9
Interest cost	2	2	2
Expected return on plan assets	(6)	(6)	(4)
Amortization of prior service cost	(6)	(8)	(2)
Amortization of net actuarial loss	2	3	1
Net curtailments and settlements (Note 6)	(29)	—	—
Net pension expense (benefit)	$ (19)	$ 5	$ 6

The components of net periodic benefit cost other than service cost and net curtailments and settlements are included in other (income) expense, net in the consolidated statements of operations. Net curtailments and settlements relate to the remeasurement of our pension benefit obligation as a result of workforce reductions in connection with our restructuring programs. See Note 6: Asset Impairment, Restructuring and Other Special Charges for further information.

The following represents the amounts recognized for these plans in other comprehensive income (loss):

	2021	2020	2019
Actuarial gain (loss) arising during period	$ 29	$ (18)	$ (46)
Prior year service cost during the year	—	—	75
Amortization of prior service cost, including settlements, in net loss	(36)	(8)	(2)
Amortization of net actuarial loss, including curtailments, in net loss	22	3	1
Foreign currency exchange rate changes and other	—	1	1
Total other comprehensive income (loss) during period	$ 15	$ (22)	$ 29

Benefit Plan Investments

Our benefit plan investment policies are set with specific consideration of return and risk requirements in relationship to the respective liabilities. Our plan assets in our Switzerland and German pension plans represent approximately 88% of our plan assets for these pension plans. Given the long-term nature of our liabilities, these plans have the flexibility to manage an above-average degree of risk in the asset portfolios. At the investment-policy level, there are no specifically prohibited investments. However, within individual investment manager mandates, restrictions and limitations are contractually set to align with our investment objectives, ensure risk control and limit concentrations.

We manage our portfolio to minimize concentration of risk by allocating funds within asset categories. In addition, within a category we use different managers with various management objectives to eliminate any significant concentration of risk.

The investment strategy for the legacy Elanco plans is to diversify in five major categories with a designated percentage invested in each including 36% fixed-income securities, 32% equity securities, a share of 21% in real estate and 11% in other alternative investments.

The acquired Bayer Animal Health plans are managed separately. The underlying investments are classified in the same categories with designated percentages in each of the following: 44% fixed-income securities, 28% equity securities and 28% in other alternative investments

Each category is diversified and comprised of the following:

- Fixed-income securities - Swiss bonds, global aggregates, global aggregate corporates, global government bonds, emerging market local currencies and emerging markets hard currencies.
- Equity securities - Swiss equities, global equities, low volatility equities (to reduce risk), and emerging market equities.
- Real estate - Swiss real estate and global real estate funds.
- Other alternative investments - cash, cash equivalents and investments in senior secured loans.

We determine the fair value of the investments based on a market approach using quoted market values, significant other observable inputs for identical or comparable assets or liabilities.

Real estate is mostly comprised of public holdings. Real estate investments in registered investment companies that trade on an exchange are classified as Level 1 on the fair value hierarchy. Other real estate investments are marked to fair value using models that are supported by observable market-based data (Level 2).

The fair values of these pension plan assets as of December 31, 2021 by asset category are as follows:

		Fair Value Measurements Using			
Asset Class	**Total**	**Quoted Prices in Active Markets for Identical Assets (Level 1)**	**Significant Observable Inputs (Level 2)**	**Significant Unobservable Inputs (Level 3)**	**Investments Valued at NAV[(1)]**
Public equity securities	63	60	—	—	3
Fixed income:					
Developed markets	76	75	—	—	1
Emerging markets	11	11	—	—	—
Real estate	26	21	5	—	—
Other	31	26	5	—	—
Total	$ 207	$ 193	$ 10	$ —	$ 4

(1) Certain investments that are measured at fair value using the NAV per share (or its equivalent) as a practical expedient have not been classified in the fair value hierarchy.

No material transfers between Level 1, Level 2, or Level 3 occurred during the year ended December 31, 2021.

The fair values of these pension plan assets as of December 31, 2020 by asset category are as follows:

		Fair Value Measurements Using			
Asset Class	Total	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Investments Valued at NAV[1]
Public equity securities	69	67	—	—	2
Fixed income:					
Developed markets	87	86	—	—	1
Emerging markets	13	13	—	—	—
Real estate	29	26	3	—	—
Other	36	31	5	—	—
Total	$ 234	$ 223	$ 8	$ —	$ 3

(1) Certain investments that are measured at fair value using the NAV per share (or its equivalent) as a practical expedient have not been classified in the fair value hierarchy.

No material transfers between Level 1, Level 2, or Level 3 occurred during the year ended December 31, 2020.

Contributions of $10 million to these pension plans are expected in 2022.

Retiree Health Benefit Plan

There are two retiree health benefit plans where the plan liabilities that relate to our employees were legally required to transfer to Elanco at the time of our separation from Lilly. The accrued retirement benefits for these plans were $4 million as of December 31, 2021 and 2020.

Defined Contribution Plans

Elanco has defined contribution savings plans that include certain employees worldwide. The purpose of these plans is generally to provide additional financial security during retirement by providing employees with an incentive to save. Our contributions to the plans are based on our employee contributions and the level of our match. Expenses related to our employees under the plans totaled $39 million, $35 million and $32 million for the years ended December 31, 2021, 2020, and 2019, respectively.

Multiemployer Plans

Through the acquisition of Bayer Animal Health, we acquired participation in certain multiemployer arrangements with Bayer-Pensionskasse VVaG, Leverkusen (Germany) (Bayer-Pensionskasse) and Rheinishche Pensionskasse VVaG, Leverkusen (Germany) (Rheinishche Pensionskasse). These plans provide for basic pension benefits to the majority of our employees in Germany. Up to a certain salary level, the benefit obligations are covered by our contributions and the contributions from employees to the plan. Contributions made to the multi-employer plan are expensed as incurred and were as follows:

	2021	2020
Bayer-Pensionskasse	$ 3	$ 1
Rheinische-Pensionskasse	1	1
Total	$ 4	$ 2

The Company-specific plan information for the Bayer-Pensionskasse and Rheinische-Pensionskasse is not publicly available, and the plans are not subject to a collective-bargaining agreement. The plans provide fixed, monthly retirement payments on the basis of the credits earned by the participating employees. To the extent that the Bayer-Pensionskasse or Rheinische-Pensionskasse is underfunded, the future contributions to the plan may increase and may be used to fund retirement benefits for employees related to other employers.

The Bayer-Pensionskasse financial statements for the years ended December 31, 2020 and 2019 indicated total assets of $11,476 million and $10,381 million, respectively; total actuarial present value of accumulated plan benefits of $10,950 million and $9,895 million, respectively; and total contributions for all participating employers of $134 million and $138 million, respectively. Our plan contributions in 2021 and 2020 did not exceed 5% of the total contributions.

The Rheinische-Pensionskasse financial statements for the years ended December 31, 2020 and 2019 indicated total assets of $1,026 million and $825 million, respectively; total actuarial present value of accumulated plan benefits of $972 million and $782 million, respectively; and total contributions for all participating employers of $52 million and $48 million, respectively. Our plan contributions in 2021 and 2020 did not exceed 5% of the total contributions.

Contributing to these types of plans creates risk that differs from providing benefits under our sponsored plans, in that if another participating employer ceases to contribute to a multiemployer plan, additional unfunded obligations may need to be funded over time by remaining participating employers.

Note 19. Earnings (Loss) Per Share

We compute basic earnings (loss) per share by dividing net earnings (loss) available to common shareholders by the actual weighted average number of common shares outstanding for the reporting period. Elanco has variable common stock equivalents relating to certain equity awards in stock-based compensation arrangements and the TEU prepaid stock purchase contracts (see Note 8: Equity for further discussion). Diluted earnings per share reflects the potential dilution that could occur if holders of the unvested equity awards and unsettled TEUs converted their holdings into common stock. The weighted average number of potentially dilutive shares outstanding is calculated using the treasury stock method. Potential common shares that would have the effect of increasing diluted earnings per share (or reducing loss per share) are considered to be anti-dilutive and as such, these shares are not included in the calculation of diluted earnings (loss) per share.

Basic and diluted earnings (loss) per share are calculated as follows:

	2021	2020	2019
Net earnings (loss) available to common shareholders	$ (472)	$ (560)	$ 68
Determination of shares:			
Weighted average common shares outstanding	487.2	441.4	369.0
Assumed conversion of dilutive common stock equivalents [1]	—	—	1.3
Diluted weighted average shares outstanding	487.2	441.4	370.3
Earnings (Loss) per share [2]			
Basic	$ (0.97)	$ (1.27)	$ 0.18
Diluted	$ (0.97)	$ (1.27)	$ 0.18

(1) During the years ended December 31, 2021 and 2020, we reported a net loss. Therefore, dilutive common stock equivalents are not assumed to have been issued since their effect is anti-dilutive. As a result, basic and diluted weighted average shares are the same, causing diluted net loss per share to be equivalent to basic net loss per share. For the years ended December 31, 2021, 2020, and 2019, approximately 1.8 million, 2.1 million, and 0.1 million, respectively, of potential common shares were excluded from the calculation of diluted earnings per share because their effect was anti-dilutive.

(2) Due to rounding conventions, earnings (loss) per share may not recalculate precisely based on the amounts presented within this table.

Note 20. Related Party Agreements and Transactions

Transactions and Agreements with Bayer

While Bayer is no longer considered a related party, we have transacted with Bayer during the period after the acquisition of Bayer Animal Health, including the period in which Bayer was considered a principal owner of Elanco. These transactions primarily related to local country asset purchases and various transitional services agreements (TSAs), contract manufacturing arrangements, and certain lease agreements to ensure business continuity after the acquisition.

For regulatory purposes in certain jurisdictions, consideration was required to be paid locally at closing in addition to amounts paid globally for the acquisition. Pursuant to the stock and asset purchase agreement, Bayer has provided a refund for payment amounts duplicated in these regions. The total amount paid to and received from Bayer in 2021 and 2020 for these local country asset purchases was approximately $16 million and $633 million, respectively. All local country asset purchases have been completed as of December 31, 2021.

