2022 Annual Report

Elanco™

Reaching the world's animals.

Reaching the world's animals

Dear Fellow Shareholders,

Determination and dedication. Our people make the difference. In the four years since completing our IPO, the global Elanco team continued to show what purpose and passion in action can do. In this time, we fully separated and established an independent company, completed the industry's largest acquisition, reset our cost base, and built a strong leadership team. Elanco is building a leading global independent animal health company with the unique ability to reach the world's animals – and 2022 included key milestones on this journey.

Pet owners, farmers, veterinarians – our deep customer relationships enable Elanco to reach across 19 animal species in more than 90 countries around the world.

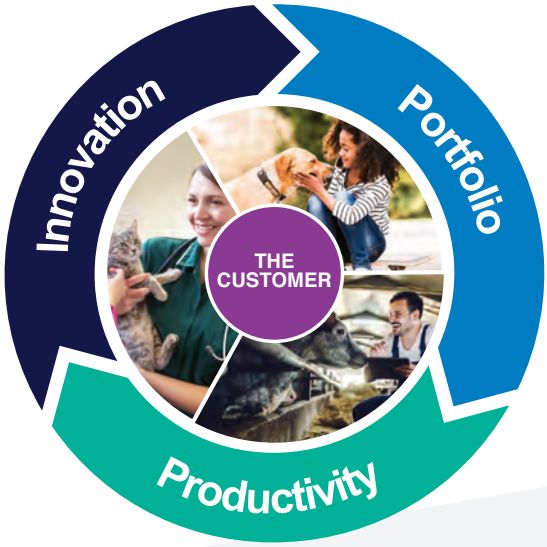
Globally, we have what is needed to navigate the difficult external environment: robust regulatory capabilities to bring timely product approvals, manufacturing, supply chain expertise, sales, technical support and interface for customers. Soon, we will have a single Enterprise Resource Planning (ERP) system to serve our global business more efficiently.

Our global reach, scale and customer relationships consistently position Elanco as a strategic partner of choice for innovators. We saw this come to life in 2022 from the licensing of Bexacat, the first SGLT-2 for feline diabetes, to the U.S. licensing rights for Bovaer, a potential blockbuster methane-reducing feed product for cattle. Additionally, we saw significant progress in our existing pipeline, shifting Elanco's focus at the close of 2022 from stand up and integration to innovation, commercial excellence and our next era of growth.

Making life better for animals, makes life better. Inspired by our Vision, our global Elanco team is energized by this unifying purpose. Our Elanco cultural foundations are shared and felt across all interactions from pet owners and farmers to veterinarians and innovators. Our ownership mindset and dedicated focus on productivity drove operational excellence through our entire organization.

Animal health remains a resilient industry. Last year presented macro-environmental and competitive factors contributing to a challenging operating environment that pressured our topline performance. However, our team stayed focused on delivering across the business.

Elanco's commitment to our Innovation, Portfolio and Productivity (IPP) strategy



Faced with a challenged macro-environmental landscape, we remained focused, executing with intention on our Innovation, Portfolio and Productivity (IPP) strategy.

We significantly advanced our innovation pipeline, expanded our portfolio, drove productivity gains across all areas of the company and positioned the business for acceleration in 2024 and beyond.

1. **Generated revenue of $4.4 billion,** with Adjusted EBITDA of $1.017 billion and Adjusted EPS of $1.11 for the full year 2022.

2. **Expanded Adjusted EBITDA margin by 80 basis points in 2022.**

3. **Delivered approximately $360 million in cumulative Adjusted EBITDA synergies in 2022** from the Bayer acquisition, exceeding our expectations.

4. **Reduced gross debt by approximately $500 million in 2022,** ending the year with net leverage of 5.5x. Debt paydown remains our key capital allocation priority.

5. **Gained eight new product approvals in major markets,** with differentiated feline innovations like Zorbium, Advantage XD and Bexacat, and important geographic expansions like Credelio for dogs in China.

6. **Contributed $133 million in revenue from innovation in 2022,** an incremental $61 million year over year.

7. **See a path to U.S. approval for six products with blockbuster potential** by the first half of 2024.

Dedication to delivering consistent high impact innovation

During her first 18 months with Elanco, Dr. Ellen de Brabander, Executive Vice President of Innovation and Regulatory Affairs, leveraged her extensive experience and expertise in animal health research and development to integrate and reshape our research and development (R&D) organization. With her leadership, our global R&D team implemented a disciplined approach to prioritize the portfolio and optimize resource allocation.

Result

Rapid pipeline advancement and setting a strong foundation as we enter the most significant launch window in our history.

With a path to six potential blockbuster approvals by the first half of 2024, we expect our innovation portfolio to add $600-700 million in revenue by 2025.

The consistent delivery of milestones across the pipeline from research through late-stage development provides the proof points. We are nearing our significant era of innovation, resulting in both growth and a positive impact on society.

Innovation

Bolstered our Pet Health business

with the addition of several life-enhancing and life-saving solutions including Advantage XD for cats, an extended duration flea prevention, as well as by receiving U.S. approval for Bexacat and Zorbium for pain.

Elanco announced U.S. Food and Drug Administration (FDA) approval of Bexacat™ (bexagliflozin tablets), the first orally administered prescription medication to improve glycemic control in cats with diabetes mellitus, expanding Elanco's innovative feline portfolio while addressing an unmet need for this chronic condition in adult cats. Bexacat can help improve the welfare of cats by making it easier for their owners to administer care. An estimated 600,000 cats in the U.S. are diagnosed with diabetes during their lifetime. Research shows 125,000 cats go untreated.

Initiated U.S. submission

for assets in our exciting late-stage pipeline that are expected to position Elanco to capture significant value in the attractive canine parasiticide and dermatology markets, including:

- Differentiated broad-spectrum parasiticide.
- JAK inhibitor for canine dermatology.

Expect to initiate submission for our IL-31 monoclonal antibody product for canine dermatology in the first half of 2024.

Progress and outlook for Elanco's next era of growth

Preparing for a historic innovation launch window in 2023 and 2024

✓ Progress since Q3 2022 Earnings Call
› Addition since Q3 2022 Earnings Call
^ $10-$49M
^^ ≥$100M

Asset	US Regulatory Agency	Species	Exploratory Development	Product Development	Initial Submission[1]	Approval[2]	Launch[1]	Peak Sales Opportunity[3]
Bexacat SGLT-2 Diabetes	FDA (Rx)					✓ Q4 2022	Q2 2023	^
KIND-030 Parvovirus	USDA (Rx)					Q1 2023 (conditional)	H2 2023	^^
› **K9 Advantix** Flea/Tick	EPA (OTC)					✓ Q1 2023	Q1 2023	^
› **Advantage** Flea	EPA (OTC)					✓ Q1 2023		^
Broad Spectrum Parasiticide	FDA (Rx)					H1 2024		^^
JAK Inhibitor Dermatology	FDA (Rx)				✓ Q4 2022	H1 2024		^^
IL-31 SA Antibody Dermatology	USDA (Rx)				H1 2023	H1 2024		^^
› **Bovaer** Methane Reduction	FDA					H1 2024		^^

(1) Expected submission and launch timing is based on internal estimates and could change as programs evolve.
(2) Potential approval timing is subject to regulatory agency outcomes.
(3) Potential peak sales represent the level of annual sales expected for a product on a global basis at its peak.
(4) Potential launch timing is subject to regulatory approvals at the state level.

Elanco is positioned to be the lead partner in animal protein sustainability, helping our customers achieve climate neutrality

Innovation

We also made strides in delivering key innovation in our Farm Animal business.

We are pleased by the enhancements we made in our medicated feed portfolio, with a bolt-on acquisition in the antibiotic alternative space expected to contribute $20 million to $30 million in innovation revenue in 2023.

In 2022, we saw increased adoption of Experior and added U.S. commercial rights for Bovaer to our pipeline. We made tangible progress on farmers' future ability to monetize environmental sustainability efforts. Key to this effort, we launched UpLook, an analytics engine built on years of Elanco data to help producers benchmark their footprint and measure their reduction in emissions. In partnership with High Alpha Innovation, we also co-created and provided seed funding for Athian, a start-up company designed to validate, aggregate and monetize carbon credits for the livestock industry. In 2023, we expect Athian will mint the first carbon credits for producers – proof that livestock sustainability can transition from strategy to tangible action with the potential to create value for farmers, investors and society as a whole.

The momentum behind our innovation pipeline is creating an exciting trajectory that will improve the lives of animals and the planet.

Innovation

Elanco Rumensin

Elanco Experior

Equip customers with product solutions and tools that reduce environmental impact, with focus on innovation

Analytics

Elanco UpLook Knowledge Solutions

Develop services, analyses and partnerships designed to help capture value for sustainability projects

Value Creation

Athian
Sustainable Livestock Systems

Establish a mechanism to certify, aggregate and monetize efforts and build a climate neutral ecosystem to bring value to producers

Advocacy

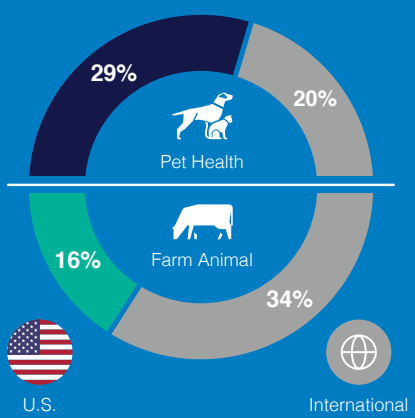
...accelerating the change TOGETHER

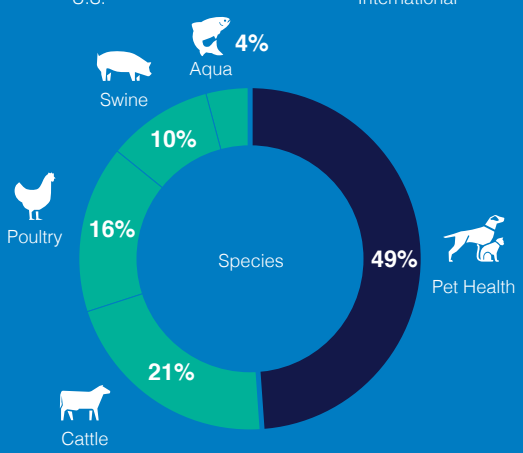
Lead the climate neutrality conversation and drive change across species, borders and issues

Optimizing portfolio for strategic long-term value

As an established market leader, Elanco is committed to delivering value across our diverse portfolio. While external and competitive factors challenged growth in 2022, we expect stabilization in the coming year and remain confident in our ability to deliver long-term growth from our existing portfolio.

Diverse, global portfolio balanced across geography and species





Portfolio

Pet Health

Our global Pet Health portfolio contributed more than $2.1 billion in revenue for the full year. We delivered key expansions and remained the market leader in the U.S. for retail over-the-counter (OTC) parasiticides.

Galliprant and our global pain portfolio grew double digits in 2022. Despite expected competition in this market, our existing strength in this category and the addition of Zorbium enables our pain portfolio to remain a key contributor to our long-term Pet Health strategy.

Additionally, we advanced our digital selling capabilities with deeper multi-touchpoint interactions with veterinarians and enhanced engagement tactics for our field-based team. We expect to employ these techniques across brands as well as integrate these capabilities into our future launch plans to capture the full market potential of our new and existing products.

Digital selling capabilities helped drive the ramp of Zorbium, resulting in cumulative clinic penetrations in more than 11,500 clinics in just six months, more than doubling historic rates.

Farm Animal

Our global Farm Animal portfolio contributed more than $2.2 billion in revenue for the full year. We are pleased with the increasing influence and market position we have established in this space.

In the U.S., we are the second largest player, and outside the U.S., we remained competitive in the medicated feed additive space – leading in poultry and swine. In addition, we continue to benefit from our position as the second largest player in aqua, which grew 32% year over year in constant currency in 2022.

Looking at our complete product offering in Pet Health and Farm Animal, we delivered 2% price growth. The strength of our product offering, combined with Elanco's commitment to deep customer relationships, solidifies our foundation as we further our global reach.

Productivity

Ongoing commitment to operational discipline & productivity

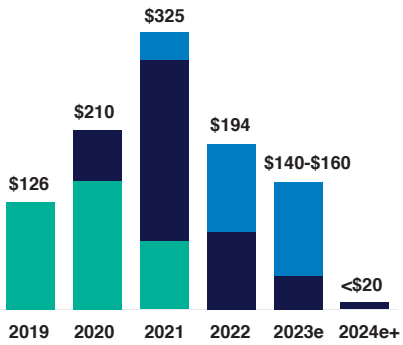
In 2022, we navigated challenging external environmental factors and competitive pressures by leveraging our operational capabilities – contributing to a 10% reduction in operating expenses for the year. Through 2022, we delivered approximately $360 million in cumulative Adjusted EBITDA synergies from the Bayer acquisition, exceeding our expectations and accelerating savings.