Transactions and Agreements with Lilly

Lilly is no longer considered a related party as of the completion of the exchange offer on March 11, 2019, whereby Lilly shareholders exchanged all or a portion of Lilly common stock for shares of Elanco common stock owned by Lilly, resulting in the full separation of Elanco and the disposal of Lilly's entire ownership and voting interest in Elanco. However, we had related party transactions with Lilly through the completion of the exchange offer. Activities while Lilly was a related party, as well as prior agreements with Lilly, are detailed below.

TSA

Historically, Lilly provided us significant shared services and resources related to corporate functions such as executive oversight, treasury, legal, finance, human resources, tax, internal audit, financial reporting, information technology and investor relations, which we refer to collectively as the "Lilly Services." Under the terms of the TSA, we were able to use Lilly Services for a fixed term established on a service-by-service basis. We paid Lilly mutually agreed-upon fees for the Lilly Services provided under the TSA, which were based on Lilly's cost (including third-party costs) of providing the Lilly Services through March 31, 2021 and subject to a mark-up of 7% thereafter. All operations-focused TSAs that went into effect after our separation from Lilly were exited as planned during the first half of 2021.

Separation Activities

Subsequent to our initial public offering, there were transactions between us and Lilly related primarily to the completion of the local country asset purchases and finalization of assets and liabilities associated with the legal separation from Lilly, combined income tax returns and the impact of the tax matters agreement, historical Lilly retirement benefits, and centralized cash management. The most significant of these activities includes the finalization of the local country valuation of business and the resulting impact on deferred tax assets and the impact of combined tax returns.

Other Activities

We shared certain services and back-office functions with Lilly, which in certain instances resulted in Lilly paying costs for Elanco (e.g., utilities, local country operating costs, etc.) that were then passed through to Elanco for reimbursement. These amounts are included in cash flows from operating activities in the consolidated statements of cash flows. In addition, we operated through a single treasury settlement process and prior to the local country asset purchases (as described below) continued to transact through Lilly's processes in certain instances. As a result of these activities, there were certain amounts of financing that occurred between Lilly and Elanco during the years ended December 31, 2020 and 2019. These amounts are included in cash flows from financing activities in the consolidated statements of cash flows.

Local Country Asset Purchases

The legal transfer of certain of our net assets did not occur prior to the separation due to certain regulatory requirements in each of these countries. The related assets, liabilities, and results of operations have been reported in the consolidated financial statements, as we were responsible for the business activities conducted by Lilly on our behalf and were subject to the risks and entitled to the benefits generated by these operations and assets under the terms of the MSA. We held restricted cash, and an associated payable to Lilly, of $11 million as of December 31, 2020 and 2019 to fund the acquisition of these assets. As of December 31, 2021, all of these assets had been legally acquired and we had no restricted cash on our consolidated balance sheet.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS AND FINANCIAL DISCLOSURE

None

ITEM 9A. CONTROLS AND PROCEDURES

Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this report. Based on the evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of such period our disclosure controls and procedures are effective in recording, processing, summarizing, and reporting, on a timely basis, information required to be disclosed by us in the reports that we file or submit under the Exchange Act, and that information is accumulated and communicated to the Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely discussions regarding required disclosure.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f)). Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our internal control over financial reporting based on the Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework). We acquired KindredBio in August 2021, and management has excluded KindredBio's internal control over financial reporting from our assessment of the effectiveness of our internal control as of December 31, 2021. KindredBio represents approximately 2% of consolidated total assets and less than 1% of consolidated revenue as of and for the year ended December 31, 2021. Based on this evaluation, our management has concluded that, as of December 31, 2021, our internal control over financial reporting was effective.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. In addition, projections of any evaluation of effectiveness to future periods are subject to risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Ernst & Young LLP, an independent registered public accounting firm, has audited the effectiveness of our internal controls over financial reporting as of December 31, 2021 as stated in their report which is included herein.

Changes in Internal Control

There were no changes in our internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f)) that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting during the quarter ended December 31, 2021.

ITEM 9B. OTHER INFORMATION

Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Elanco Animal Health Incorporated

Opinion on Internal Control Over Financial Reporting

We have audited Elanco Animal Health Incorporated's internal control over financial reporting as of December 31, 2021, based on criteria established in Internal Control – Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework) (the COSO criteria). In our opinion, Elanco Animal Health Incorporated (the Company) maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on the COSO criteria.

As indicated in the accompanying Management's Report on Internal Control over Financial Reporting, management's assessment of and conclusion on the effectiveness of internal control over financial reporting did not include the internal controls of KindredBio, which is included in the 2021 consolidated financial statements of the Company and constituted 2% of consolidated total assets as of December 31, 2021 and less than 1% of revenues for the year then ended. Our audit of internal control over financial reporting of the Company also did not include an evaluation of the internal control over financial reporting of KindredBio.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets of the Company as of December 31, 2021 and 2020, the related consolidated statements of operations, comprehensive income (loss), equity and cash flows for each of the three years in the period ended December 31, 2021, and the related notes and our report dated February 28, 2022 expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ Ernst & Young LLP

Indianapolis, Indiana
February 28, 2022

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS, AND CORPORATE GOVERNANCE

Information on Directors, Executive Officers and Corporate Governance can be found in the Proxy Statement under "Proposal No. 1: Election of Directors," "Corporate Governance," and "Executive Officers." That information is incorporated in this report by reference.

ITEM 11. EXECUTIVE COMPENSATION

Information on director compensation, executive compensation, and compensation committee matters can be found in the Proxy Statement under "Non-Employee Director Compensation," "Corporate Governance – Board and Committee Information – Board Committees," "Compensation Discussion and Analysis," and "Executive Compensation Tables." That information is incorporated in this report by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Security Ownership of Certain Beneficial Owners and Management

Information relating to ownership of the company's common stock by management and by persons known by the company to be the beneficial owners of more than five percent of the outstanding shares of common stock is found in the Proxy Statement under "Stock Ownership Information." That information is incorporated in this report by reference.

Securities Authorized for Issuance Under Equity Compensation Plans

Information about our compensation plans under which shares of our common stock have been authorized for issuance as of December 31, 2021 can be found in the Proxy Statement under "Equity Compensation Plan Information" and is incorporated in this report by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Related Person Transactions

Information relating to related person transactions and the board's policies and procedures for approval of related person transactions can be found in the Proxy Statement under "Corporate Governance – Related Party Transactions." That information is incorporated in this report by reference.

Director Independence

Information relating to director independence can be found in the Proxy Statement under "Corporate Governance – Director Independence" and is incorporated in this report by reference.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information related to the fees and services of our principal independent accountants, Ernst & Young LLP, Auditor Firm ID: 42, can be found in the Proxy Statement under "Proposal No. 2: Ratification of Selection of Independent Auditor." That information is incorporated in this report by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

1. Financial Statements

The following consolidated financial statements of the company and its subsidiaries are found at Item 8:

- Consolidated Statements of Operations—Years Ended December 31, 2021, 2020, and 2019
- Consolidated Statements of Comprehensive Income (Loss)—Years Ended December 31, 2021, 2020, and 2019
- Consolidated Balance Sheets—December 31, 2021 and 2020
- Consolidated Statements of Equity—Years Ended December 31, 2021, 2020, and 2019

- Consolidated Statements of Cash Flows—Years Ended December 31, 2021, 2020, and 2019
- Notes to Consolidated Financial Statements

2. Financial Statement Schedules

The consolidated financial statement schedules of the company and its subsidiaries have been omitted because they are not required, are inapplicable, or are adequately explained in the financial statements.

Financial statements of interests of 50 percent or less, which are accounted for by the equity method, have been omitted because they do not, considered in the aggregate as a single subsidiary, constitute a significant subsidiary.

3. Exhibits

The following exhibits are either filed or furnished herewith (as applicable) or, if so indicated, incorporated by reference to the documents indicated in parentheses, which have previously been filed or furnished with the Securities and Exchange Commission.

Exhibit Number	Description
2.1	Agreement and Plan of Merger by and among Elanco Animal Health Incorporated, Elanco Athens Inc. and Aratana Therapeutics, Inc., dated April 26, 2019 (incorporated by reference to Exhibit 2.1 of the Current Report on Form 8-K filed with the SEC on April 26, 2019).
2.2	Share and Asset Purchase Agreement, dated as of August 20, 2019, between Bayer Aktiengesellschaft and Elanco Animal Health Incorporated (incorporated by reference to Exhibit 2.1 of the Current Report on Form 8-K filed with the SEC on August 20, 2019).
2.3	Amendment No. 1 to Share and Asset Purchase Agreement, dated as of October 15, 2019, between Bayer Aktiengesellschaft and Elanco Animal Health Incorporated (incorporated by reference to Exhibit 2.1 of the Current Report on Form 8-K filed with the SEC on October 17, 2019).
2.4	Amendment No. 2 to Share and Asset Purchase Agreement, dated as of January 17, 2020, between Bayer Aktiengesellschaft and Elanco Animal Health Incorporated (incorporated by reference to Exhibit 2.1 of the Current Report on Form 8-K filed with the SEC on January 17, 2020).
2.5	Amendment No. 3 to Share and Asset Purchase Agreement, dated as of June 15, 2020, between Bayer Aktiengesellschaft and Elanco Animal Health Incorporated (incorporated by reference to Exhibit 2.1 of the Current Report on Form 8-K filed with the SEC on June 18, 2020).
2.6	Amendment No. 4 to Share and Asset Purchase Agreement, dated as of July 30, 2020, between Bayer Aktiengesellschaft and Elanco Animal Health Incorporated (incorporated by reference to Exhibit 2.5 of the Current Report on Form 8-K filed with the SEC on August 3, 2020).
2.7	Annex 27 to the Share and Asset Purchase Agreement, dated as of August 20, 2019, between Bayer Aktiengesellschaft and Elanco Animal Health Incorporated (Incorporated by reference to Exhibit 4.3 of the Registration Statement on Form S-3 (File No. 333-235991) filed with the SEC on January 21, 2020).
2.8	Agreement and Plan of Merger, dated as of June 15, 2021, by and among Elanco Animal Health Incorporated, Knight Merger Sub, Inc., and Kindred Biosciences, Inc. (incorporated by reference to Exhibit 2.1 of the Current Report on Form 8-K filed with the SEC on June 16, 2021).
2.9	First Amendment to Agreement and Plan of Merger, dated as of June 30, 2021, by and among Elanco Animal Health Incorporated, Knight Merger Sub, Inc., and Kindred Biosciences, Inc. (incorporated by reference to Exhibit 2.1 of the Current Report on Form 8-K filed with the SEC on July 1, 2021).
3.1	Amended and Restated Articles of Incorporation of Elanco Animal Health Incorporated, effective September 18, 2018 (incorporated by reference to Exhibit 3.1 of the Current Report on Form 8-K filed with the SEC on September 26, 2018).
3.2	Amended and Restated Bylaws of Elanco Animal Health Incorporated, effective February 22, 2022 (incorporated by reference to Exhibit 3.1 of the Current Report on Form 8-K filed with the SEC on February 24, 2022).