Debt paydown remained a key capital allocation priority as we reduced gross debt by approximately $500 million in 2022 from $6.4 billion to $5.9 billion. As a result, we ended the year with a net leverage ratio of 5.5x Adjusted EBITDA.

Finally, we will deliver operational efficiencies through our ERP systems integration. We believe, moving past this critical milestone in the first half of 2023 will contribute to improved free cash flow, allowing us to reinvest in the business and further progress our debt paydown.

Estimated project cash costs

$ millions



~$360M Independent Company Stand-Up

~$400M Bayer Business Integration

~$240-$260M Bayer Systems Integration

Making the world better through

Elanco's HEALTHY PURPOSE™

Accountability and clarity across our global Environmental, Social and Corporate Governance (ESG) priorities are at the center of our Elanco Healthy Purpose initiative. In 2022, select members of the management team and certain Board members engaged in informative dialogue with shareholders. The sessions covered our business strategy, corporate governance policies, sustainability initiatives, human capital management and compensation practices.

Ingrained in all aspects of the business, our approach to sustainability and to the management of ESG issues is driven from within our organization, demonstrated by the commitment of our people and the power of our Elanco Healthy Purpose platform. The combination of our global reach and strong business position helped us progress toward our 2030 Healthy Purpose commitments as we continue to promote the health and well-being of animals, people, the planet and our enterprise.

We expanded our dedicated sustainability and ESG leadership and expertise, while reinforcing Board and internal steering committee oversight.

More work must be done. Healthy animals are an essential part of the solution to many of the most pressing issues facing our global society and Elanco and our employees remain committed to enriching the lives of animals and their owners worldwide while optimizing our global operations and minimizing our environmental footprint.

ESG highlights

One of our largest manufacturing sites, in **Kiel Germany**, transitioned in 2022 to purchasing

100%

of electricity

from renewable sources

In 2021, more than

88%

of electricity

purchased at another of our largest manufacturing sites, in **Fort Dodge Iowa**, was generated from renewable sources

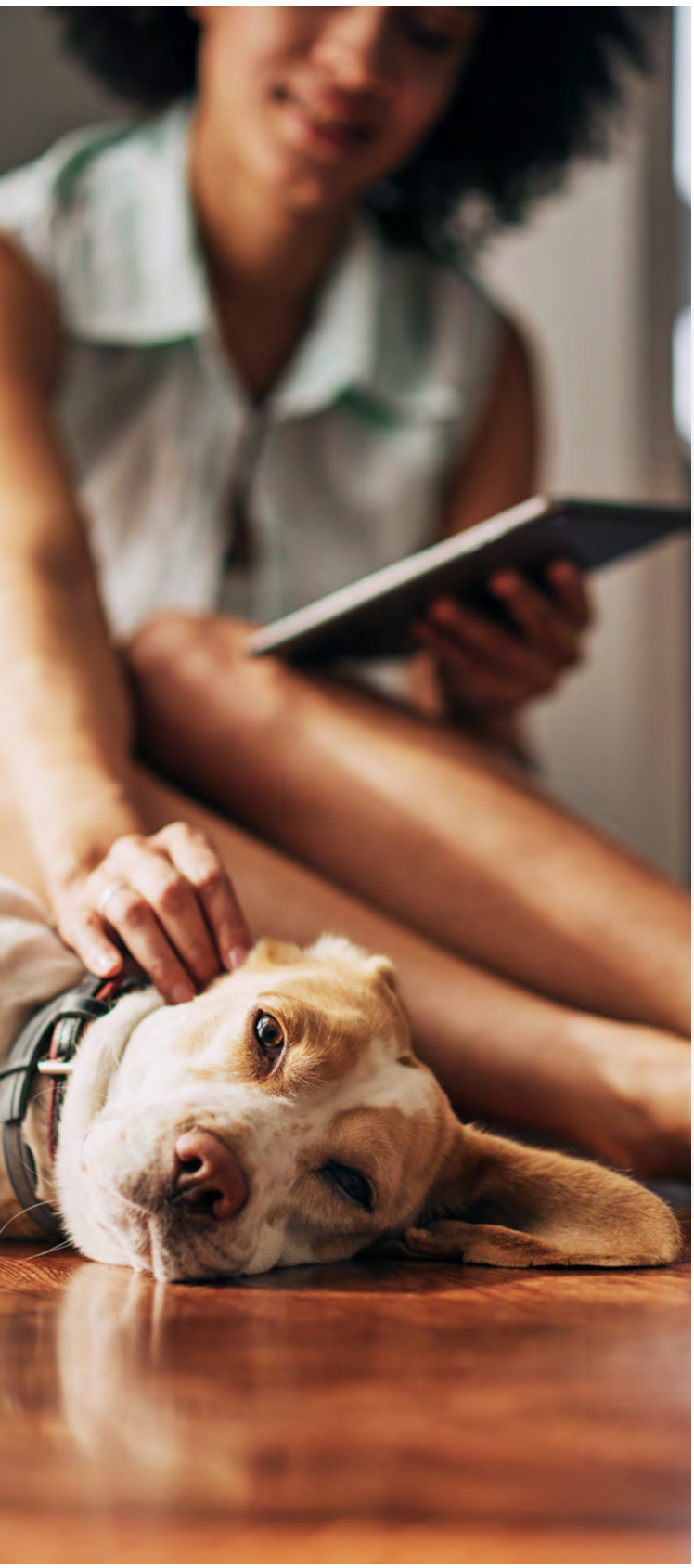
We exceeded our 2023 target for employee volunteerism a year in advance – exceeding 12,800 hours, a

37% increase over 2021

Elanco employees also contributed nearly

$120,000

to more than 348 causes worldwide



Delivering our next era of innovation and growth for long-term value creation

Proof points and progress sum up 2022. Turning to 2023, we're poised to begin delivering our next era of innovation and growth. Our team is laser-focused on the next 12 months but also sees the future and beyond as our next great era: one rooted in the consistent delivery of high-impact innovation, enabled by our dedication to operational discipline, and fueled by our commitment to commercial excellence.

Elanco's potential to create long-term sustainable value as a strong independent company is more compelling than ever. As we look ahead, our innovation pipeline is on track as we continue to meet significant milestones, with revenue from innovation accelerating in 2023.

In the immediate future, our team is committed to delivering value from our existing portfolio with a return to growth in the second half of 2023. Our renewed focus on refreshing and extending our brands expands our ability to reach the world's animals and deliver on our customer promise.

We continue to increase operational efficiencies as we complete our systems integration, decreasing our operational complexity and enhancing our customer experience while improving Elanco's free cash flow generation.

With the added emphasis on launch readiness, the Elanco Executive Committee reinforced our commitment to commercial excellence. Our teams are more focused than ever on effective and efficient execution to capture the full value of our future technology.

Finally, Elanco is at an important inflection point. I am confident in our path ahead. We have the right talent in place to carry our strategy forward. Thank you for your support as Elanco positions itself to deliver long-term value to stakeholders over time.

Jeff Simmons

President and
Chief Executive Officer,
Elanco

Board of Directors

R. David Hoover

Chairman, Elanco Animal Health
Retired CEO, Ball Corp.

Board Member
Since Sept 2018

Kapila Kapur Anand

Retired Partner, KPMG

Board Member
Since Sept 2018

Michael J. Harrington

Retired SVP and
General Counsel,
Eli Lilly and Company

Board Member
Since Sept 2018

Deborah T. Kochevar

D.V.M., Ph.D.,
D.A.C.V.C.P.

Senior Fellow, Fletcher
School of Law and
Diplomacy and Dean
Emerita, Tufts University

Board Member
Since Mar 2019

William F. Doyle

Executive Chairman,
Novocure Ltd.,

Board Member
Since Dec 2020

Jeffrey N. Simmons

President and CEO,
Elanco Animal Health

Board Member
Since Sept 2018

Lawrence E. Kurzius

Chairman, President
and CEO, McCormick & Co.

Board Member
Since Sept 2018

John P (JP) Bilbrey

Retired CEO,
President,
The Hershey Company,

Board Member
Since Mar 2019

Kirk McDonald

CEO, GroupM,
North America

Board Member
Since Mar 2019

Denise Scots-Knight

CEO and Co-Founder,
Mereo BioPharma Group plc

Board Member
Since Mar 2019

Paul S. Herendeen

Retired CFO, Bausch
Health Companies, Inc.

Board Member
Since Dec 2020

Art A. Garcia

Retired EVP and CFO,
Ryder System, Inc.

Board Member
Since May 2019

Elanco Executive Committee

Tim Bettington
Executive Vice President, Corporate Strategy and Market Development

Dr. Ellen de Brabander
Executive Vice President, Innovation and Regulatory Affairs

Dr. Ramiro Cabral
Executive Vice President, Elanco International

David Kinard
Executive Vice President, Human Resources, Corporate Communications and Administration

Marcela Kirberger
Executive Vice President. General Counsel and Corporate Secretary

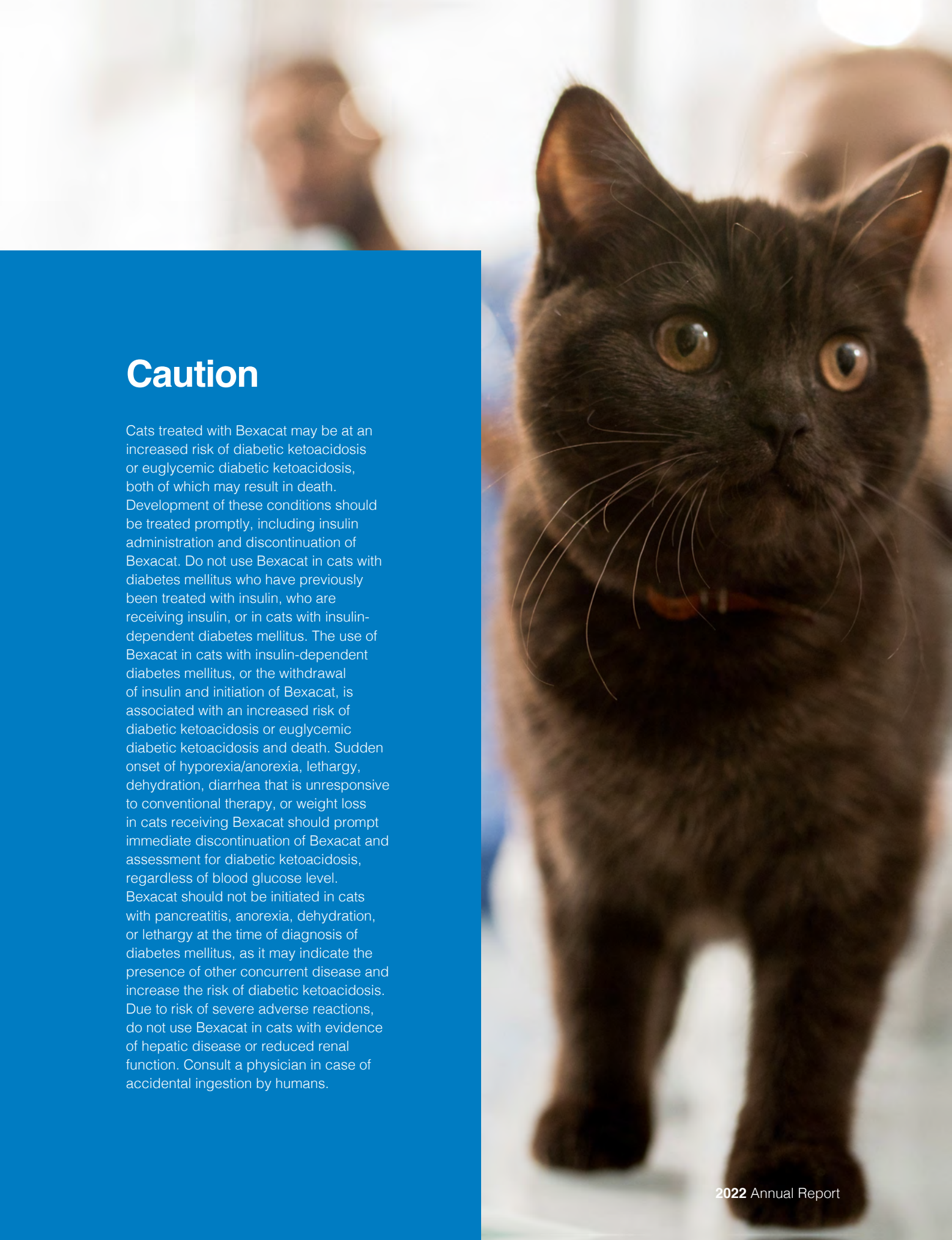
Bobby Modi
Executive Vice Pesident, U.S. Pet Health and Global Digital Transformation

Dr. José Manuel Correia de Simas
Executive Vice President, U.S. Farm Animal Business

Jeffrey Simmons
President and CEO

David Urbanek
Executive Vice President, Manufacturing and Quality

Todd Young
Executive Vice President, Chief Financial Officer



Caution

Cats treated with Bexacat may be at an increased risk of diabetic ketoacidosis or euglycemic diabetic ketoacidosis, both of which may result in death. Development of these conditions should be treated promptly, including insulin administration and discontinuation of Bexacat. Do not use Bexacat in cats with diabetes mellitus who have previously been treated with insulin, who are receiving insulin, or in cats with insulin-dependent diabetes mellitus. The use of Bexacat in cats with insulin-dependent diabetes mellitus, or the withdrawal of insulin and initiation of Bexacat, is associated with an increased risk of diabetic ketoacidosis or euglycemic diabetic ketoacidosis and death. Sudden onset of hyporexia/anorexia, lethargy, dehydration, diarrhea that is unresponsive to conventional therapy, or weight loss in cats receiving Bexacat should prompt immediate discontinuation of Bexacat and assessment for diabetic ketoacidosis, regardless of blood glucose level. Bexacat should not be initiated in cats with pancreatitis, anorexia, dehydration, or lethargy at the time of diagnosis of diabetes mellitus, as it may indicate the presence of other concurrent disease and increase the risk of diabetic ketoacidosis. Due to risk of severe adverse reactions, do not use Bexacat in cats with evidence of hepatic disease or reduced renal function. Consult a physician in case of accidental ingestion by humans.