4.1	Form of Certificate of Common Stock (incorporated by reference to Exhibit 4.1 of Amendment No. 1 to Registration Statement on Form S-1 (Registration No. 333-226536) filed with the SEC on August 28, 2018).
4.2	Indenture, dated August 28, 2018, between Elanco Animal Health Incorporated and Deutsche Bank Trust Company Americas, as trustee (incorporated by reference to Exhibit 4.2 of Amendment No. 1 to Registration Statement on Form S-1 (Registration No. 333-226536) filed with the SEC on August 28, 2018).
4.3	First Supplemental Indenture, dated August 28, 2018, between Elanco Animal Health Incorporated and Deutsche Bank Trust Company Americas, as trustee (incorporated by reference to Exhibit 4.3 of Amendment No. 1 to Registration Statement on Form S-1 (Registration No. 333-226536) filed with the SEC on August 28, 2018).
4.4	Second Supplemental Indenture, dated as of January 27, 2020, between Elanco Animal Health Incorporated and Deutsche Bank Trust Company Americas, as trustee, including the form of amortizing note (incorporated by reference to Exhibit 4.4 of Current Report on Form 8-K filed with the SEC on January 27, 2020).
4.5	Purchase Contract Agreement, dated as of January 27, 2020, between Elanco Animal Health Incorporated and Deutsche Bank Trust Company Americas, as purchase contract agent, as attorney-in-fact for holders of the purchase contracts referred to therein and as trustee under the indenture referred to therein, including the form of unit and form of purchase contract (incorporated by reference to Exhibit 4.1 of Current Report on Form 8-K filed with the SEC on January 27, 2020).
4.6	Description of Securities (incorporated by reference to Exhibit 4.6 of the Annual Report on Form 10-K filed February 28, 2020)
10.1	Master Separation Agreement, dated September 24, 2018, between Eli Lilly and Company and Elanco Animal Health Incorporated (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the SEC on September 26, 2018).
10.2	Transitional Services Agreement, dated September 24, 2018, between Eli Lilly and Company and Elanco Animal Health Incorporated (incorporated by reference to Exhibit 10.2 of the Current Report on Form 8-K filed with the SEC on September 26, 2018).
10.3	Tax Matters Agreement, dated September 24, 2018, between Eli Lilly and Company and Elanco Animal Health Incorporated (incorporated by reference to Exhibit 10.3 of the Current Report on Form 8-K filed with the SEC on September 26, 2018).
10.4	Employee Matters Agreement, dated September 24, 2018, between Eli Lilly and Company and Elanco Animal Health Incorporated (incorporated by reference to Exhibit 10.4 of the Current Report on Form 8-K filed with the SEC on September 26, 2018).
10.5	Toll Manufacturing and Supply Agreement, dated September 24, 2018, between Eli Lilly Export S.A. and Elanco UK AH Limited (incorporated by reference to Exhibit 10.5 of the Current Report on Form 8-K filed with the SEC on September 26, 2018).
10.6	Transitional Trademark License Agreement, dated September 24, 2018, among Eli Lilly and Company, Elanco Animal Health Incorporated and Elanco US Inc. (incorporated by reference to Exhibit 10.7 of the Current Report on Form 8-K filed with the SEC on September 26, 2018).
10.7	Intellectual Property and Technology License Agreement, dated September 24, 2018, among Eli Lilly and Company, Elanco Animal Health Incorporated and Elanco US Inc. (incorporated by reference to Exhibit 10.8 of the Current Report on Form 8-K filed with the SEC on September 26, 2018).
10.8	Credit Agreement, dated as of August 1, 2020, among Elanco Animal Health Incorporated, as borrower, Elanco US Inc., as co-borrower, the lenders party thereto from time to time, Goldman Sachs Bank USA, as term loan administrative agent, and as collateral agent and security trustee, and JPMorgan Chase Bank, N.A., as revolver administrative facility agent (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the SEC on August 3, 2020).
10.9	Incremental Assumption Agreement, dated August 12, 2021, by and among Elanco Animal Health Incorporated, Elanco US Inc., the subsidiary loan parties party thereto, Farm Credit Mid-America, PCA, as incremental term lender, and Goldman Sachs Bank USA, as the term facility agent (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the SEC on August 12, 2021).
10.10	Elanco Animal Health Incorporated Directors' Deferral Plan as amended (incorporated by reference to Exhibit 10.1 of the Quarterly Report on Form 10-Q filed with the SEC on May 14, 2019)*

10.11	Director Letter Agreement between Emu Holdings Company and R. David Hoover, dated as of May 25, 2018 (incorporated by reference to Exhibit 10.19 of Elanco Animal Health Incorporated's registration statement on Form S-1 (File No. 333-226536) filed with the SEC on August 2, 2018)*
10.12	Form of 2018 Change in Control Severance Pay Plan for Select Employees (incorporated by reference to Exhibit 10.20 of Amendment No. 1 to Elanco Animal Health Incorporated's registration statement on Form S-1 (File No. 333-226536) filed with the SEC on August 28, 2018).*
10.13	Form of Elanco Animal Health Incorporated Restricted Stock Unit Awards Agreement (incorporated by reference to Exhibit 10.21 of Amendment No. 1 to Elanco Animal Health Incorporated's registration statement on Form S-1 (File No. 333-226536) filed with the SEC on August 28, 2018).*
10.14	Form of Elanco Animal Health Incorporated Nonqualified Stock Option Award Agreement (incorporated by reference to Exhibit 10.22 of Amendment No. 1 to Elanco Animal Health Incorporated's registration statement on Form S-1 (File No. 333-226536) filed with the SEC on August 28, 2018).*
10.15	Retention Bonus Agreement, dated October 18, 2018, by and between Elanco US Inc. and Todd S. Young (incorporated by reference to Exhibit 10.2 to Elanco Animal Health Incorporated's Report on Form 8-K filed with the SEC on October 30, 2018).*
10.16	Employment Offer Letter with Mr. Todd S. Young, dated October 15, 2018, by and between Elanco US Inc. and Todd S. Young (incorporated by reference to Exhibit 10.1 to Elanco Animal Health Incorporated's Report on Form 8-K filed with the SEC on October 30, 2018).*
10.17	Services Agreement, dated as of January 1, 2022, by and between MBRD Service Company and Elanco US Inc. (filed herewith).*
10.18	Form of Performance Award Agreement (Incorporated by reference to Exhibit 10.1 to Form 8-K filed with the SEC on February 19, 2019)*
10.19	Form of Restricted Stock Unit Award Agreement (Incorporated by reference to Exhibit 10.2 to Form 8-K filed with the SEC on February 19, 2019)*
10.20	Form of Restricted Stock Unit Award Agreement (incorporated by reference to Exhibit 10.22 to Annual Report on Form 10-K filed with the SEC on February 20, 2019)*
10.21	Form of Replacement Performance Award Agreement for Certain Named Executive Officers (incorporated by reference to Exhibit 10.23 to Annual Report on Form 10-K filed with the SEC on February 20, 2019)*
10.22	Form of Replacement Performance Award Agreement for Jeffery N. Simmons (incorporated by reference to Exhibit 10.24 to Annual Report on Form 10-K filed with the SEC on February 20, 2019)*
10.23	Form of Replacement Restricted Stock Unit Award Agreement for Certain Named Executive Officers (incorporated by reference to Exhibit 10.25 to Annual Report on Form 10-K filed with the SEC on February 20, 2019)*
10.24	Form of Elanco Animal Health Incorporated Restricted Stock Unit Award Agreement for non-employee directors with respect to annual awards (incorporated by reference to Exhibit 10.2 of the Quarterly Report on Form 10-Q with the SEC on May 14, 2019).*
10.25	Form of Elanco Animal Health Incorporated Restricted Stock Unit Award Agreement for non-employee directors with respect to one-time founder award (incorporated by reference to Exhibit 10.3 of the Quarterly Report on Form 10-Q filed with the SEC on May 14, 2019).*
10.26	Elanco Animal Health Incorporated Replacement Restricted Stock Unit Award Agreement, dated March 12, 2019, by Elanco Animal Health Incorporated (incorporated by reference to Exhibit 10.4 of the Quarterly Report on Form 10-Q filed with the SEC on May 14, 2019).*
10.27	Elanco Animal Health Incorporated Executive Deferral Plan (incorporated by reference to Exhibit 10.1 of the Quarterly Report on Form 10-Q filed with the SEC on August 13, 2019)
10.28	Form of Elanco Animal Health Incorporated Restricted Stock Unit Award Agreement for executives with respect to 2020 annual awards (incorporated by reference to Exhibit 10.1 of the Quarterly Report on Form 10-Q filed with the SEC on May 7, 2020)*
10.29	Form of Elanco Animal Health Incorporated Performance-Based Award Agreement for executives with respect to 2020 annual awards (incorporated by reference to Exhibit 10.2 of the Quarterly Report on Form 10-Q filed with the SEC on May 7, 2020).*

10.30	Form of Elanco Animal Health Incorporated Sign-On Restricted Stock Unit Award Agreement for executives (incorporated by reference to Exhibit 10.4 of the Quarterly Report on Form 10-Q filed with the SEC on May 7, 2020).*
10.31	Elanco Executive Severance Pay Plan and Summary (filed incorporated by reference to Exhibit 10.31 of the Annual Report on Form 10-K filed with the SEC on March 1, 2021)*
10.32	Form of Elanco Animal Health Incorporated Restricted Stock Unit Award Agreement for executives with respect to 2021 annual awards (incorporated by reference to Exhibit 10.1 of the Quarterly Report on Form 10-Q filed with the SEC on May 7, 2021).*
10.33	Form of Elanco Animal Health Incorporated Performance-Based Award Agreement for executives with respect to 2021 annual awards (incorporated by reference to Exhibit 10.2 of the Quarterly Report on Form 10-Q filed with the SEC on May 7, 2021).*
10.34	Elanco Animal Health Incorporated Corporate Bonus Plan (incorporated by reference to Exhibit 10.3 of the Quarterly Report on Form 10-Q filed with the SEC on May 7, 2021).*
10.35	Elanco Animal Health Incorporated Amended and Restated 2018 Elanco Stock Plan (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the SEC on May 21, 2021).*
21.1	Subsidiaries of Elanco Animal Health Incorporated (filed herewith).
23.1	Consent of Ernst & Young LLP (filed herewith).
31.1	Section 302 Certification of the Chief Executive Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
31.2	Section 302 Certification of the Chief Financial Officer pursuant to Rule 13a-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002 (filed herewith).
32	Certification of the Chief Executive Officer and the Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (filed herewith).
101	Interactive Data Files.
104	The cover page from the Company's Annual Report on Form 10-K for the year ended December 31, 2021, formatted in Inline XBRL.