Reconciliation of U.S. GAAP Net Loss for the year ended December 31, 2022 to EBITDA, Adjusted EBITDA, and Adjusted EBITDA Margin, which is Adjusted EBITDA divided by total Revenue, is as follows:

($ in millions)

Reported Net Loss	$ (78)
Net interest expense	241
Income tax expense	6
Depreciation and amortization	682
EBITDA	$ 851
Non-GAAP Adjustments:	
Asset impairment, restructuring, and other special charges	183
Accelerated depreciation[1]	(19)
Other expense, net	2
Adjusted EBITDA	$1,017
Adjusted EBITDA Margin	23.1%

Numbers may not add due to rounding.

(1) Represents depreciation of certain assets that was accelerated during the periods presented. This amount must be added back to arrive at Adjusted EBITDA because it is included in Asset impairment, restructuring, and other special charges but it has already been excluded from EBITDA in the "Depreciation and amortization" row above.

Reconciliation of GAAP EPS to selected Adjusted EPS for the year ended December 31, 2022 is as follows:

EPS	$ (0.16)
Amortization of intangible assets	1.07
Asset impairment, restructuring and other special charges	0.37
Interest expense, net of capitalized interest	0.04
Other (income) expense, net	0.00
Subtotal	$ 1.49
Tax Impact of Adjustments[1]	(0.23)
Total Adjustments to EPS	$ 1.26
Adjusted EPS[2]	$ 1.11

Numbers may not add due to rounding.

(1) Tax impact includes the favorable adjustment relating to the valuation allowance recorded against our deferred tax assets during 2022 (impact of $0.13 per share).

(2) Adjusted EPS is calculated as the sum of EPS and Total Adjustments to EPS.

Reconciliation of gross debt to net debt for the year ended December 31, 2022 is as follows:

($ in millions)	
Long-term debt	$ 5,448
Current portion of long-term debt	388
Less: Unamortized debt issuance costs	(64)
Total gross debt	5,900
Less: Cash and cash equivalents	345
Net Debt	$5,555

Disclaimers

This Annual Report, including Elanco's Annual Report on Form 10-K included herein, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, including but not limited to statements about expected synergies and cost savings and future product launches and associated revenue. These forward-looking statements are based on Elanco's current expectations and assumptions regarding, among other things, its operations, performance, and financial condition, and are subject to change. You are cautioned not to place undue reliance on these forward-looking statements, which are subject to risks, uncertainties, and assumptions that are difficult to predict, including those identified in the included Annual Report on Form 10-K under "Item 1A. Risk Factors" and elsewhere therein. Elanco undertakes no duty to update forward-looking statements.

Elanco uses non-GAAP financial measures, such as EBITDA, adjusted EBITDA, adjusted EPS, adjusted gross margin and net debt leverage to assess and analyze our operational results and trends. We believe these non-GAAP financial measures are useful to investors because they provide greater transparency regarding our operating performance. The non-GAAP financial measures included herein should not be considered substitutes for U.S. GAAP reported measures. Non-GAAP financial measures may not be comparable to similarly titled measures used by other companies, including those in our industry. More information regarding our use of non-GAAP financial measures is included on our website at www.elanco.com.

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

Form 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2022

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 and zip code 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

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. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2022, the last business day of the Registrant's most recently completed second fiscal quarter, was approximately $9.3 billion. The registrant has no non-voting common stock.

The number of shares of common stock outstanding as of February 24, 2023 was 491,543,501.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy materials for its 2023 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, 2022
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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 recent business acquisitions, expected synergies and cost savings, product launches, expectations relating to human capital resources, the coronavirus (COVID-19) global pandemic, the conflict involving Russia and Ukraine and the potential impact on our business and global economic conditions, 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;
- demand, supply and operational challenges associated with the effects of a human disease outbreak, epidemic, pandemic or other widespread public health concern;
- the potential impact on our business and global economic conditions resulting from the conflict involving Russia and Ukraine;
- the success of our research and development (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, including those related to climate change, 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;
- the lack of availability or significant increases in the cost of raw materials;
- the impact of increased or decreased sales into our distribution channels 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, including the risk to our reputation 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 the 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 Kindred Biosciences, Inc. (KindredBio) and the animal health business of Bayer Aktiengesellschaft (Bayer Animal Health) and specifically the impact of the integration of ERP systems scheduled for April 2023 and related sales order processing blackout periods and their impact on revenue allocation across the first and second quarters of 2023;
- the effect of our substantial indebtedness on our business, including restrictions in our debt agreements that will limit our operating flexibility;
- risks related to certain governance provisions in our constituent documents; and
- any failure to maintain an effective system of disclosure controls and internal control over financial reporting, including arising from an identified material weakness.

See "Item 1A. Risk Factors" in Part I 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 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 our customers to shop where and how they want. As a result, we have increased scale and reach as well as a more balanced portfolio between pet health and farm animal. Refer to “Item 8. Financial Statements and Supplementary Data — Note 6: Acquisitions, Divestitures and Other Arrangements” for additional information.

We are committed to fulfilling our customer 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 2022 and 2021, we launched nine new products in major geographies and delivered many geographic expansion and life cycle management enhancements of existing products across pet health and farm animal. Additionally, in 2021, we advanced our opportunities to access the fast-growing pet dermatology market through the acquisition of KindredBio, adding three potential pipeline blockbusters with launches beginning as early as 2024. As part of the acquisition, we also secured full ownership of the canine parvovirus therapy that is expected to be conditionally approved by the U.S. Department of Agriculture (USDA) in the first quarter of 2023. 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 6: Acquisitions, Divestitures and Other Arrangements.”

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 part of our strategy is then 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 addition, we continue to enhance our approach to sustainability and environmental, social, and governance (ESG), which is focused on four interconnected pillars, called Elanco's *Healthy Purpose*™*,* to create a meaningful impact today and for years to come:

Healthier Enterprise: Growing our business with integrity and excellence with respect to all stakeholders, where all employees feel safe, engaged and accountable as owners.

Healthier Animals: Helping pets and farm animals live healthy, quality lives by continuously expanding our portfolio, while identifying new and innovative animal care products, practices, and services.

Healthier People: Improving people's lives and livelihoods by promoting animal companionship and enabling sustainable production of meat, milk, fish and eggs.

Healthier Planet: Minimizing our own environmental footprint, while leveraging product and service innovations to help our stakeholders advance their sustainability efforts.

In 2022 and 2021, our business, operations, financial condition and results have been impacted by worldwide economic conditions. The global economy has been impacted by the COVID-19 pandemic and the conflict between Russia and Ukraine as well as supply chain disruptions and inflationary pressures. We continue to monitor these factors and have worked with our customers, employees, suppliers and other stakeholders to mitigate their impacts. 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," "Item 1A. Risk Factors – We could experience demand, supply and operational challenges associated with the effects of a human disease outbreak, epidemic, pandemic or other widespread public health concern," and "Item 1A. Risk Factors – 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."

Commercial Operations

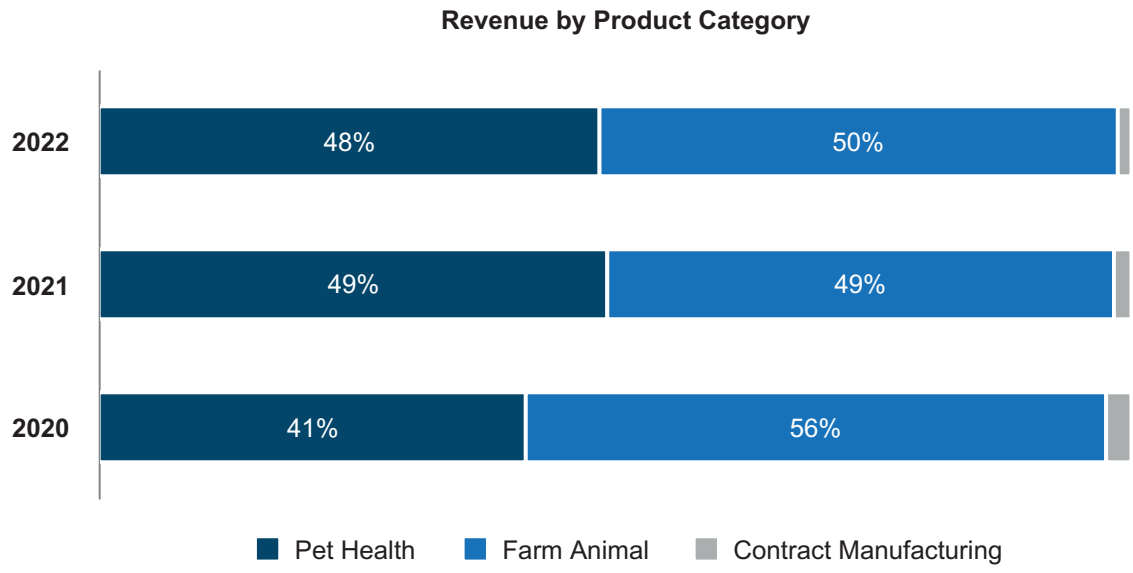
We operate our business in a single segment directed at fulfilling our vision of food and companionship enriching life – all to advance the health of animals, people and the planet. For additional information about our business segment, refer to "Item 8. Financial Statements and Supplementary Data — Note 18: 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 parasiticide portfolios in the pet health sector based on indications, species and formulations, with products that protect pets from worms, 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 our prescription parasiticide products, *Credelio*™, *Interceptor Plus*™, and *Trifexis*. Our vaccines portfolio provides differentiated prevention coverage for a number of important pet health risks and is available in the U.S. only. In therapeutics, we have a broad pain and osteoarthritis portfolio across species, modes of action, indications and disease stages. Pet owners are increasingly 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 certain cardiovascular and dermatology indications.

Farm Animal: Our farm animal portfolio consists of products designed to prevent, control and treat health challenges, primarily focused on cattle (beef and dairy), swine, poultry, and aquaculture (cold and warm water) production. Our products include medicated feed additives, injectable antibiotics, vaccines, insecticides, and enzymes, among others. We have a wide range of farm animal products, including *Rumensin* and *Baytril*™, both of which are used extensively in ruminants (e.g., cattle, sheep and 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:



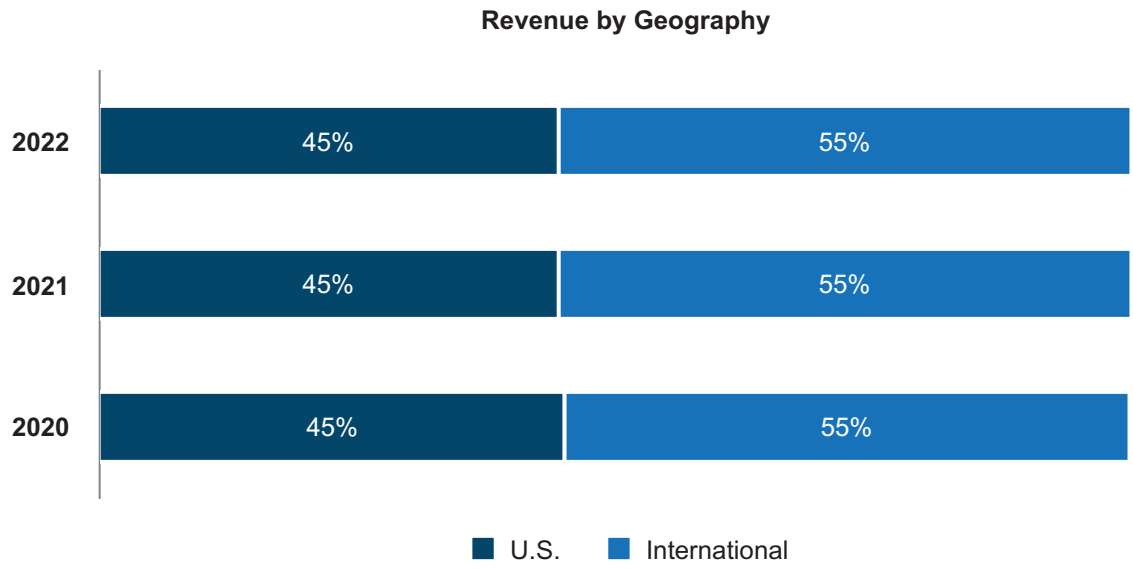
Contract manufacturing represents revenue from arrangements in which we manufacture products on behalf of a third party, including supply agreements associated with divestitures of products related to the acquisition of Bayer Animal Health.

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 advance 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 $2,446 million accounted for 55% of our total revenues in 2022. 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 and pet owners better care for pets. We partner with our customers 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 48% of our revenue for the year ended December 31, 2022.

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 50% of our revenue for the year ended December 31, 2022.

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

In 2022, our top selling products as a percentage of total revenue were as follows:

	2022
Top selling products:	
Seresto	8 %
Rumensin	6 %
Top five selling products:	
Seresto, Rumensin, Advocate, Advantix, and Maxiban	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 2022:

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.	Cats, 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

Product	Description	Primary Species
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
TruCan™ [(1)] (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
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

[(1)] Formerly marketed as *Duramune*™.

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)
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
Hemicell (endo-1, 4-â-mannanase)	Enzyme supplement for poultry and swine feeds that contain a source of â-mannanase, which hydrolyses the â-mannans present in soybean and corn meal.	Poultry, 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
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

Product	Description	Primary Species
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

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 certain parasiticide product offerings in the first half of the year. For example, based upon historical results, approximately 75% 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 2022, 8% of our revenue was from products classified as shared-class antibiotics (3% from sales in the U.S. and 5% from international sales), which is down from 9% in 2021. Revenue from animal-only antibiotics and ionophores represented 15% of our total revenue in 2022 (13% from ionophores), which is up from 14% in 2021. 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 2,010 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 supporting 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 top selling 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 11% of our revenue for the year ended December 31, 2022. Our next two largest customers, which are also third-party distributors, represented approximately 7% and 5%, respectively, of our revenue for the year ended December 31, 2022.

Research and Development

Our R&D organization is comprised of internal research, development, regulatory and external innovation collaborations. As of December 31, 2022, we employed approximately 1,080 employees in our global R&D and Regulatory Affairs organizations. Our global R&D sites are comprised of the following:

International		U.S.
Kemps Creek, Australia	Shanghai, China	Greenfield, Indiana (R&D headquarters)
Monheim, Germany	Bangalore, India	Fort Dodge, Iowa
Sao Paulo, Brazil	Basel, Switzerland	

We incurred R&D expenses of $321 million in 2022, $369 million in 2021 and $329 million in 2020.

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

We seek to concentrate our resources on projects that match our strategy and where we can leverage our broad technical and commercial capabilities. 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 pharmaceuticals, vaccines, and sustainable animal protein projects.

Our R&D efforts are balanced across species, development phases and technology platforms. We apply large and small molecule approaches for both farm animals and pets. 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 leverages 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 portfolio fit and balance. We have a matrix organizational structure with dedicated and highly experienced project leaders with clinical, technical development and regulatory expertise and support systems. We believe this approach will allow us to consistently progress our multi-year innovation projects toward regulatory approvals, while ensuring clear visibility to the innovation portfolio composition, value, and progress.

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 18 sites comprised of the following:

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

Our global manufacturing and supply chain is also supported by a network of CMOs. As of December 31, 2022, this network was comprised of approximately 150 CMOs. Our external manufacturing network centrally governs our global CMO relationships and provides oversight to these CMOs.

We select CMOs based on several factors, including: (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 globally. Competition may vary depending on the particular region, species, product category, or individual product. We compete principally on the basis of product quality, price, cost-effectiveness, promotional effectiveness, new product development and product differentiation. Certain products, both existing and new products that we introduce, may compete with other branded or generic products already on the market or that are later developed by competitors. When competitors introduce new products with ease-of-use, therapeutic or cost advantages, our products may become subject to decreased sales and/or price reductions.

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. While many of the patents and patent applications in our portfolio are the result of our own work, others have been developed in collaboration with partners, acquired through business transactions, or 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 expiring 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 extend 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., supplementary protection certificates (SPCs) have been granted which expire in September 2026.
- The *Milbemax* formulation patents extend through July 2024 in the U.S., Europe, and other key markets.
- Certain legacy *Advantage Family* products acquired from Bayer Animal Health, including *Advantage, Advantix, Advocate,* and *Advantage Multi* are off patent.

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 *TruCan* 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 14,500 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 regulatory 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 humans or the environment as stated in the act. Within the U.S., individual state pesticide authorities must also approve pesticide products that have been approved by the EPA before distribution in that state. 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 within 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 whether 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, which 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 European Commission's 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, it 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, it conducts the evaluation of biocides for the EU.

Since the U.K. formally left the EU on January 31, 2020, the Veterinary Medicines Directorate (VMD) became 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 in December 2020, which went into effect in May 2021. The agreement includes regulatory and customs cooperation mechanisms, as well as provisions supporting 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 additives/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 this committee to establish acceptably 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

Employees. As of December 31, 2022, we employed approximately 9,000 full time employees. In addition, we employed approximately 740 fixed-duration employees, which are individuals hired for a pre-defined length of time (one to four years). Together, they total approximately 9,740 employees worldwide. Of the 9,740 global employees, approximately 30% are U.S.-based and approximately 70% 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.

Our Culture. 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.

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. Our efforts to enhance 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 people of color (U.S.) in leadership.

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 initiatives aligned to Elanco's *Healthy Purpose*, which is our ESG and sustainability framework, to advance the well-being of animals, people, the planet and our enterprise, enabling us to realize our vision of "Food and Companionship Enriching Life."

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. We made no capital expenditures for environmental-related items in 2022.

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. Several new start-up companies also compete in the animal health industry. 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. 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.

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 we can and the ability of competitors to access more or newer technology than we can. 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.

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 our products obsolete 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.

Our business is subject to substantial regulation.

As a global company, we are subject to various state, federal and international laws and regulations, including regulations relating to the development, quality assurance, manufacturing, importation, distribution, marketing, and sale of our products. In addition, our manufacturing facilities, 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 applicable 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.

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. For more information, see “Item 1. Business — 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 2022, 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 2022, our revenue from shared-class antibiotics decreased approximately 11% in comparison to 2021, excluding the impact of foreign exchange rates, and represented 8% (3% from sales in the U.S. and 5% from international sales) of total revenue, down from 16% in 2015. The comparison to 2015 is impacted by our 2020 acquisition of Bayer Animal Health, which added certain shared-class antibiotics to our portfolio while significantly increasing our overall annual revenue.

From 2015 to 2022, we experienced a flat CAGR in revenue from animal-only antibiotics, excluding the impact of foreign exchange rates. During 2022, our revenue from animal-only antibiotics increased approximately 2% in comparison to 2021, excluding the impact of foreign exchange rates, and represented 15% (6% from sales in the U.S. and 9% from international sales) and of total revenue, down from 23% in 2015. In 2022, 13% 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.

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 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*, *Advocate*, *Advantix*, and *Maxiban* contributed approximately 24% of our revenue in 2022. Any issues with these top products, particularly *Seresto* and *Rumensin*, which contributed approximately 8% and 6%, respectively, of our revenue in 2022, could have a material adverse effect on our business, financial condition and results of operations.

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 the *Advantage Family*, *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, 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 CAGR of 3% from 2015 to 2022 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. For further information, 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.

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 toward 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 toward 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.

We could experience demand, supply and operational challenges associated with the effects of a human disease outbreak, epidemic, pandemic or other widespread public health concern.

Our business has been and may continue to be negatively impacted by human disease outbreaks, epidemics, pandemics or other widespread public health concerns, such as the COVID-19 pandemic, including its variants, and the related travel restrictions and governmental mandates. These impacts include, but are not limited to:

- Reductions in demand or significant volatility in demand for one or more of our products, caused by, among other things: the temporary inability of our customers to purchase our products due to illness, quarantine, travel restrictions, and/or financial hardship; decreased veterinary visits; farm animal processing plant shutdowns; shifts in demand by trading down to lower priced products; or stockpiling activity;
- Inability to meet customer needs and achieve cost targets due to disruptions in our manufacturing and supply chains caused by labor constraints or inability to obtain key raw materials, increased transportation costs, or other manufacturing and distribution disruptions;
- Failure of third parties on which we rely, including our suppliers, contract manufacturers, distributors, contractors, and other external business partners, to meet their obligations, which may be caused by their own financial or operational challenges;
- Limited ability to access the global financial market, which could negatively impact our short-term and long-term liquidity; or
- Significant changes in the political environments in the markets in which we manufacture, sell or distribute our products, including lockdowns, import/export restrictions, or other governmental mandates that limit or close operating and manufacturing facilities, restrict travel to perform necessary business functions, or otherwise prevent us or our third-party partners, suppliers or customers from sufficiently staffing operations, including operations necessary for the production, distribution and sale of our products.

Despite our efforts to manage and limit these impacts, they are ultimately dependent on factors beyond our control, including the duration and severity of any such outbreak as well as third-party actions taken to contain its spread and mitigate its effects. For COVID-19, the emergence of variants may continue to occur across the geographies in which we operate, leading to varied government and consumer responses, resulting in further volatility in our results and operations.

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 licenses or acquisitions, including the acquisitions of Bayer Animal Health and KindredBio. We commit substantial effort, funds and other resources to R&D, primarily through our own dedicated resources but also 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 revenue that is 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 could 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.

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 and 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 continue to 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.

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.

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, made a request to temporarily remove *Seresto* collars from the market and, during a hearing at which our President and Chief Executive Officer (CEO) testified, again called for removal of the 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.

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 and again in 2021, we conducted restructuring programs which included the elimination of positions across several countries, primarily in sales and marketing, R&D, 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.

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 75% 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.

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

- weather conditions, including those related to climate change, and the availability of natural resources;
- increased or decreased inventory levels in our distribution channels;
- 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 the headings "Our business may be negatively affected by weather conditions and the availability of natural resources" and "Increased or decreased inventory levels in our distribution channels 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 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.

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. For more information, 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 in our distribution channels 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 and retailers who, in turn, sell our products to third parties. Inventory levels at our distributors and retailers increase or decrease as a result of various factors, including end customer demand, new customer contracts, heightened 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 and have led 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 accounting principles generally accepted in the United States (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, 2022, we had recorded on our balance sheet goodwill of $6.0 billion and identifiable intangible assets of $4.8 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, customer relationships from business combinations and software. We also have indefinite-lived intangible assets, which primarily 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 18 internal manufacturing sites located in 11 countries. We also employ a network of approximately 150 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.

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.

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.

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.

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.

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.

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 at 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 for 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.

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 Russia-Ukraine conflict and the related government and other entity responses;
- 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 U.K. from the EU; 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 or our service providers' 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 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.

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, in which our employees participate 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, 2022, for pension plans with projected benefit obligations in excess of plan assets, the projected benefit obligation was $301 million with plan assets of $150 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 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 shareholders 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, may not realize the anticipated benefits therefrom.

After the closing of an acquisition 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;
- the 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.

Additionally, as a result of our acquisition of Bayer Animal Health, we are operating under two separate enterprise resource planning (ERP) systems to support business operations such as invoicing, manufacturing, shipping, inventory control, procurement, supply chain management and financial reporting. We have started the process of integrating these two ERP systems into one primary platform and expect to complete the implementation process during 2023. ERP integrations have inherent risks, which can complicate our business operations and potentially lead to breakdowns in data integrity. The integration activities have also required, and will continue to require, significant resources to deploy. If we are unable to successfully integrate our systems to support critical business operations and to produce information for business decision-making activities, we could experience a material adverse impact on our business or an inability to timely and accurately report our financial results.

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 shareholders. 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.

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 10: 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. 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 the heading "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 U.K.'s Financial Conduct Authority (FCA), which regulates LIBOR, announced its intention to stop persuading or compelling banks to submit LIBOR quotations after 2021.

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. Even though our credit facilities have either already transitioned to SOFR or 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 shareholders' 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 shareholder 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; and
- the exclusive right of our board of directors to amend our amended and restated bylaws.

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.

If we fail to maintain an effective system of disclosure controls and internal control over financial reporting, our ability to produce timely and accurate financial statements or comply with applicable laws and regulations could be adversely impacted.