*Management contracts or compensatory plans or arrangements

ITEM 16. FORM 10-K SUMMARY

Not applicable.

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

ELANCO ANIMAL HEALTH INCORPORATED
(Registrant)

Date: February 28, 2022

/s/ Jeffrey N. Simmons
Jeffrey N. Simmons
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

/s/ Jeffrey N. Simmons Jeffrey N. Simmons President and Chief Executive Officer (principal executive officer) and Director	Date:	February 28, 2022
/s/ Todd S. Young Todd S. Young Executive Vice President, Chief Financial Officer (principal financial officer)	Date:	February 28, 2022
/s/ James M. Meer James M. Meer Senior Vice President, Chief Accounting Officer (principal accounting officer)	Date:	February 28, 2022
/s/ R. David Hoover R. David Hoover Chairman of the Board	Date:	February 28, 2022
/s/ Kapila Kapur Anand Kapila Kapur Anand Director	Date:	February 28, 2022
/s/ John P. Bilbrey John P. Bilbrey Director	Date:	February 28, 2022
/s/ William F. Doyle William F. Doyle Director	Date	February 28, 2022

/s/ Scott Ferguson	Date:	February 28, 2022
Scott Ferguson Director		
/s/ Art A. Garcia	Date:	February 28, 2022
Art A. Garcia Director		
/s/ Michael J. Harrington	Date:	February 28, 2022
Michael J. Harrington Director		
/s/ Paul Herendeen	Date:	February 28, 2022
Paul Herendeen Director		
/s/ Deborah T. Kochevar	Date:	February 28, 2022
Deborah T. Kochevar Director		
/s/ Lawrence E. Kurzius	Date:	February 28, 2022
Lawrence E. Kurzius Director		
/s/ Kirk McDonald	Date:	February 28, 2022
Kirk McDonald Director		
/s/ Denise Scots-Knight Ph.D.	Date:	February 28, 2022
Denise Scots-Knight Ph.D. Director		

Exhibit 10.17

SERVICES AGREEMENT

This Services Agreement (this "**Agreement**"), dated as of January 1, 2022 (the "**Effective Date**"), is by and between MBRD Service Company, an Indiana limited liability company, with offices located at 9400 Priority Way W. Drive, Indianapolis, IN 46240 (the "**Service Provider**") and Elanco US Inc., a Delaware corporation, with offices located at 2500 Innovation Way, Greenfield, IN 46140 (the "**Elanco**").

RECITALS

WHEREAS, Elanco desires to retain Service Provider to provide certain research and development services in connection with Elanco's microbiome and nutritional health projects upon the terms and conditions hereinafter set forth, and Service Provider is willing to perform such services.

In consideration of the mutual covenants and agreements hereinafter set forth, the parties agree as follows:

1. Definitions.

"**Action**" has the meaning set forth in Section 11.1.

"**Affiliate**" of a Person means any other Person that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with, such Person. The term "control" (including the terms "controlled by" and "under common control with") means the possession, directly or indirectly, of the power to direct or cause the direction of the management and policies of a Person, whether through the ownership of voting securities, by contract, or otherwise.

"**Agreement**" has the meaning set forth in the preamble.

"**Change Order**" has the meaning set forth in Section 5.2.

"**Confidential Information**" means any information that is treated as confidential by a party, including but not limited to all non-public information about its business affairs, products or services, Intellectual Property Rights, trade secrets, third-party confidential information, and other sensitive or proprietary information, whether disclosed orally or in written, electronic, or other form or media, and whether or not marked, designated, or otherwise identified as "confidential". Confidential Information shall not include information that: (a) is already known to the Receiving Party without restriction on use or disclosure prior to receipt of such information from the Disclosing Party; (b) is or becomes generally known by the public other than by breach of this Agreement by, or other wrongful act of, the Receiving Party; (c) is developed by the Receiving Party independently of, and without reference to, any Confidential Information of the Disclosing Party; or (d) is received by the Receiving Party from a third party who is not under any obligation to the Disclosing Party to maintain the confidentiality of such information.

"**Deliverables**" means all documents, Work Product, and other materials that are delivered to Elanco hereunder or prepared by or on behalf of Service Provider in the course of performing the Services, including any items identified as such in a Statement of Work.

"**Disclosing Party**" means a party that discloses Confidential Information under this Agreement.

"**Elanco**" has the meaning set forth in the preamble.

"**Elanco Contract Manager**" has the meaning set forth in Section 4.1.

"**Elanco Equipment**" means any equipment, including lab equipment, systems, cabling, or facilities provided by Elanco and used directly or indirectly in the provision of the Services.

"**Elanco Materials**" any documents, data, know-how, methodologies, software, and other materials provided to Service Provider by Elanco, including computer programs, reports, and specifications.

"**Force Majeure Event**" has the meaning set forth in Section 16.

"**Intellectual Property Rights**" means any and all rights arising in the U.S. or any other jurisdiction throughout the world in and to (1) patents, patent disclosures and inventions (whether patentable or not), (2) trademarks, service marks, trade dress, trade names, logos, corporate names and domain names, and other designations of source, sponsorship, affiliation or origin, together with all related goodwill, (3) copyrights, copyrightable works and other works of authorship (including computer programs), mask works, data, data collections and databases, (4) trade secrets, know-how and other confidential or proprietary information, (5) moral rights, and (6) any and all other intellectual property rights, in each case whether registered or unregistered and including all related rights of priority under international conventions, all pending and future applications and registrations and continuations, divisions, continuations-in-part, reissues, extensions, substitutions, re-examinations and renewals thereof, and all similar or equivalent rights or forms of protection in any part of the world.

"**Law**" means any statute, law, ordinance, regulation, rule, code, order, constitution, treaty, common law, judgment, decree, other requirement, or rule of law of any federal, state, local, or foreign government or political subdivision thereof, or any arbitrator, court, or tribunal of competent jurisdiction.

"**Losses**" mean all losses, damages, liabilities, deficiencies, actions, judgments, interest, awards, penalties, fines, costs, or expenses of whatever kind, including reasonable attorneys' fees and the cost of enforcing any right to indemnification hereunder and the cost of pursuing any insurance providers.

"**Microbiome Platform**" means Elanco's microbiome and nutritional health projects, including its platform for discovering and developing next-generation microbiome-targeting solutions for human and animal health.

"**Permitted Subcontractor**" has the meaning set forth in Section 3.1(g).

"**Person**" means an individual, corporation, partnership, joint venture, limited liability company, governmental authority, unincorporated organization, trust, association, or other entity.

"**Project**" means a project as described in a Statement of Work.

"**Receiving Party**" means a party that receives or acquires Confidential Information directly or indirectly under this Agreement.

"**Service Provider**" has the meaning set forth in the preamble.

"**Service Provider Contract Manager**" has the meaning set forth in Section 3.1(a)(i).

"**Service Provider Equipment**" means any equipment, systems, cabling, or facilities provided by or on behalf of Service Provider and used directly or indirectly in the provision of the Services.

"**Service Provider Personnel**" means all employees and Permitted Subcontractors, if any, engaged by Service Provider to perform the Services.

"**Services**" mean the professional and other services to be provided by Service Provider under this agreement, as described in more detail in a Statement of Work, and Service Provider's obligations under this Agreement.

"**Statement of Work**" or "**SOW**" means each Statement of Work entered into by the parties and attached to this Agreement, substantially in the form of **Exhibit A**.

"**Term**" has the meaning set forth in Section 6.1.

"**Work Product**" means all writings, works of authorship, inventions, discoveries, developments, processes, techniques, methods, devices, technologies, ideas, concepts, research, proposals, materials and other tangible and intangible work product of any nature whatsoever that are conceived, made, reduced to practice, invented, discovered, created, authored, modified, improved or otherwise originated by or on behalf of Service Provider individually or jointly with Elanco or others in the course of performing the Services or other work performed by or on behalf of Elanco under or in connection with the Services or this Agreement or at any time during or after the termination of the parties' relationship hereunder (1) at Elanco's expense, (2) based on, derived from or otherwise using Elanco's Confidential Information or Intellectual Property, or (3) that result from any use of Elanco's facilities, personnel, or materials, and all printed, physical and electronic copies and other tangible embodiments of any of the foregoing.

2. Services.

2.1 Service Provider shall provide the Services to Elanco as described in more detail in each Statement of Work in accordance with the terms and conditions of this Agreement.

2.2 Each Statement of Work shall include the following information, if applicable:

(a) a detailed description of the Services to be performed pursuant to the Statement of Work;

(b) the date upon which the Services will commence and the term of such Statement of Work;

(c) the names of the Service Provider Contract Manager;

(d) any criteria for completion of the Services; and

(e) any other terms and conditions agreed upon by the parties in connection with the Services to be performed pursuant to such Statement of Work.