A material weakness is a deficiency or combination of deficiencies in our internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our consolidated financial statements would not be prevented or detected on a timely basis. If we experience a material weakness or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations. Any failure to maintain effective disclosure controls and internal control over financial reporting could have an adverse effect on our business, financial condition, and results of operations.

In connection with preparing the financial statements as of and for the year ended December 31, 2022, a cumulative error was identified relating to the valuation allowance for taxes for a Southeast Asia affiliate. While immaterial to prior years, correcting this cumulative error in 2022 would have caused the 2022 results to be materially misstated. Therefore, immaterial revisions were made to the consolidated financial statements as of and for the years ended December 31, 2021 and 2020. We determined that this error was the result of a control deficiency that constituted a material weakness in our internal control over financial reporting related to income taxes. The material weakness had not been remediated as of December 31, 2022.

Although we intend to take remedial actions in response to this control deficiency, there is no assurance that we will be able to prevent a material error or future control deficiencies (including material weaknesses) from occurring. Our inability to assert that our internal control over financial reporting is effective could result in a loss of investor confidence in the accuracy and completeness of our financial reports, which could cause the price of our common stock to decline, and we may be subject to investigation, litigation, increases in insurance premiums or regulatory fines and sanctions.

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 2025.

Our global manufacturing network is comprised of 18 manufacturing sites. The largest manufacturing site in our network is located in Clinton, Indiana. In addition, our global manufacturing network is supplemented by approximately 150 CMOs. For more information, 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 2025. For more information, 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 "Item 8. Financial Statements and Supplementary Data — Note 17: Commitments and Contingencies " 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.” The TEUs were delisted from trading when they converted to shares of our common stock as scheduled on February 1, 2023.

Holders

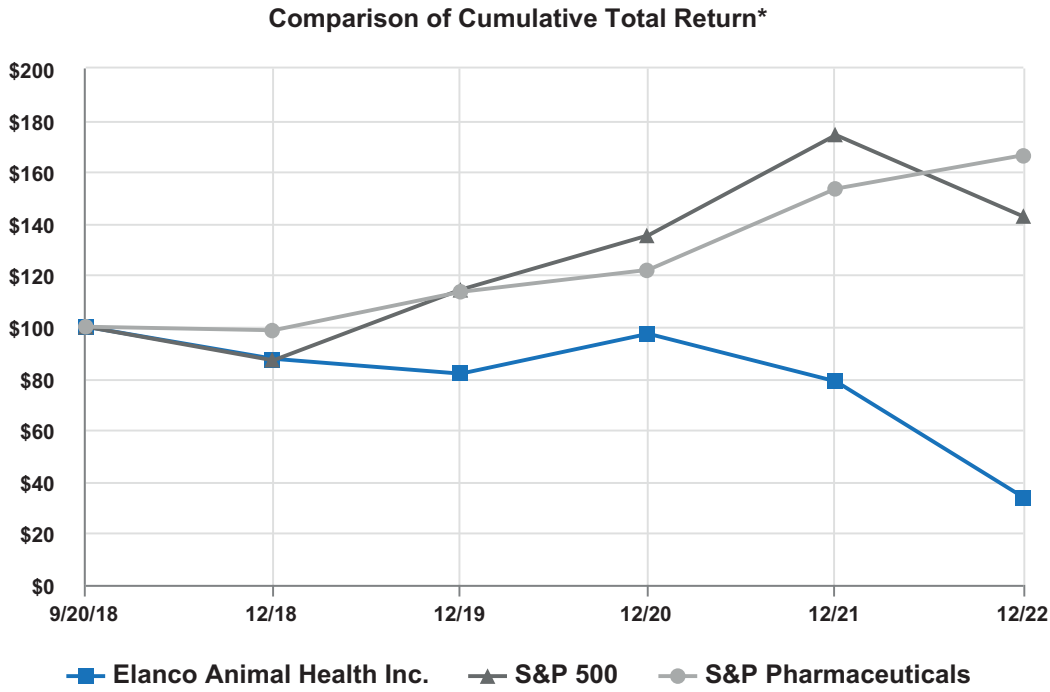
There were 234 holders of record of our common stock as of February 24, 2023. This does not include the number of shareholders who hold shares of our common stock through banks, brokers or other financial institutions.

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 for the period ended on December 31, 2022. The graph assumes that $100 was invested on September 20, 2018 (our initial public offering date) 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	December 31, 2022
Elanco Animal Health Inc.	$ 100.00	$ 87.58	$ 81.81	$ 85.19	$ 78.83	$ 38.76
S&P 500 Index	100.00	86.97	114.36	135.40	174.26	142.70
S&P 500 Pharmaceuticals Index	100.00	98.62	113.50	122.04	153.47	166.44

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 ended December 31, 2021 and 2020, refer to Item 7 of Part II in our Annual Report on Form 10-K for the year ended December 31, 2021 filed with the Securities and Exchange Commission on February 28, 2022.

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. We advance our vision by offering products in two primary categories: pet health and farm animal.

On August 27, 2021, we acquired KindredBio, a biopharmaceutical company that developed 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 6: Acquisitions, Divestitures and Other Arrangements 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 6: Acquisitions, Divestitures and Other Arrangements 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 and 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, allowing our customers to shop where and how they want.

A summary of our 2022, 2021 and 2020 revenue and net loss is as follows:

	Year Ended December 31,		
	2022	2021	2020
Revenue	$ 4,411	$ 4,764	$ 3,271
Net loss	(78)	(483)	(574)

As a global company, significant portions of our revenue and expenses are recorded in currencies other than the U.S. dollar. Accordingly, in any period, our reported revenue, expenses and resulting earnings (loss) are impacted by changes in the exchange rates of those currencies relative to the U.S. dollar.

Increases or decreases in inventory levels in our distribution channels 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, blackout shipping periods due to system downtime, implementations and integrations, 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

Industry Trends

The animal health industry, which includes 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
- owners sharing a unique and loving bond with their pets.

As demand for animal protein grows, farm animal health is becoming increasingly important. We believe that 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

Global Macroeconomic Environment

Our operations are conducted globally, and we are exposed to and are impacted by various global macroeconomic factors. Global economic conditions continue to create uncertainty, most notably due to the Russia-Ukraine conflict, the COVID-19 pandemic, supply chain disruptions, and rising inflation. Continued evolution of these conditions has led to economic slowdowns in certain countries and/or regions. It has also led to volatility in consumer behavior, which has reduced demand due to consumption decreases and retailer destocking, particularly impacting our parasiticide products. We expect these global macroeconomic factors to continue in 2023.

Russia-Ukraine Conflict

In February 2022, Russia commenced military action against Ukraine. In response, the U.S. and certain other countries imposed and continue to impose significant sanctions and export controls against Russia, Belarus and certain individuals and entities connected to Russian or Belarusian political, business, and financial organizations. The U.S. and certain other countries could impose further sanctions, trade restrictions, and other retaliatory actions if the conflict continues or worsens. The broader consequences of the conflict, including related inflationary pressures, geopolitical tensions, additional retaliatory actions taken by the U.S. and other countries, and any counter retaliatory actions by Russia or Belarus in response, including, for example, potential cyberattacks or the disruption of energy and commodity exports, are likely to cause regional instability and could materially adversely affect global trade, currency exchange rates, regional economies and the global economy. The situation remains uncertain and it is difficult to predict the impact that the conflict and actions taken in response to the conflict will have on our business; however, they could increase our costs, disrupt our supply chain, reduce our sales and earnings, or otherwise adversely affect our business and results of operations.

As a global animal health leader, we have an obligation to support the health of animals and people. At the center of that work is ensuring access and availability of food and avoiding the spread of disease. At this time, we are limiting our business in Russia to only the essential products that support these needs, while complying with all imposed sanctions. We do not currently manufacture products or source any materials from companies in Russia for use in our products, but that could change because of new laws requiring products sold in Russia to be produced there as well. We do not conduct business with the Russian government. During the year ended December 31, 2022, revenue to Russian and Ukrainian customers represented approximately 2% of our consolidated revenue. Assets held in Russia as of December 31, 2022 represented less than 1% of our consolidated assets.

COVID-19 Pandemic

We continue to closely monitor the impact of the COVID-19 pandemic, including its variants, and the related economic effects on all aspects of our business, including impacts on our operations, supply chain, and customer demand. The extent to which the COVID-19 pandemic may impact our financial condition and results of operations remains uncertain and is dependent on developments that are out of our control, including a resurgence in positive cases, the emergence of new variants, governmental actions in response to the pandemic (for example, the lockdown orders in China that were lifted in late 2022), and the successful administration of effective vaccines and boosters. We cannot predict the impact that the ongoing COVID-19 pandemic will have on our employees, customers, vendors and suppliers; however, the COVID-19 pandemic has had and may continue to have an adverse impact on our business.

Supply Chain

We continue to experience disruption and volatility in our global supply chain network. This disruption, combined with increased demand for key raw materials and labor constraints, has also impacted our suppliers, resulting in shortages of raw materials and 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, targeted increases of certain safety stocks, and alternative sources of materials. 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 high shipping costs, negatively impacting our profitability.

Inflation

We are experiencing, and expect to continue to experience, inflationary pressures due to, among other things, the geopolitical events and macroeconomic factors noted above. Increased inflation rates primarily impact us by increasing our costs, including raw materials, labor, energy, transportation, and other input costs, adversely affecting our profit margins, operating results, and cash flows. In response to these inflationary costs, we have implemented price increases and may implement additional price increases in the future.

Revision of Prior Period Financial Statements Primarily Relating to Tax Valuation Allowance Adjustment

In connection with the preparation of our financial statements as of and for the year ended December 31, 2022, a cumulative error was identified relating to the valuation allowance for taxes for a Southeast Asia affiliate. While immaterial to prior years, correcting this cumulative error in 2022 would have caused the 2022 financial statements to be materially misstated. Therefore, immaterial revisions in relation to this item were made to our financial statements as of and for the years ended December 31, 2021 and 2020. The correction of this error was immaterial to our financial statements for those years.

As a result of having to make the revisions related to this error, we made other immaterial revisions to the consolidated financial statements as of and for the years ended December 31, 2021 and 2020. All of the revisions are reflected throughout this Form 10-K. See Note 2: Revision of Previously Issued Consolidated Financial Statements to the consolidated financial statements for additional information.

Acquisitions of Bayer Animal Health and KindredBio

We have incurred 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 2022 and 2021 are 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. The ERP system integration of legacy Bayer Animal Health to the Elanco system is expected to be completed early in the second quarter of 2023. As a result, there may be a timeframe during which inventory shipments cannot occur. In response to this, we have built some additional inventory as of December 31, 2022 and expect to continue to increase our inventories on hand to ensure that our product is available to customers. Alternatively, we anticipate that certain customers may modify purchasing habits, which would cause a shift of revenue from the second quarter to the first quarter of 2023. In addition, we started extending payment terms in 2023 and may need to continue to extend payment terms to certain customers depending on the estimated timeframe during which shipments cannot occur and based on geography.

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 develop internally and may develop through joint ventures and products that we are able to obtain through licenses or acquisitions, 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 product quality, price, cost-effectiveness, promotional effectiveness, new product development and product differentiation. Certain products, both existing and new products that we introduce, may compete with other branded or generic products already on the market or that are later developed by competitors. 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.

Our acquisitions in the six years prior to the acquisition of Bayer Animal Health added, in the aggregate, $1.4 billion in revenue, 4,600 full-time employees, and 12 manufacturing and eight R&D sites. The acquisitions 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 2022, 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 marketing, selling and administrative functions. Our manufacturing cost savings strategies included improving manufacturing processes and headcount through lean manufacturing (minimizing waste while maintaining productivity), closing and selling manufacturing sites, consolidating our CMO network, strategically insourcing certain projects, and pursuing cost savings opportunities through alternate sources of supply. Additional cost savings have resulted from reducing the number of R&D sites, sales force consolidation and reducing discretionary and other general and administrative operating expenses.

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, 2022 and 2021, approximately 51% 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 decreased revenue by approximately 4% during the year ended December 31, 2022. Currency movements increased revenue by approximately 1% and decreased revenue by approximately 1% during the years ended December 31, 2021 and 2020, 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.

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.

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.

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, 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.

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, including but not limited to the factors identified in "Key Trends and Conditions Affecting Our Results of Operations."

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 3: Basis of Presentation to the consolidated financial statements.