3. Service Provider's Obligations.

3.1 The Service Provider shall:

(a) subject to the prior written approval of Elanco, appoint a Service Provider employee to serve as a primary contact with respect to this Agreement and who will have the authority to act on behalf of Service Provider in connection with matters pertaining to this Agreement (the "**Service Provider Contract Manager**")

(b) maintain the same Service Provider Contract Manager throughout the Term of this Agreement except for changes in such personnel due to Elanco's request pursuant to Section 3.1(c);

(c) upon the reasonable written request of Elanco, promptly replace the Service Provider Contract Manager;

(d) before the date on which the Services are to start, obtain, and at all times during the Term of this Agreement maintain, all necessary licenses and consents and comply with all relevant Laws applicable to the provision of the Services;

(e) comply with, and ensure that all Service Provider Personnel comply with, all rules, regulations, and policies of Elanco that are communicated to Service Provider in writing, including security procedures concerning systems and data and remote access thereto, building security procedures, including the restriction of access by Elanco to certain areas of its premises or systems for security reasons, and general health and safety practices and procedures;

(f) maintain complete and accurate records relating to the provision of the Services under this Agreement, including records of the time spent and materials used by Service Provider in providing the Services in such form as Elanco shall approve. During the Term and for one (1) year thereafter, upon Elanco's written request, Service Provider shall allow Elanco or Elanco's representative to inspect and make copies of such records;

(g) obtain Elanco's written approval, which may be given or withheld in Elanco's sole discretion, prior to entering into agreements with or otherwise engaging any Person, including all subcontractors and Affiliates of Service Provider, other than Service Provider's employees, to provide any Services and Deliverables to Elanco (each such approved subcontractor or other third party, a "**Permitted Subcontractor**"). Elanco's approval shall not relieve Service Provider of its obligations under the Agreement, and Service Provider shall remain fully responsible for the performance of each such Permitted Subcontractor and its employees and for their compliance with all of the terms and conditions of this Agreement as if they were Service Provider's own employees. Nothing contained in this Agreement shall create any contractual relationship between Elanco and any Service Provider subcontractor or supplier; and

(h) require each Permitted Subcontractor to be bound in writing by the confidentiality and intellectual property assignment or license provisions of this Agreement, and, upon Elanco's written request, to enter into a non-disclosure or intellectual property assignment or license agreement in a form that is reasonably satisfactory to Elanco.

3.2 Service Provider is responsible for all Service Provider Personnel and for the payment of their compensation, including, if applicable, withholding of income taxes, and the payment and withholding of social security and other payroll taxes, unemployment insurance, workers' compensation insurance payments, and disability benefits.

3.3 Service Provider acknowledges that time is of the essence with respect to Service Provider's obligations hereunder and that prompt and timely performance of all such obligations is strictly required.

4. Elanco's Obligations. Elanco shall:

4.1 cooperate with Service Provider in all matters relating to the Services and appoint an Elanco employee to serve as the primary contact with respect to this Agreement and who will have the authority to act on behalf of Elanco with respect to matters pertaining to this Agreement (the "**Elanco Contract Manager**");

4.2 provide, subject to Section 3.1(f), such access to Elanco's premises and such office accommodation and other facilities as may reasonably be required by Service Provider for the purposes of performing the Services;

4.3 respond promptly to any Service Provider request to provide direction, information, approvals, authorizations, or decisions that are reasonably necessary for Service Provider to perform Services in accordance with the requirements of this Agreement; and

4.4 provide such Elanco Materials as Service Provider may reasonably request, in order to carry out the Services.

5. Change Orders.

5.1 If Elanco wishes to change the scope or performance of the Services, it shall submit details of the requested change to Service Provider in writing. Service Provider shall, within a reasonable time after receiving a Elanco-initiated request, provide a written estimate to Elanco of:

(a) the likely time required to implement the change;

(b) any necessary variations to the fees and other charges for the Services arising from the change;

(c) the likely effect of the change on the Services;

(d) any other impact the change might have on the performance of this Agreement; and

(e) any other information reasonably requested by the Elanco.

5.2 Promptly after receipt of the written estimate, the parties shall negotiate and agree in writing on the terms of such change (a "**Change Order**"). Neither party shall be bound by any Change Order unless mutually agreed upon in writing in accordance with Section 17.10.

6. Term and Termination.

6.1 Term. This Agreement shall commence as of the Effective Date and shall continue thereafter for a period of (1) year (the "**Term**"), unless sooner terminated pursuant to this Section 6.

6.2 Termination for Convenience. Elanco, in its sole discretion, may terminate this Agreement or any Statement of Work, in whole or in part, at any time without cause, by providing at least thirty (30) days' prior written notice to Service Provider.

6.3 Termination for Cause. Either party may terminate this Agreement or any SOW, effective upon written notice to the other party (the "**Defaulting Party**"), if the Defaulting Party:

(a) breaches this Agreement, and such breach is incapable of cure, or with respect to a breach capable of cure, the Defaulting Party does not cure such breach within fifteen (15) days after receipt of written notice of such breach; or

(b) (i) becomes insolvent or admits its inability to pay its debts generally as they become due; (ii) becomes subject, voluntarily or involuntarily, to any proceeding under any domestic or foreign bankruptcy or insolvency law, which is not fully stayed within sixty (60) business days or is not dismissed or vacated within sixty (60) days after filing; (iii) is dissolved or liquidated or takes any corporate action for such purpose; (iv) makes a general assignment for the benefit of creditors; or (v) has a receiver, trustee, custodian, or similar agent appointed by order of any court of competent jurisdiction to take charge of or sell any material portion of its property or business.

6.4 Effects of Termination or Expiration. Upon expiration or termination of this Agreement for any reason:

(a) Service Provider shall (i) promptly deliver to Elanco all Deliverables (whether complete or incomplete) for which Elanco has paid, all Elanco Equipment and all Elanco Materials in its possession, (ii) promptly remove any Service Provider Equipment located at Elanco's premises, (iii) provide reasonable cooperation and assistance to Elanco upon Elanco's written request in transitioning the Services to a different Service Provider, and (iv) on a pro rata basis, repay all fees and expenses paid in advance for any Services not performed or Deliverables not provided.

(b) Each party shall (i) return to the other party all documents and tangible materials (and any copies) containing, reflecting, incorporating, or based on the other party's Confidential Information, (ii) permanently delete all of the other party's Confidential Information from its computer systems, and (iii) certify in writing to the other party that it has complied with the requirements of this clause; provided, however, that Elanco may retain copies of any Confidential Information of Service Provider incorporated in the Deliverables or to the extent necessary to allow it to make full use of the Services and any Deliverables.

(c) In no event shall Elanco be liable for any Service Provider Personnel termination costs arising from the expiration or termination of this Agreement.

6.5 Survival. The rights and obligations of the parties set forth in this Section 6.5 and Section 1, Section 8, Section 9, Section 10, Section 12, Section 6.4, Section 13, and Section 15, and any right or obligation of the parties in this Agreement which, by its nature, should

survive termination or expiration of this Agreement, will survive any such termination or expiration of this Agreement.

7. Fees and Expenses; Payment Terms.

7.1 In consideration of the provision of the Services by the Service Provider and the rights granted to Elanco under this Agreement, Elanco shall pay the fees set forth in the applicable Statement of Work. Payment to Service Provider of such fees and the reimbursement of expenses pursuant to this Section 7 shall constitute payment in full for the performance of the Services, and, Elanco shall not be responsible for paying any other fees, costs, or expenses.

7.2 Where Services are provided for a fixed price, the total fees for the Services shall be the amount set out in the applicable Statement of Work. The total price shall be paid to Service Provider in installments, as set out in the Statement of Work. At the end of a period specified in the applicable Statement of Work in respect of which an installment is due, Service Provider shall issue invoices to Elanco for the fees that are then payable, together with a detailed breakdown of any expenses incurred in accordance with Section 7.4.

7.3 Service Provider shall issue invoices to Elanco only in accordance with the terms of this Section, and Elanco shall pay all properly invoiced amounts due to Service Provider within thirty (30) days after Elanco's receipt of such invoice, except for any amounts disputed by Elanco in good faith. All payments hereunder shall be in U.S. dollars and made by check or wire transfer.

7.4 Elanco shall be responsible for all sales, use, and excise taxes, and any other similar taxes, duties, and charges of any kind imposed by any federal, state, or local governmental entity on any amounts payable by Elanco hereunder. Any such taxes, duties, and charges currently assessed or which may be assessed in the future, that are applicable to the Services are for the Elanco's account, and Elanco hereby agrees to pay such taxes; *provided, that*, in no event shall Elanco pay or be responsible for any taxes imposed on, or with respect to, Service Provider's income, revenues, gross receipts, personnel, or real or personal property or other assets.

7.5 Without prejudice to any other right or remedy it may have, Elanco reserves the right to set off at any time any amount owing to it by Service Provider against any amount payable by Elanco to Service Provider under this Agreement.

8. Intellectual Property Rights; Ownership.

8.1 Elanco is, and shall be, the sole and exclusive owner of all right, title, and interest in and to the Work Product and the Deliverables, including all Intellectual Property Rights therein. Service Provider agrees, and will cause its Service Provider Personnel to agree, that with respect to any Deliverables or Work Product that may qualify as "work made for hire" as defined in 17 U.S.C. §101, such Deliverables are hereby deemed a "work made for hire" for Elanco. To the extent that any of the Deliverables or Work Product do not constitute a "work made for hire", Service Provider hereby irrevocably assigns, and shall cause the Service Provider Personnel to irrevocably assign to Elanco, in each case without additional consideration, all right, title, and interest throughout the world in and to the Deliverables and Work Product, including all Intellectual Property Rights therein. The Service Provider shall cause the Service Provider Personnel to irrevocably waive, to the extent permitted by applicable Law, any and all claims such Service Provider Personnel may now or hereafter have in any jurisdiction to so-called "moral rights" or rights of droit moral with respect to the Deliverables or Work Product.

8.2 Upon the request of Elanco, Service Provider shall, and shall cause the Service Provider Personnel to, promptly take such further actions, including execution and delivery of all appropriate instruments of conveyance, as may be necessary to assist Elanco to prosecute, register, perfect, or record its rights in or to any Deliverables or Work Product. Service Provider shall promptly make full written disclosure to Service Provider of all Work Product, whether or not such Work Product is patentable, copyrightable or protected as a trade secret. Service Provider shall at all times keep and maintain full, current, accurate and authentic records of all Work Product. Such records may be in the form of notes, sketches, drawings, flow charts, electronic files, laboratory notebooks, reports or any other format that may be specified by Elanco. The records shall at all times be the exclusive property and Confidential Information of Elanco. The Work Product is and shall at all times remain the Confidential Information of Elanco and is subject to all Service Provider obligations and restrictions set forth herein with respect to such Confidential Information. Without limitation of such obligations or restrictions, Service Provider shall not disclose to any third party the nature or details of any Work Product without Elanco's prior written consent.

8.3 Elanco and its licensors are, and shall remain, the sole and exclusive owner of all right, title, and interest in and to the Elanco Materials, including all Intellectual Property Rights therein. Service Provider shall have no right or license to use any Elanco Materials except solely during the Term of the Agreement to the extent necessary to provide the Services to Elanco. All other rights in and to the Elanco Materials are expressly reserved by Elanco.

9. Confidential Information.

9.1 The Receiving Party agrees:

(a) not to disclose or otherwise make available Confidential Information of the Disclosing Party to any third party without the prior written consent of the Disclosing Party; *provided, however*, that the Receiving Party may disclose the Confidential Information of the Disclosing Party to its and its Affiliates, and their officers, employees, consultants, and legal advisors who have a "need to know", who have been apprised of this restriction, and who are themselves bound by nondisclosure obligations at least as restrictive as those set forth in this Section 9;

(b) to use the Confidential Information of the Disclosing Party only for the purposes of performing its obligations under the Agreement or, in the case of Elanco, to make use of the Services and Deliverables; and

(c) to promptly notify the Disclosing Party in the event it becomes aware of any loss or disclosure of any of the Confidential Information of Disclosing Party.

9.2 If the Receiving Party becomes legally compelled to disclose any Confidential Information, the Receiving Party shall provide:

(a) prompt written notice of such requirement so that the Disclosing Party may seek, at its sole cost and expense, a protective order or other remedy; and

(b) reasonable assistance, at the Disclosing Party's sole cost and expense, in opposing such disclosure or seeking a protective order or other limitations on disclosure.

If, after providing such notice and assistance as required herein, the Receiving Party remains required by Law to disclose any Confidential Information,

the Receiving Party shall disclose no more than that portion of the Confidential Information which, on the advice of the Receiving Party's legal counsel, the Receiving Party is legally required to disclose.

10. Representations and Warranties.

10.1 Each party represents and warrants to the other party that:

(a) it is duly organized, validly existing and, where such concept is applicable, in good standing as a corporation or other entity as represented herein under the laws and regulations of its jurisdiction of incorporation, organization, or chartering;

(b) it has the full right, power, and authority to enter into this Agreement, to grant the rights and licenses granted hereunder, and to perform its obligations hereunder;

(c) the execution of this Agreement by its representative whose signature is set forth at the end hereof has been duly authorized by all necessary corporate action of the party; and

(d) when executed and delivered by such party, this Agreement will constitute the legal, valid, and binding obligation of such party, enforceable against such party in accordance with its terms.

10.2 Service Provider represents and warrants to Elanco that:

(a) it shall perform the Services using personnel of required skill, experience, and qualifications and in a professional and workmanlike manner in accordance with best recognized industry standards for similar services and shall devote adequate resources to meet its obligations under this Agreement;

(b) it is in compliance with, and shall perform the Services in compliance with, all applicable Laws;

(c) Elanco will receive good and valid title to all Deliverables, free and clear of all encumbrances and liens of any kind;

(d) (i) none of the Services, Deliverables, Work Product and Elanco's use thereof infringe or will infringe any Intellectual Property Right of any third party arising under the Law of the United States, and, (ii) as of the date hereof, there are no pending or, to Service Provider's knowledge, threatened claims, litigation, or other proceedings pending against Service Provider by any third party based on an alleged violation of such Intellectual Property Rights, in each case, excluding any infringement or claim, litigation or other proceedings to the extent arising out of (x) any Elanco Materials or any instruction, information, designs, specifications, or other materials provided by Elanco to Service Provider, (y) use of the Deliverables in combination with any materials or equipment not supplied or specified by Service Provider, if the infringement would have been avoided by the use of the Deliverables not so combined, and (z) any modifications or changes made to the Deliverables by or on behalf of any Person other than Service Provider. Service Provider's sole liability and Elanco's sole and exclusive remedy for Service Provider's breach of this Section 10.2(d) are Service Provider's obligations under Section 11.2;

(e) the Services and Deliverables will be in conformity in all material respects with all requirements or specifications stated in this Agreement and the applicable Statement of Work. In the event of Service Provider's breach of the foregoing warranty, Service Provider's sole and exclusive obligation and liability and Elanco's sole and exclusive remedy shall be as follows:

(i) The Service Provider shall use reasonable efforts to cure such breach; provided, that if Service Provider cannot cure such breach within a reasonable time (but no more than thirty (30) days) after Elanco's written notice of such breach, Elanco may, at its option, terminate the Agreement by serving written notice of termination in accordance with Section 17.4.

(ii) In the event the Agreement is terminated in accordance with this Section 10.2(e), Service Provider shall within thirty (30) days after the effective date of termination, refund to Elanco any fees paid by the Elanco as of the date of termination for such Service or Deliverable.

10.3 EXCEPT FOR THE EXPRESS WARRANTIES IN THIS AGREEMENT, (A) EACH PARTY HEREBY DISCLAIMS ALL WARRANTIES, EITHER EXPRESS, IMPLIED, STATUTORY, OR OTHERWISE UNDER THIS AGREEMENT, AND (B) SERVICE PROVIDER SPECIFICALLY DISCLAIMS ALL IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

11. Indemnification.

11.1 Service Provider shall defend, indemnify, and hold harmless Elanco and Elanco's Affiliates/Authorized Service Recipients and their officers, directors, employees, agents, successors, and permitted assigns (each, a "**Elanco Indemnitee**") from and against all Losses arising out of or resulting from any third-party claim, suit, action, or proceeding (each, an "**Action**") arising out of or resulting from:

(a) bodily injury, death of any person, or damage to real or tangible, personal property resulting from the willful, fraudulent, or negligent acts or omissions of Service Provider or Service Provider Personnel; and

(b) Service Provider's breach of any representation, warranty, or obligation of Service Provider set forth in this Agreement Section 10.1 or Section 10.2 of this Agreement.

11.2 Service Provider shall defend, indemnify, and hold harmless the Elanco Indemnitees from and against all Losses based on a claim that any of the Services or Deliverables or Elanco's receipt or use thereof infringes any Intellectual Property Right of a third party arising under the Laws of the United States; *provided, however*, that Service Provider shall have no obligations under this Section 11.2 with respect to claims to the extent arising out of:

(a) any Elanco Materials or any instruction, information, designs, specifications, or other materials provided by Elanco in writing to Service Provider;

(b) use of the Deliverables in combination with any materials or equipment not supplied to Elanco or specified by Service Provider in writing, if the infringement would have been avoided by the use of the Deliverables not so combined; or

(c) any modifications or changes made to the Deliverables by or on behalf of any Person other than Service Provider or Service Provider Personnel.

11.3 Elanco shall defend, indemnify, and hold harmless Service Provider and its officers, directors, employees, agents, successors, and permitted assigns from and against all Losses arising out of or resulting from any third-party Action arising out of or resulting from:

(a) bodily injury, death of any person, or damage to real or tangible, personal property resulting from the negligent or willful acts or omissions of Elanco; and

(b) Elanco's breach of any representation, warranty, or obligation of Elanco in this Agreement/representation or warranty set forth in Section 10.1 of this Agreement.

11.4 The party seeking indemnification hereunder shall promptly notify the indemnifying party in writing of any Action and cooperate with the indemnifying party at the indemnifying party's sole cost and expense. The indemnifying party shall immediately take control of the defense and investigation of such Action and shall employ counsel of its choice to handle and defend the same, at the indemnifying party's sole cost and expense. The indemnifying party shall not settle any Action in a manner that adversely affects the rights of the indemnified party without the indemnified party's prior written consent, which shall not be unreasonably withheld or delayed. The indemnified party's failure to perform any obligations under this Section 11.4 shall not relieve the indemnifying party of its obligations under this Section 11.4 except to the extent that the indemnifying party can demonstrate that it has been materially prejudiced as a result of such failure. The indemnified party may participate in and observe the proceedings at its own cost and expense.

11.5Notwithstanding anything to the contrary in this Agreement, the indemnifying party is not obligated to indemnify, hold harmless, or defend the indemnified party against any claim (whether direct or indirect) to the extent such claim or corresponding losses arise out of or result from, in whole or in part, the indemnified party's gross negligence or more culpable act or omission (including recklessness or willful misconduct).

12. Limitation of Liability.

12.1 EXCEPT AS OTHERWISE PROVIDED IN SECTION 12.2, IN NO EVENT WILL EITHER PARTY BE LIABLE TO THE OTHER OR TO ANY THIRD PARTY FOR ANY LOSS OF USE, REVENUE, OR PROFIT OR LOSS OF DATA OR FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, EXEMPLARY, SPECIAL, OR PUNITIVE DAMAGES WHETHER ARISING OUT OF BREACH OF CONTRACT, TORT (INCLUDING NEGLIGENCE), OR OTHERWISE, REGARDLESS OF WHETHER SUCH DAMAGE WAS FORESEEABLE AND WHETHER OR NOT SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

12.2 The exclusions in Section 12.1 shall not apply to:

(a) damages or other liabilities arising out of or relating to a party's failure to comply with its obligations under Section 8 (Intellectual Property Rights; Ownership);

(b) damages or other liabilities arising out of or relating to a party's failure to comply with its obligations under Section 9 (Confidentiality);

(c) a party's indemnification obligations under Section 11 (Indemnification);

(d) damages or other liabilities arising out of or relating to a party's gross negligence, willful misconduct, or intentional acts;

(e) death or bodily injury or damage to real or tangible personal property resulting from a party's negligent acts or omissions;

(f) damages or liabilities to the extent covered by a party's insurance; and

(g) a party's obligation to pay attorneys' fees and court costs in accordance with Section 15.15.