	Year Ended December 31,			% Change	
(Dollars in millions)	2022	2021	2020	22/21	21/20
Revenue	$ 4,411	$ 4,764	$ 3,271	(7)%	46%
Costs, expenses and other:					
Cost of sales	1,913	2,132	1,667	(10)%	28%
% of revenue	43%	45%	51%		
Research and development	321	369	329	(13)%	12%
% of revenue	7%	8%	10%		
Marketing, selling and administrative	1,265	1,403	997	(10)%	41%
% of revenue	29%	29%	30%		
Amortization of intangible assets	528	556	360	(5)%	54%
% of revenue	12%	12%	11%		
Asset impairment, restructuring and other special charges	183	634	623	(71)%	2%
Interest expense, net of capitalized interest	241	236	150	2%	57%
Other (income) expense, net	32	5	(178)	NM	NM
Loss before income taxes	(72)	(571)	(677)	87%	16%
% of revenue	(2)%	(12)%	(21)%	NM	NM
Income tax expense (benefit)	6	(88)	(103)	107%	15%
Net loss	$ (78)	$ (483)	$ (574)	84%	16%

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)	2022	2021	2020	2022	2021	2020	22/21	21/20
Pet Health	$ 2,138	$ 2,350	$ 1,356	48 %	49 %	41 %	(9)%	73%
Farm Animal	2,219	2,332	1,835	50 %	49 %	56 %	(5)%	27%
Subtotal	4,357	4,682	3,191	99 %	98 %	98 %	(7)%	47%
Contract Manufacturing [1]	54	82	80	1 %	2 %	2 %	(34)%	3%
Total	$ 4,411	$ 4,764	$ 3,271	100 %	100 %	100 %	(7)%	46%

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 2022

(Dollars in millions)	Revenue	Price	FX Rate	Volume	Total	CER [1]
Pet Health	$ 2,138	2%	(4)%	(7)%	(9)%	(5)%
Farm Animal	2,219	2%	(5)%	(2)%	(5)%	—%
Subtotal	4,357	2%	(4)%	(5)%	(7)%	(2)%
Contract Manufacturing	54	—%	(4)%	(29)%	(34)%	(29)%
Total	$ 4,411	2%	(4)%	(5)%	(7)%	(3)%

Full year 2021

(Dollars in millions)	Revenue	Price	FX Rate	Volume [2]	Total	CER [1]
Pet Health	$ 2,350	4%	1%	68%	73%	72%
Farm Animal	2,332	—%	1%	26%	27%	26%
Subtotal	4,682	2%	1%	44%	47%	46%
Contract Manufacturing	82	—%	—%	3%	3%	3%
Total	$ 4,764	2%	1%	43%	46%	45%

Note: Numbers may not add due to rounding

[1] 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.

[2] Impact of 2021 revenue from Bayer Animal Health is reflected in volume.

Revenue

Pet Health revenue decreased by $212 million or 9%, driven by a decrease in volume and an unfavorable impact from foreign exchange rates, partially offset by an increase in price. On a constant currency basis, the decrease of 5% was primarily attributable to lower demand as a result of increased competition impacting certain parasiticide products as well as the overall deterioration in global macroeconomic conditions, which particularly impacted sales of over-the-counter U.S. parasiticide products. The impact was partially offset by growth in our global pain portfolio.

Farm Animal revenue decreased by $113 million or 5%, driven by an unfavorable impact from foreign exchange rates and a decrease in volume, partially offset by an increase in price. On a constant currency basis, revenue was flat year over year. Growth driven by increased demand for aqua products and the contribution from innovation was offset by a continued decline in swine, particularly driven by market conditions in Asia and to a lesser extent competition in Europe, as well as the impact of generic competition for certain cattle brands and the impact of supply chain disruptions.

Contract Manufacturing revenue decreased by $28 million to $54 million and represented 1% of total revenue.

Cost of Sales

	Year Ended December 31,			% Change	
(Dollars in millions)	2022	2021	2020	22/21	21/20
Cost of sales	$ 1,913	$ 2,132	$ 1,667	(10)%	28 %
% of revenue	43 %	45 %	51 %		

Cost of sales as a percentage of revenue decreased in 2022 as compared to 2021 primarily due to amortization of the fair value adjustment of $64 million recorded from the acquisition of Bayer Animal Health in 2021. Excluding the $64 million fair value adjustment for the year ended December 31, 2021, cost of sales as a percentage of revenue would have been approximately 43%, consistent with 2022. Cost of sales decreased in 2022 primarily due to lower revenue, improvements in manufacturing productivity and the impact of foreign exchange, partially offset by inflationary impacts on input costs, freight, and conversion costs as well as unfavorable product mix.

Research and Development

	Year Ended December 31,			% Change	
(Dollars in millions)	2022	2021	2020	22/21	21/20
Research and development	$ 321	$ 369	$ 329	(13)%	12 %
% of revenue	7 %	8 %	10 %		

R&D expenses decreased $48 million to $321 million in 2022 as compared to 2021. R&D expenses in the current year were favorably impacted by cost savings realized as a result of 2021 restructuring activities, lower professional services costs due the rationalization of certain R&D projects, and the impact of foreign exchange.

Marketing, Selling and Administrative

	Year Ended December 31,			% Change	
(Dollars in millions)	2022	2021	2020	22/21	21/20
Marketing, selling and administrative	$ 1,265	$ 1,403	$ 997	(10)%	41 %
% of revenue	29 %	29 %	30 %		

Marketing, selling and administrative expenses decreased $138 million in 2022 compared to 2021, primarily driven by disciplined cost management across the business, cost savings realized as a result of 2021 restructuring activities, a decrease in advertising and promotional costs, and the impact of foreign exchange, partially offset by increases in legal expenses during the period.

Amortization of Intangible Assets

	Year Ended December 31,			% Change	
(Dollars in millions)	2022	2021	2020	22/21	21/20
Amortization of intangible assets	$ 528	$ 556	$ 360	(5)%	54 %

Amortization of intangible assets decreased $28 million to $528 million in 2022 as compared to 2021, primarily due to the impact of foreign exchange rates.

Asset Impairment, Restructuring and Other Special Charges

(Dollars in millions)	Year Ended December 31, 2022	2021	2020	% Change 22/21	21/20
Asset impairment, restructuring and other special charges	$ 183	$ 634	$ 623	(71)%	2 %

For additional information regarding our asset impairment, restructuring and other special charges, see Note 7: Asset Impairment, Restructuring and Other Special Charges to the consolidated financial statements.

Asset impairment, restructuring and other special charges decreased $451 million to $183 million in 2022 as compared to 2021, due in part to a $177 million year over year decrease in severance charges and overall acquisition-related expenses. Also contributing to the decrease were certain nonrecurring charges recorded during 2021, including a $279 million charge to write down assets at our Shawnee and Speke manufacturing sites that were classified as held for sale to an amount equal to fair value less costs to sell, $66 million of impairment charges for intangible assets that were subject to product rationalization, a $26 million charge to establish a liability for future royalty and milestone payments relating to our canine parvovirus license agreement with KindredBio, and an $8 million charge related to a litigation settlement for a matter that originated prior to our acquisition of Bayer Animal Health. These decreases were partially offset by $29 million of nonrecurring pension curtailment gains recorded during 2021 as well as a $22 million asset write-down charge recorded upon the final sale of our Speke manufacturing site and a one-time charge of $59 million related to the expensing of an IPR&D asset licensed from BexCaFe, LLC (BexCaFe) during 2022. See Note 6: Acquisitions, Divestitures and Other Arrangements for further discussion.

Interest Expense, Net of Capitalized Interest

(Dollars in millions)	Year Ended December 31, 2022	2021	2020	% Change 22/21	21/20
Interest expense, net of capitalized interest	$ 241	$ 236	$ 150	2 %	57 %

Interest expense increased $5 million to $241 million in 2022, primarily due to $20 million in debt extinguishment losses recorded upon the retirement of a portion of the aggregate principal on our 4.272% Senior Notes due August 28, 2023 and our Term Loan B during the year and higher interest on variable-rate debt due to rate increases, partially offset by a lower average debt balance and the favorable impact of refinancing at lower interest rates.

Other (Income) Expense, Net

(Dollars in millions)	Year Ended December 31, 2022	2021	2020	% Change 22/21	21/20
Other (income) expense, net	$ 32	$ 5	$ (178)	NM	NM

Other expense increased $27 million in 2022 as compared to 2021, primarily due to a $14 million increase in foreign exchange losses and a $14 million decrease in up-front payments received and milestones earned from business development arrangements.

Other expense recorded during 2022 primarily consisted of foreign exchange losses and mark-to-market adjustments on equity investments, partially offset by up-front payments received in relation to license and asset assignment agreements, the gain recognized on the disposal of our microbiome R&D platform, and certain components of net periodic benefit cost. See Note 19: Retirement Benefits to the consolidated financial statements for further discussion related to net periodic benefit cost (income) recorded during the period. 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.

Income Tax Expense (Benefit)

(Dollars in millions)	Year Ended December 31, 2022	2021	2020	% Change 22/21	21/20
Income tax expense (benefit)	6	(88)	(103)	107 %	15 %
Effective tax rate	(8)%	15 %	15 %		

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 expense was $6 million in 2022 compared to an income tax benefit of $88 million in 2021. The change was primarily due to an increase in taxes on international operations driven by increased taxable income as well as an increase in state taxes in separate filing states offset by other decreases, including a $16 million Brazil income tax refund claim resulting from a Supreme Court decision rendered in 2022 that determined certain Brazil state valued-added tax (VAT) incentives were not subject to federal tax, a $17 million tax benefit due to the termination of interest rate swaps and a $12 million net reduction in taxes associated with the divestiture of the Speke manufacturing site. See Note 16: Income Taxes to our consolidated financial statements for further discussion.

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 intend to indefinitely reinvest foreign earnings for continued use in our foreign operations. See Note 16: Income Taxes to the consolidated financial statements for further discussion. As our business evolves, 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 integration of Bayer Animal Health. 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):	2022	2021	2020	22/21	21/20
Operating activities	$ 452	$ 483	$ (41)	$ (31)	$ 524
Investing activities	(179)	(530)	(4,779)	351	4,249
Financing activities	(549)	210	4,954	(759)	(4,744)
Effect of exchange rate changes on cash and cash equivalents	(17)	(31)	27	14	(58)
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (293)	$ 132	$ 161	$ (425)	$ (29)

Operating Activities

Our cash flow from operating activities decreased $31 million to $452 million for the year ended December 31, 2022 from $483 million for the year ended December 31, 2021. The decrease is primarily the result of a decrease in cash due to changes in operating assets and liabilities, particularly accounts receivable, inventories, and other assets, as compared to the prior year. This decrease was partially offset by a decrease in net loss after adjusting for non-cash items, as well as proceeds of $207 million from interest rate swap settlements in the current year. Due to the system integration scheduled to be completed in April 2023, we have and may need to further increase inventories on hand and extend payment terms for some customers during the first and second quarters of 2023 to ensure that our product is available for a period of time during which there may be no shipments. 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, except for those related to the system integration described above, it is also possible that we will need to extend payment terms in certain situations as a result of the COVID-19 global health pandemic, competitive pressures, macroeconomic factors and the need for certain inventory levels in our distribution channels 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 $351 million to $179 million for the year ended December 31, 2022 compared to $530 million for the year ended December 31, 2021. The decrease was primarily driven by cash paid for the acquisition of KindredBio during the year ended December 31, 2021, as well as a year over year decrease in cash paid for purchases of intangible assets. These decreases were partially offset by a year over year increase in cash used for purchases of property and equipment.

Financing Activities

Our cash used in financing activities was $549 million for the year ended December 31, 2022 compared to cash provided by financing activities of $210 million for the year ended December 31, 2021. Cash used for financing activities during 2022 primarily reflected the tender offer completed during the year as well as net repayments on our revolving credit facility and the repayment of indebtedness outstanding under our term loan B credit facility, partially offset by proceeds from our newly issued incremental term facilities. Cash provided by financing activities during 2021 primarily reflected proceeds from our borrowings under our debt financing arrangement with Farm Credit Mid-America, PCA, net 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.

Capital Expenditures and Software Purchases

Capital expenditures were $137 million during 2022, an increase of $11 million compared to 2021. Purchases of software were $34 million during 2022, an increase of $1 million compared to 2021. We expect 2023 capital expenditures and software purchases to be approximately $165 million to $190 million.

Description of Indebtedness

For a complete description of our debt and available credit facilities as of December 31, 2022, see Note 10: Debt to the consolidated financial statements.

Contractual Obligations

Our contractual obligations and commitments as of December 31, 2022 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. Purchase obligations consist of open purchase orders as of December 31, 2022 and contractual payment obligations with significant vendors which are noncancelable and are not contingent. These obligations are primarily short-term in nature. See Note 14: 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 estimates 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 4: Summary of Significant Accounting Policies and Note 5: 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 that is equal to the excess of the asset's carrying value over its fair value generally 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. We have historically performed our annual goodwill and indefinite-lived intangible asset impairment assessment as of the last day of the fourth fiscal quarter of each year. During the fourth quarter of 2022, we elected to change the date of our annual impairment assessment from December 31st to October 1st. The change was made to more closely align the impairment assessment date with our annual planning and budgeting process as well as our long-term planning and forecasting process. We have determined that this change in accounting principle is preferable and will not affect the consolidated financial statements. Pursuant to this change in accounting principle, in 2022 we performed an impairment assessment as of the first day of our fourth fiscal quarter. The change in impairment assessment date did not delay or avoid an impairment charge. This change is not applied retrospectively as it is impracticable to do so because retrospective application would require application of significant estimates and assumptions with the use of hindsight. Accordingly, the change has been applied prospectively.