13. Insurance.

13.1 At all times during the Term of this Agreement, Service Provider shall procure and maintain, at its sole cost and expense, at least the following types and amounts of insurance coverage:

(a) Commercial General Liability with limits no less than $1,000,000 per occurrence and $3,000,000 in the aggregate, including bodily injury and property damage and products and completed operations and advertising liability, which policy will include contractual liability coverage insuring the activities of Service Provider under this Agreement;

(b) Worker's Compensation insurance as required by applicable law; and

(c) Errors and Omissions/Professional Liability with limits no less than $2,000,000 in the aggregate.

13.2All insurance policies required pursuant to this Section 13 shall:

(a) be issued by insurance companies reasonably acceptable to Elanco;

(b) provide that such insurance carriers give Elanco at least 30 days' prior written notice of cancellation or non-renewal of policy coverage; *provided that,* prior to such cancellation, the Service Provider shall have new insurance policies in place that meet the requirements of this Section 13;

(c) waive any right of subrogation of the insurers against Elanco or any of its Affiliates;

(d) provide that such insurance be primary insurance and any similar insurance in the name of and/or for the benefit of Elanco shall be excess and non-contributory; and

(e) name Elanco and Elanco's Affiliates, including, in each case, all successors and permitted assigns, as additional insureds.

13.3Upon the written request of Elanco, Service Provider shall provide Elanco with copies of the certificates of insurance and policy endorsements for all insurance coverage required by this Section 13, and shall not do anything to invalidate such insurance. This Section 13 shall not be construed in any manner as waiving, restricting, or limiting the liability of either party for any obligations imposed under this Agreement (including but not limited to, any provisions requiring a party hereto to indemnify, defend, and hold the other harmless under this Agreement).

14. Force Majeure.

14.1No party shall be liable or responsible to the other party, or be deemed to have defaulted under or breached this Agreement, for any failure or delay in fulfilling or performing any term of this Agreement, when and to the extent such failure or delay is caused by or results from acts beyond the impacted party's (**"Impacted Party"**) reasonable control, including without limitation the following force majeure events ("**Force Majeure Events**"): (a) acts of God; (b) flood, fire, earthquake, epidemics, pandemics, or explosion; (c) war, invasion, hostilities (whether war is declared or not), terrorist threats or acts, riot, or other civil unrest; (d) government order, law, or actions; (e) embargoes or blockades in effect on or after the date of this Agreement; (f) national or regional emergency; and (g) strikes, labor stoppages or slowdowns, or other industrial disturbances; and (h) telecommunication breakdowns, power outages or shortages, lack of warehouse or storage space, inadequate transportation services, or inability or delay in obtaining supplies of adequate or suitable materials. The Impacted Party shall give notice within 5 days of the Force Majeure Event to the other party, stating the period of time the occurrence is expected to continue.

14.2 During the Force Majeure Event, the non-affected party may similarly suspend its performance obligations until such time as the affected party resumes performance.

14.3 The affected party shall use diligent efforts to end the failure or delay and ensure the effects of such Force Majeure Event are minimized and shall resume performance of its obligations as soon as reasonably practicable after the removal of the cause. If the affected party's failure or delay remains uncured for a period of forty-five (45) days following written notice given by it under this Section 14, either party may thereafter terminate this Agreement or the applicable Statement of Work, or both, upon fifteen (15) days' written notice.

15. Miscellaneous.

15.1 Each party shall, upon the reasonable request, and at the sole cost and expense, of the other party, promptly execute such documents and perform such acts as may be necessary to give full effect to the terms of this Agreement.

15.2 The relationship between the parties is that of independent contractors. Nothing contained in this Agreement shall be construed as creating any agency, partnership, joint venture, or other form of joint enterprise, employment, or fiduciary relationship between the parties, and neither party shall have authority to contract for or bind the other party in any manner whatsoever.

15.3 Neither party shall issue or release any announcement, statement, press release, or other publicity or marketing materials relating to this Agreement, or otherwise use the other party's trademarks, service marks, trade names, logos, symbols, or brand names, in each case, without the prior written consent of the other party.

15.4 All notices, requests, consents, claims, demands, waivers, and other communications hereunder shall be in writing and shall be deemed to have been given (a) when delivered by hand (with written confirmation of receipt); (b) when received by the addressee if sent by a nationally recognized overnight courier (receipt requested); (c) on the date sent by email if sent during normal business hours of the recipient, and on the next business day if sent after normal business hours of the recipient or (d) on the third day after the date mailed, by certified mail, return receipt requested, postage prepaid. Such communications must be sent to the respective parties at the addresses indicated below (or at

such other address for a party as shall be specified in a notice given in accordance with this Section 15.4.

If to Service Provider:	Aaron Schacht 9400 Priority Way West Drive Indianapolis, IN 46240 Email: aaron@schacht.com Attention: CEO
If to Elanco:	Ellen De Brabander 2500 Innovation Way Greenfield, Indiana 46140 Email: ellen.de_brabander@elancoah.com Attention: Executive Vice President, Innovation, Regulatory and Business Development
and a copy to Elanco:	Marcela Kirberger 2500 Innovation Way Greenfield, Indiana 46140 Email: marcela.kirberger@elancoah.com Attention: Executive Vice President, General Counsel & Corporate Secretary

15.5 For purposes of this Agreement, (a) the words "include," "includes," and "including" shall be deemed to be followed by the words "without limitation"; (b) the word "or" is not exclusive; and (c) the words "herein," "hereof," "hereby," "hereto," and "hereunder" refer to this Agreement as a whole. Unless the context otherwise requires, references herein: (x) to Sections, Schedules, Exhibits, and Statements of Work refer to the Sections of, and Schedules, Exhibits, and Statements of Work attached to this Agreement; (y) to an agreement, instrument, or other document means such agreement, instrument, or other document as amended, supplemented, and modified from time to time to the extent permitted by the provisions thereof and (z) to a statute means such statute as amended from time to time and includes any successor legislation thereto and any regulations promulgated thereunder. This Agreement shall be construed without regard to any presumption or rule requiring construction or interpretation against the party drafting an instrument or causing any instrument to be drafted. The Schedules, Exhibits, and Statements of Work referred to herein shall be construed with, and as an integral part of, this Agreement to the same extent as if they were set forth verbatim herein.

15.6 This Agreement, together with all Schedules, Exhibits, and Statements of Work and any other documents incorporated herein by reference, constitutes the sole and entire agreement of the parties to this Agreement with respect to the subject matter contained herein, and supersedes all prior and contemporaneous understandings and agreements, both written and oral, with respect to such subject matter. In the event of any conflict between the terms and provisions of this Agreement and those of any Schedule, Exhibit or Statement of Work, the following order of precedence shall govern: (a) first, this Agreement, exclusive of its Exhibits and Schedules; (b) second, the applicable Statement of Work; and (c) third, any Exhibits and Schedules to this Agreement.

15.7 Neither party may assign, transfer, or delegate any or all of its rights or obligations under this Agreement, including by operation of law, change of control, or merger, without the prior written consent of the other party; provided, that, Elanco may assign the Agreement to an Affiliate of such party or to a successor of all or substantially all of the assets of such party through merger, reorganization, consolidation, or acquisition. No assignment shall relieve the assigning party of any of its obligations hereunder. Any attempted assignment, transfer, or other conveyance in violation of the foregoing shall be null and void. This Agreement shall be binding upon and shall inure to the benefit of the parties hereto and their respective successors and permitted assigns.

15.8 This Agreement is for the sole benefit of the parties hereto and their respective successors and permitted assigns and nothing herein, express or implied, is intended to or shall confer upon any other Person any legal or equitable right, benefit, or remedy of any nature whatsoever, under or by reason of this Agreement.

15.9 The headings in this Agreement are for reference only and shall not affect the interpretation of this Agreement.

15.10 This Agreement may be amended, modified, or supplemented only by an agreement in writing signed by each party hereto. No waiver by any party of any of the provisions hereof shall be effective unless explicitly set forth in writing and signed by the party so waiving. Except as otherwise set forth in this Agreement, no failure to exercise, or delay in exercising, any rights, remedy, power, or privilege arising from this Agreement shall operate or be construed as a waiver thereof; nor shall any single or partial exercise of any right, remedy, power, or privilege hereunder preclude any other or further exercise thereof or the exercise of any other right, remedy, power, or privilege.

15.11 If any term or provision of this Agreement is invalid, illegal, or unenforceable in any jurisdiction, such invalidity, illegality, or unenforceability shall not affect any other term or provision of this Agreement or invalidate or render unenforceable such term or provision in any other jurisdiction. Upon such determination that any term or other provision is invalid, illegal, or unenforceable, the parties hereto shall negotiate in good faith to modify this Agreement so as to effect the original intent of the parties as closely as possible in a mutually acceptable manner in order that the transactions contemplated hereby be consummated as originally contemplated to the greatest extent possible.

15.12 This Agreement shall be governed by and construed in accordance with the internal laws of the State of Delaware without giving effect to any choice or conflict of law provision or rule (whether of the State of Delaware or any other jurisdiction) that would cause the application of Laws of any jurisdiction other than those of the State of Delaware. Any legal suit, action, or proceeding arising out of or related to this Agreement or the Services provided hereunder shall be instituted exclusively in the federal courts of the United States or the courts of the State of Delaware in each case located in the city of Wilmington and County of New Castle, and each party irrevocably submits to the exclusive

jurisdiction of such courts in any such suit, action, or proceeding. Service of process, summons, notice, or other document by mail to such party's address set forth herein shall be effective service of process for any suit, action, or other proceeding brought in any such court.

15.13 Each party irrevocably and unconditionally waives any right it may have to a trial by jury in respect of any legal action arising out of or relating to this Agreement or the transactions contemplated hereby.

15.14 Each party acknowledges that a breach by a party of Section 8 (Intellectual Property Rights; Ownership) or Section 9 (Confidentiality) may cause the non-breaching party irreparable damages, for which an award of damages would not be adequate compensation and agrees that, in the event of such breach or threatened breach, the non-breaching party will be entitled to seek equitable relief, including a restraining order, injunctive relief, specific performance, and any other relief that may be available from any court, in addition to any other remedy to which the non-breaching party may be entitled at law or in equity. Such remedies shall not be deemed to be exclusive but shall be in addition to all other remedies available at law or in equity, subject to any express exclusions or limitations in this Agreement to the contrary.