When required, a comparison of fair value to the carrying amount of assets is performed to determine the amount of any impairment. In the third quarter of 2022, a significant change in our market capitalization relative to our book value, among other factors, triggered an impairment review. Based on our qualitative assessment, we concluded that it was more likely than not that the fair value of our single reporting unit was less than its carrying value, and therefore, we were required to perform a quantitative goodwill impairment test, which involved comparing the estimated fair value of our single reporting unit with its carrying value, including goodwill. As a result of the quantitative assessment, we concluded that no impairment existed with respect to our goodwill because the estimated fair value of our single reporting unit exceeded the carrying amount by more than 20%. Given the general worldwide economic conditions, we reevaluated our impairment testing from a qualitative perspective as December 31, 2022, which did not result in a change to our previous conclusion that no impairment exists.

Significant management judgment is required in estimating fair values in our impairment reviews and in the creation of forecasts of future operating results that are used in the discounted cash flow method of valuation. These include, but are not limited to, estimates and assumptions regarding (1) our future cash flows, revenue, and other profitability measures such as gross margin and EBITDA margin, (2) the long-term growth rate of our business, and (3) the determination of our weighted-average cost of capital, which is a factor in determining the discount rate. 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, results of research and development, and changes in macroeconomic conditions, including rising interest rates and inflation. A change in these assumptions or the use of alternative estimates and assumptions could have a significant impact on the estimated fair value and may expose us to impairment losses.

During the years ended December 31, 2022, 2021 and 2020, we recorded asset impairments of $60 million, $66 million and $17 million, respectively. For more information related to our impairment charges, see Note 7: 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 typically 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 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 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, 2022 and 2021, we had valuation allowances of $228 million and $182 million, respectively. In recent years we have incurred pre-tax losses in the U.S. primarily as a result of transaction, restructuring, integration and other costs. As a result, we have concluded that it is “more likely than not” that a portion of the U.S. deferred assets will not be utilized, and have recorded valuation allowances of $181 million and $162 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 "Item 8. Financial Statements and Supplementary Data — Note 4: Summary of Significant Accounting Policies - Implementation of New Financial Accounting ."

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. 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 increase our net loss by less than $1 million for the year ended December 31, 2022.

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, 2022, revenue generated in Argentina represented less than 1% of our consolidated revenue. Assets held in Argentina as of December 31, 2022 represented less than 1% of our consolidated assets.

During the first quarter of 2022, Turkey's three-year cumulative inflation rate exceeded 100%, and we concluded that Turkey became a hyperinflationary economy for accounting purposes. As of April 1, 2022, we applied hyperinflationary accounting for our subsidiary in Turkey and changed its functional currency from the Turkish lira to the U.S. dollar. During the year ended December 31, 2022, revenue in Turkey represented less than 1% of our consolidated revenue. Assets held in Turkey as of December 31, 2022 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, 2022, 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 and Term SOFR. As of December 31, 2022, we held certain interest rate swap agreements with a notional value of $3,050 million and maturities ranging from 2023 to 2025 that have the economic effect of modifying our variable interest such that a portion of the variable-rate interest payable becomes fixed. As of December 31, 2022, $4,151 million and $1,749 million of our total long-term debt, including the current portion, is fixed-rate debt (including variable-rate converted to fixed-rate through the use of interest rate swaps) and unhedged variable-rate debt, respectively. During the year ended December 31, 2022, we recorded a gain of $157 million, net of taxes on these interest rate swaps in other comprehensive loss. See "Item 8. Financial Statements and Supplementary Data — Note 11: Financial Instruments and Fair Value" 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, 2022 and 2021, the related consolidated statements of operations, comprehensive loss, equity and cash flows for each of the three years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2022, 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, 2022, 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 March 1, 2023 expressed an adverse 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 accounts or disclosures to which they relate.

Sales rebates and discounts

Description of the matter

At December 31, 2022, the Company's sales rebates and discounts liability totaled $324 million. As explained in Notes 4 and 5 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 in the same period that 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 inputs and 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 inputs and 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 inputs 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 rebate programs for direct and indirect customers 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.

Valuation of goodwill

Description of the matter

At December 31, 2022, the Company's goodwill was $5,993 million. As described in Note 12 to the consolidated financial statements, goodwill is recorded as the difference, if any, between the aggregate consideration paid for an acquisition and the fair value of the net tangible and intangible assets acquired. Goodwill is tested for impairment at least annually or more frequently if events or changes in circumstances indicate that it is more likely than not that goodwill may be impaired.

Auditing management's goodwill impairment test was complex and highly judgmental because the estimate underlying the determination of fair value of the reporting unit involves management's judgments on significant assumptions. In particular, management estimates fair value using the income approach which is sensitive to certain significant assumptions, such as future revenues, gross margins, earnings before interest, taxes, depreciation and amortization (EBITDA) margins and the discount rate commensurate with the risks involved.

How we addressed the matter in our audit

We tested the Company's internal controls over its assessment of the fair value of the reporting unit. This included testing controls over management's review of the significant assumptions used in the valuation model including future revenues, gross margins, EBITDA margins and the discount rate.

To test the estimated fair value of the Company's reporting unit, our audit procedures included, among others, assessing the valuation methodology and testing the significant assumptions discussed herein. For example, we compared the significant assumptions in the prospective financial information used by management to current industry and economic trends and historical performance. We assessed the reasonableness of the future revenues, gross margins and EBITDA margins by comparing the forecasts to historical results and analyst expectations. We performed sensitivity analyses of certain significant assumptions to evaluate the change in the fair value resulting from changes in the significant assumptions. We also involved our valuation specialists to assist in the evaluation of the fair value methodology and significant assumptions in the fair value estimate. In addition, we tested management's reconciliation of the fair value of the reporting unit to the market capitalization of the Company.

/s/ Ernst & Young LLP

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

Indianapolis, Indiana
March 1, 2023

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

	Year Ended December 31,		
	2022	2021	2020
Revenue	$ 4,411	$ 4,764	$ 3,271
Costs, expenses and other:			
Cost of sales	1,913	2,132	1,667
Research and development	321	369	329
Marketing, selling and administrative	1,265	1,403	997
Amortization of intangible assets	528	556	360
Asset impairment, restructuring and other special charges	183	634	623
Interest expense, net of capitalized interest	241	236	150
Other (income) expense, net	32	5	(178)
	4,483	5,335	3,948
Loss before income taxes	(72)	(571)	(677)
Income tax expense (benefit)	6	(88)	(103)
Net loss	$ (78)	$ (483)	$ (574)
Loss per share:			
Basic	$ (0.16)	$ (0.99)	$ (1.30)
Diluted	$ (0.16)	$ (0.99)	$ (1.30)
Weighted average shares outstanding:			
Basic	488.3	487.2	441.4
Diluted	488.3	487.2	441.4

See notes to consolidated financial statements.

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

	Year Ended December 31,		
	2022	2021	2020
Net loss	$ (78)	$ (483)	$ (574)
Other comprehensive income (loss):			
Cash flow hedges, net of taxes	157	86	(61)
Foreign currency translation	(419)	(613)	558
Defined benefit pension and retiree health benefit plans, net of taxes	79	15	(21)
Other comprehensive income (loss), net of taxes	(183)	(512)	476
Comprehensive loss	$ (261)	$ (995)	$ (98)

See notes to consolidated financial statements.

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

	December 31, 2022	December 31, 2021
Assets		
Current Assets		
Cash and cash equivalents	$ 345	$ 638
Accounts receivable, net of allowances of $13 (2022) and $12 (2021)	797	833
Other receivables	205	195
Inventories	1,538	1,371
Prepaid expenses and other	394	237
Total current assets	3,279	3,274
Noncurrent Assets		
Goodwill	5,993	6,172
Other intangibles, net	4,842	5,587
Other noncurrent assets	378	390
Property and equipment, net	999	1,055
Total assets	$ 15,491	$ 16,478
Liabilities and Equity		
Current Liabilities		
Accounts payable	$ 390	$ 416
Employee compensation	146	185
Sales rebates and discounts	324	319
Current portion of long-term debt	388	294
Other current liabilities	454	433
Total current liabilities	1,702	1,647
Noncurrent Liabilities		
Long-term debt	5,448	6,025
Accrued retirement benefits	161	271
Deferred taxes	662	765
Other noncurrent liabilities	229	262
Total liabilities	8,202	8,970
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; 474,237,738 and 473,119,786 shares issued and outstanding as of December 31, 2022 and 2021, respectively	—	—
Additional paid-in capital	8,738	8,696
Accumulated deficit	(1,057)	(979)
Accumulated other comprehensive loss	(392)	(209)
Total equity	7,289	7,508
Total liabilities and equity	$ 15,491	$ 16,478

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, 2019	373.0	$ —	$ 5,637	$ 79	$ —	$ (198)	$ 25	$ (173)	$ 5,543
Net loss	—	—	—	(574)	—	—	—	—	(574)
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	—	—	47	—	—	—	—	—	47
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	(496)	(61)	360	4	303	8,457
Net loss	—	—	—	(483)	—	—	—	—	(483)
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	(979)	25	(253)	19	(209)	7,508
Net loss	—	—	—	(78)	—	—	—	—	(78)
Other comprehensive income (loss), net of taxes	—	—	—	—	157	(419)	79	(183)	(183)
Stock-based compensation	—	—	58	—	—	—	—	—	58
Issuance of stock under employee stock purchase plan	0.1	—	1	—	—	—	—	—	1
Issuance of stock under employee stock plans, net	1.0	—	(17)	—	—	—	—	—	(17)
December 31, 2022	474.2	$ —	$ 8,738	$ (1,057)	$ 182	$ (672)	$ 98	$ (392)	$ 7,289

[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,		
	2022	2021	2020
Cash Flows from Operating Activities			
Net loss	$ (78)	$ (483)	$ (574)
Adjustments to reconcile net loss to cash flows from operating activities:			
Depreciation and amortization	682	716	517
Deferred income taxes	(57)	(148)	(114)
Stock-based compensation expense	59	66	47
Asset impairment and write-down charges	81	345	25
Loss (gain) on sale of assets	5	4	(51)
Loss (gain) on divestitures	(3)	1	(170)
Inventory fair value step-up amortization	—	64	90
Loss on extinguishment of debt	20	—	3
Proceeds from interest rate swap settlements	207	—	—
Other non-cash operating activities, net	(2)	6	17
Other changes in operating assets and liabilities, net of acquisitions and divestitures:			
Receivables	14	(35)	24
Inventories	(269)	29	(95)
Other assets	(109)	25	(122)
Accounts payable and other liabilities	(98)	(116)	362
Other changes in operating assets and liabilities	—	9	—
Net Cash Provided by (Used for) Operating Activities	452	483	(41)
Cash Flows from Investing Activities			
Purchases of property and equipment	(137)	(126)	(135)
Disposals of property and equipment	—	17	72
Purchases of software	(34)	(33)	(176)
Purchases of intangible assets	(13)	(38)	—
Cash paid for acquisitions, net of cash acquired	—	(342)	(5,001)
Divestiture proceeds	13	—	435
Other investing activities, net	(8)	(8)	26
Net Cash Used for Investing Activities	(179)	(530)	(4,779)
Cash Flows from Financing Activities			
Proceeds from issuance of long-term debt	425	500	4,804
Proceeds from revolving credit facility	563	500	—
Repayments of long-term borrowings	(677)	(573)	(952)
Repayments of revolving credit facility	(813)	(250)	—
Proceeds from issuance of common stock and tangible equity units	—	—	1,220
Debt issuance costs	(2)	(2)	(102)
Early redemption and tender premiums paid	(14)	—	—
Funding related to construction of corporate headquarters	(15)	64	—
Other financing activities, net	(16)	(29)	(16)
Net Cash Provided by (Used for) Financing Activities	(549)	210	4,954
Effect of exchange rate changes on cash and cash equivalents	(17)	(31)	27
Net increase (decrease) in cash, cash equivalents and restricted cash	(293)	132	161
Cash, cash equivalents and restricted cash at January 1	638	506	345
Cash, cash equivalents and restricted cash at December 31	$ 345	$ 638	$ 506

See notes to consolidated financial statements.

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 6: Acquisitions, Divestitures and Other Arrangements for additional information.