15.15 If any action, suit, or other legal or administrative proceeding is instituted or commenced by either party hereto against the other party arising out of or related to this Agreement, the prevailing party shall be entitled to recover its reasonable attorneys' fees and court costs from the non-prevailing party.

15.16 This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall be deemed to be one and the same agreement. A signed copy of this Agreement delivered by facsimile, email or other means of electronic transmission shall be deemed to have the same legal effect as delivery of an original signed copy of this Agreement.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement as of the date first above written.

ELANCO US INC

By_____

Name:

Title:

MBRD Services Company

By_____

Name: Aaron Schacht

Title: Manager

EXHIBIT A – FORM STATEMENT OF WORK

EXHIBIT A

Form of Statement of Work

Statement of Work Number: [NUMBER]

This Statement of Work ("**SOW**"), adopts and incorporates by reference the terms and conditions of the Services Agreement ("**Services Agreement**"), which was entered into on January 1, 2022, by and between MBRD Service Company, an Indiana limited liability company, with offices located at 9400 Priority Way W. Drive, Indianapolis, IN 46240 ("**Service Provider**") and Elanco US Inc, an Indiana corporation ("**Elanco**," and together with Service Provider, the "**Parties**," and each, a "**Party**"), as it may be amended from time to time. This SOW is effective beginning on [] ("**Commencement Date**") and will remain in effect until [] ("**Expiration Date**"), unless earlier terminated in accordance with the Services Agreement. Transactions performed under this SOW will be conducted in accordance with and be subject to the terms and conditions of this SOW and the Services Agreement. Capitalized terms used but not defined in this SOW shall have the meanings set out in the Services Agreement.

1. Description of Services. Service Provider will provide certain research and development services in connection with Elanco's microbiome and nutritional health projects.

2. Contract Managers and Key Personnel. The following named individuals are appointed as the contract manager of each party and Key Personnel under the terms of the Services Agreement:

(a) Elanco Contract Manager:

(b) Service Provide Contract Manager:

3. [Permitted Subcontractors. The following subcontractors are Permitted Subcontractors under Section 3.1(h) of the Services Agreement: [SUBCONTRACTOR NAMES].]

4. Work Schedule and Deliverables. The relevant Project activities and Deliverable completion dates, and terms associated with this SOW are as follows:

Line Item	Task	Completion Date
1		
2		
3		
4		

5. Fees. All fees and costs listed below are based on the scope and assumptions included in this SOW.

Fees	**Cost Structure (fixed price)**

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF, the Parties hereto have executed this SOW as of the date first above written.

ELANCO US INC.

By_____

Name:

Title:

MBRD Services Company, LLC

By_____

Name: Aaron Schacht

Title: Manager

SUBSIDIARIES OF THE COMPANY
EXHIBIT 21.1

The following is a list of subsidiaries of the company as of December 31, 2021, omitting some subsidiaries which, considered in the aggregate, would not constitute a significant subsidiary.

Subsidiary Name	Jurisdiction
Aratana Therapeutics, Inc.	United States
ChemGen Corporation	Massachusetts
Dista Products Limited	United Kingdom
Elanco (Shanghai) Animal Health Co., Ltd.	China
Elanco (Taiwan) Animal Health Co. Ltd.	Taiwan
Elanco (Thailand) Ltd.	Thailand
Elanco AH Portugal, Unipessoal Lda	Portugal
Elanco Animal Health Holdings BV	Netherlands
Elanco Animal Health (Pty) Ltd.	South Africa
Elanco Animal Health UK Limited	United Kingdom
Elanco Animal Health Panama, S. De R.L.	Panama
Elanco Animal Health Korea, Co., Ltd.	Korea
Elanco Animal Vaccines Limited	United Kingdom
Elanco S.R.L.	Argentina
Elanco Australasia Pty. Ltd.	Australia
Elanco Australia Holding Pty Ltd	Australia
Elanco Bangladesh Limited	Bangladesh
Elanco Belgium BV	Belgium
Elanco Brazil Holdings Ltda	Brazil
Elanco Canada Limited	Canada
Elanco Centre de Recherche Sante Animale SA	Switzerland
Elanco Chile SpA	Chile
Elanco Colombia S.A.S.	Colombia
Elanco Denmark ApS	Denmark
Elanco Denmark ApS -- Norway Branch	Norway
Elanco Denmark ApS -- Sweden Branch	Sweden
Elanco Deutschland GmbH	Germany
Elanco Europe GmbH	Switzerland
Elanco Europe Ltd.	United Kingdom
Elanco Financing (Netherlands) B.V.	Netherlands
Elanco Financing S.A.	Switzerland
Elanco France S.A.S.	France
Elanco GmbH	Germany
Elanco Hayvan Sağlığı Limited Şirketi	Turkey
Elanco India Private Limited	India
Elanco Innovation and Alliance Centre India LLP	India
Elanco International, Inc.	Indiana
Elanco Ireland Limited	Ireland
Elanco Italia S.p.A.	Italy
Elanco Japan K.K .	Japan
Elanco Malaysia Sdn Bhd	Malaysia
Elanco Nederland B.V.	Netherlands
Elanco Netherlands Holding B.V.	Netherlands
Elanco New Zealand	New Zealand

Elanco Philippines Inc.	Philippines
Elanco Polska spółka z ograniczoną odpowiedzialnością	Poland
Elanco Solution Center Polska spółka z ograniczoną odpowiedzialnością	Poland
Elanco Rus Ltd.	Russia
Elanco Salud Animal S.A. de C.V.	Mexico
Elanco Saude Animal Ltda.	Brazil
Elanco Shanghai - Beijing Branch	China
Elanco Spain S.L. - Portugal Branch	Portugal
Elanco Spain, S.L.	Spain
Elanco Tiergesundheit AG -- Algeria Branch	Algeria
Elanco Tiergesundheit AG -- Austria Branch	Austria
Elanco Tiergesundheit AG -- Czech Branch	Czech
Elanco Tiergesundheit AG -- Egypt Representative Office	Egypt
Elanco Tiergesundheit AG -- Lebanon Representative Office	Lebanon
Elanco Tiergesundheit AG -- Saudi Arabia Branch	Saudi Arabia
Elanco Tiergesundheit AG – South Africa Branch	South Africa
Elanco Tiergesundheit AG -- Vietnam Representative Office	Vietnam
Elanco Tiergesundheit AG	Switzerland
Elanco Tiergesundheit AG --Tunisia Representative Office	Tunisia
Elanco UK AH Limited	United Kingdom
Elanco US Inc.	Delaware
Elanco Veterina SVN d.o.o.	Slovenia
Elanco Vietnam Company Limited	Vietnam
Immuno-Vet Services (Pty) Ltd.	South Africa
Immunovet Services Zambia Ltd.	South Africa
Ivy Animal Health, Inc.	Delaware
Kindred BioSciences, Inc.	Delaware
Lohmann Animal Health (Malaysia) Sdn. Bhd	Malaysia
Lohmann Animal Health Beteiligungs GmbH	Germany
Lohmann Animal Health GmbH	Germany
Lohmann Animal Health International Inc.	Maine
Lohmann Animal Health Phils. Corp.	Philippines
Lohmann Animal Health S. A. (Pty) Ltd.	South Africa
Lohmann Asia Holding Co. Ltd.	Thailand
Prevtec do Brasil	Brazil
Prevtec Microbia GmbH	Germany
Prevtec Microbia HK Ltd.	China
Pt. Elanco Animal Health Indonesia	Indonesia
Vericore Limited	United Kingdom
Vet Therapeutics, Inc.	United States
Elanco Hong Kong Limited	Hong Kong
The Representative Office of Elanco Vietnam Company Limited in Hanoi City	Vietnam
The Representative Office of Elanco Vietnam Company Limited in Dong Nai	Vietnam
Elanco (Sichuan) Animal Health Co., Ltd.	China
EIO Insurance Company, Inc.	United States
Bayer HealthCare Animal Health Inc. (Delaware)	United States
Elanco Austria GmbH	Austria
Bayer Animal Health GmbH	Germany
Elanco Hungary Kft.	Hungary
Elanco Global Holdings BV	Netherlands

Elanco Poland	Poland
KVP Pharma+Veterinar Produkte GmbH	Germany

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements (Form S-3 ASR No. 333-235991 and Form S-8 Nos. 333-227447 and 333-258652) of Elanco Animal Health Incorporated and in the related Prospectus of our reports dated February 28, 2022, with respect to the consolidated financial statements of Elanco Animal Health Incorporated, and the effectiveness of internal control over financial reporting of Elanco Animal Health Incorporated, included in this Annual Report (Form 10-K) for the year ended December 31, 2021.

/s/ Ernst & Young LLP

Indianapolis, Indiana

February 28, 2022

EXHIBIT 31.1

CERTIFICATIONS

I, Jeffrey N. Simmons, certify that:

1. I have reviewed this report on Form 10-K of Elanco Animal Health Incorporated;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s Board of Directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize, and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: February 28, 2022

By: /s/ Jeffrey N. Simmons
Jeffrey N. Simmons
President and Chief Executive Officer

EXHIBIT 31.2

CERTIFICATIONS

I, Todd S. Young, certify that:

1. I have reviewed this report on Form 10-K of Elanco Animal Health Incorporated;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and

5. The registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s Board of Directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize, and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: February 28, 2022

By: /s/ Todd S. Young
Todd S. Young
Executive Vice President and Chief Financial Officer

EXHIBIT 32

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Elanco Animal Health Incorporated, an Indiana corporation (the "Company"), does hereby certify that, to the best of their knowledge:

The Annual Report on Form 10-K for the year ended December 31, 2021 (the "Form 10-K") of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 28, 2022

/s/ Jeffrey N. Simmons
Jeffrey N. Simmons
President and Chief Executive Officer

Date: February 28, 2022

/s/ Todd S. Young
Todd S. Young
Executive Vice President and Chief Financial Officer