Note 2. Revision of Previously Issued Consolidated Financial Statements

In connection with the preparation of our financial statements as of and for the year ended December 31, 2022, a cumulative error was identified relating to the valuation allowance for taxes for a Southeast Asia affiliate. While immaterial to prior years, correcting this cumulative error in 2022 would have caused the 2022 financial statements to be materially misstated. The cumulative impact related to the Southeast Asia tax matter was a $20 million increase in income tax expense, of which $14 million and $6 million related to 2021 and 2020, respectively. In conjunction with making these corrections, we made other adjustments to the prior years to revise uncorrected errors. These corrections resulted in a $4 million cumulative adjustment to equity as of January 1, 2020. In accordance with Securities and Exchange Commission Staff Accounting Bulletin No. 99, *Materiality*, and Accounting Standards Codification (ASC) 250, *Accounting Changes and Error Corrections*, we assessed the materiality of these corrections and concluded that they were not material, individually or in the aggregate, to our prior period consolidated financial statements. Therefore, amendments of previously filed reports are not required.

The following tables represent revisions to our consolidated statements of operations, consolidated statements of equity and consolidated statements of cash flows for the years ended December 31, 2021 and 2020, as well as revisions to our consolidated balance sheet as of December 31, 2021, in accordance with ASC 250. The revisions to our consolidated statements of comprehensive loss were limited to the net loss revisions outlined below. We have also updated all accompanying notes and disclosures impacted by the revisions. The tables below include only those line items that include revisions to previously reported amounts. Revisions to our unaudited interim consolidated financial statements for the affected prior periods are disclosed in Note 21: Selected Quarterly Data.

Consolidated Statements of Operations

	Year Ended December 31, 2021			Year Ended December 31, 2020		
	As Reported	Revisions	As Revised	As Reported	Revisions	As Revised
Revenue	$ 4,765	$ (1)	$ 4,764	$ 3,273	$ (2)	$ 3,271
Cost of sales	2,134	(2)	2,132	1,667	—	1,667
Research and development	369	—	369	327	2	329
Marketing, selling and administrative	1,404	(1)	1,403	996	1	997
Asset impairment, restructuring and other special charges	628	6	634	623	—	623
Loss before income taxes	(567)	(4)	(571)	(672)	(5)	(677)
Income tax benefit	(95)	7	(88)	(112)	9	(103)
Net loss	(472)	(11)	(483)	(560)	(14)	(574)
Loss per share:						
Basic	$ (0.97)	$ (0.02)	$ (0.99)	$ (1.27)	$ (0.03)	$ (1.30)
Diluted	$ (0.97)	$ (0.02)	$ (0.99)	$ (1.27)	$ (0.03)	$ (1.30)
Weighted average shares outstanding:						
Basic	487.2	487.2	487.2	441.4	441.4	441.4
Diluted	487.2	487.2	487.2	441.4	441.4	441.4

Consolidated Balance Sheet

	December 31, 2021		
	As Reported	Revisions	As Revised
Inventories	$ 1,373	$ (2)	$ 1,371
Total current assets	3,276	(2)	3,274
Other noncurrent assets	387	3	390
Property and equipment, net	1,061	(6)	1,055
Total assets	16,483	(5)	16,478
Accounts payable	418	(2)	416
Sales rebates and discounts	316	3	319
Other current liabilities	430	3	433
Total current liabilities	1,643	4	1,647
Deferred taxes	745	20	765
Other noncurrent liabilities	261	1	262
Total liabilities	8,945	25	8,970
Accumulated deficit	(949)	(30)	(979)
Total equity	7,538	(30)	7,508
Total liabilities and equity	16,483	(5)	16,478

Consolidated Statements of Equity

	Additional Paid-In Capital			Retained Earnings (Accumulated Deficit)		
	As Reported	Revisions	As Revised	As Reported	Revisions	As Revised
December 31, 2019	$ 5,636	$ 1	$ 5,637	$ 84	$ (5)	$ 79
Net loss	—	—	—	(560)	(14)	(574)
Stock-based compensation	48	(1)	47	—	—	—
December 31, 2020	8,650	—	8,650	(477)	(19)	(496)
Net loss	—	—	—	(472)	(11)	(483)
December 31, 2021	8,696	—	8,696	(949)	(30)	(979)

Consolidated Statements of Cash Flows

	December 31, 2021			December 31, 2020		
	As Reported	Revisions	As Revised	As Reported	Revisions	As Revised
Net loss	$ (472)	$ (11)	$ (483)	$ (560)	$ (14)	$ (574)
Deferred income taxes	(154)	6	(148)	(125)	11	(114)
Stock-based compensation expense	66	—	66	48	(1)	47
Asset impairment and write-down charges	339	6	345	25	—	25
Receivables	(25)	(10)	(35)	14	10	24
Inventories	27	2	29	(95)	—	(95)
Other assets	22	3	25	(123)	1	(122)
Accounts payable and other liabilities	(120)	4	(116)	369	(7)	362

Note 3. 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 4. 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 is generally once the goods have shipped and the customer has assumed title. 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 estimates 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. Reserves for sales returns are recorded concurrently with revenue recognition as a deduction to arrive at our net product sales and a liability.

Research and Development Expenses

Research and development expenses include the following:

- Research and development costs, which are expensed as incurred; and
- Milestone payment obligations incurred prior to regulatory approval of the product, which are accrued when the event requiring payment of the milestone occurs.

Goodwill and Intangible Assets

We have historically performed our annual goodwill and indefinite-lived intangible asset impairment assessment as of the last day of the fourth fiscal quarter of each year. During the fourth quarter of 2022, we elected to change the date of our annual impairment assessment from December 31st to October 1st. The change was made to more closely align the impairment assessment date with our annual planning and budgeting process as well as our long-term planning and forecasting process. We have determined that this change in accounting principle is preferable and will not affect the consolidated financial statements. Pursuant to this change in accounting principle, in 2022 we performed an impairment assessment as of the first day of our fourth fiscal quarter. The change in impairment assessment date did not delay or avoid an impairment charge. This change was not applied retrospectively as it is impracticable to do so because retrospective application would require application of significant estimates and assumptions with the use of hindsight. Accordingly, the change has been applied prospectively. See Note 12: Goodwill and Intangibles for further accounting policy information.

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 $201 million and $248 million in 2022 and 2021, respectively. 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, 2022 and was adopted on that date:

Standard	Description	Effect on the financial statements or other significant matters
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.	The adoption of this guidance did not have a material impact on our consolidated financial statements.

The following table provides a brief description of an accounting standard applicable to us that has 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 2022-06, *Reference Rate Reform (Topic 848): Deferral of the Sunset Date of Topic 848*	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. ASU 2022-06 extends the period of time entities can utilize the reference rate reform relief guidance under ASU 2020-04 from December 31, 2022 to December 31, 2024.	Adoption of the guidance is optional and effective as of March 12, 2020 through December 31, 2024. Adoption is permitted at any time during the period on a prospective basis.	Our current credit facilities reference London Inter-Bank Offered Rate (LIBOR) as a benchmark rate. The underlying credit agreements include provisions which outline criteria for establishing a consistent replacement benchmark rate in the event that LIBOR is discontinued. Therefore, it is unlikely that we will need to adopt this optional guidance. However, we will continue to evaluate the impact as reference rate reform activities occur.

Note 5. 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, 2022 and 2021, the aggregate liability for sales rebates and discounts for these countries represented approximately 77% and 74%, respectively, of our total liability.

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

	Year Ended December 31,	
	2022	2021
Beginning balance	$ 319	$ 297
Reduction of revenue	682	674
Payments	(662)	(645)
Foreign currency translation adjustments	(15)	(7)
Ending balance	$ 324	$ 319

Adjustments to revenue recognized as a result of changes in estimates for the judgments described above during the years ended December 31, 2022, 2021 and 2020 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, 2022, 2021 and 2020.

Disaggregation of Revenue

The following table summarizes our revenue disaggregated by product category:

	2022	2021
Pet Health	$ 2,138	$ 2,350
Farm Animal:		
Cattle	944	980
Poultry	716	744
Swine	384	464
Aqua	175	144
Total Farm Animal	2,219	2,332
Contract Manufacturing [(1)]	54	82
Revenue	$ 4,411	$ 4,764

[(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

Pet Health, Farm Animal and Contract Manufacturing revenues were $1,356 million, $1,835 million and $80 million, respectively, for the year ended December 31, 2020. Further disaggregation of revenue is not available due to data limitations caused by our acquisition of Bayer Animal Health during that period. While we are able to accumulate certain Farm Animal species revenue in 2020 for internal reporting purposes, it requires significant estimations and assumptions, some of which rely on data that is neither reproducible nor validated through accepted control mechanisms. Therefore, we do not have sufficiently reliable data to disclose Farm Animal revenue by species in 2020.

Note 6. Acquisitions, Divestitures and Other Arrangements

During 2021 and 2020, we completed the acquisitions of KindredBio and Bayer Animal Health, respectively. 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 developed 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.

In May 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 $29 million liability upon the closing of our acquisition of KindredBio. Refer to Note 7: 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 fair value of 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		13
Property and equipment		33
Intangible assets, primarily acquired in-process research and development (IPR&D)		333
Deferred income taxes, net		(30)
Total identifiable net assets		380
Goodwill		35
Settlement of liability related to previous license agreement		29
Total consideration transferred	$	444

The valuation of assets acquired and liabilities assumed was finalized during the third quarter of 2022. The measurement period adjustments recorded in 2022 and 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, changes in the estimated fair value of acquired IPR&D and minor tax and working capital adjustments. The net impact of these adjustments was not material.

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 and $267 million for the years ended December 31, 2021 and 2020 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 year ended December 31, 2020 was $592 million. 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 was amortized to cost of sales as the inventory was sold to customers. As of December 31, 2021, the fair value step-up adjustment was 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 19: 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.

Pro forma financial information (unaudited)

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

	2020
Revenue	$ 4,439
Loss before income taxes	(680)

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 and Bayer Animal Health. 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 and Bayer Animal Health.

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.

Pending Acquisitions

NutriQuest U.S.

On December 17, 2022, we entered into an asset purchase agreement to acquire certain U.S. marketed products, pipeline products and inventory of NutriQuest, LLC (NutriQuest). NutriQuest is a provider of swine, poultry, and dairy nutritional health products to animal producers. Pursuant to the terms and conditions set forth in the asset purchase agreement, total consideration includes a $19 million up-front payment, excluding the value of inventory, to be paid in two installments, as well as up to $85 million of additional cash consideration if specific development, sales, and geographic expansion milestones are achieved. The transaction closed on January 3, 2023, and the accounting for this acquisition was incomplete at the time the consolidated financial statements were issued. We anticipate that this transaction will be accounted for as a business combination under the acquisition method of accounting.

NutriQuest Brazil

On January 22, 2023, we entered into an asset purchase agreement to acquire inventory and distribution rights for certain marketed products and certain other assets of NutriQuest Nutricao Animal Ltda (NutriQuest Brazil). Pursuant to the terms and conditions set forth in the asset purchase agreement, total consideration is $24 million to be paid in two installments, subject to certain post-closing adjustments. The transaction is expected to close during the second quarter of 2023. We anticipate that this transaction will be accounted for as a business combination under the acquisition method of accounting.

Divestitures

Microbiome R&D platform carve-out

In April 2022, we signed an agreement to transfer assets associated with our microbiome R&D platform to a newly created, independent biopharmaceutical company, BiomEdit, focused on developing solutions for animal and human health. As part of the agreement, we retain a non-voting, minority stake in the company. Assets transferred include intellectual property and laboratory equipment. The book values of those assets were not material. In addition, we have entered into transitional services agreements with the company for certain services. We have 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. During the year ended December 31, 2022, we recorded a gain on the disposal of approximately $3 million.

Shawnee and Speke divestitures

During 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, Kansas (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. In August 2021 and February 2022, we completed the sales of our Shawnee and Speke sites, respectively. Upon closing the sale of the Speke site, we recorded a contract asset of $55 million for the favorable supply agreement, which is included in prepaid expenses and other and other noncurrent assets on our consolidated balance sheets. Our fair value assessment for the favorable supply agreement was estimated using a combined income and market approach which incorporated Level 3 inputs. The divestitures did not represent a strategic shift that has or will have a major effect on our operations and financial results, and therefore did not qualify for reporting as discontinued operations. See Note 7: Asset Impairment, Restructuring and Other Special Charges for further information.

Based on the terms of the agreements, we expect to receive aggregate gross cash proceeds of $78 million from the sales of Shawnee and Speke over a period of three years, which began in the second half of 2022. During the year ended December 31, 2022, we received cash proceeds of $13 million. Receivables for the remaining expected cash proceeds are included in other receivables and other noncurrent assets on our consolidated balance sheets.

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.

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 31, 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 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
Inventories	$ 31
Property and equipment, net	50
Total assets held for sale	$ 81

BexCaFe Arrangement

In June 2022, we signed a license agreement with BexCaFe for the development and commercialization of products related to *Bexacat,* an oral treatment intended to reduce glucose levels in diabetic cats. BexCaFe held the rights to the compound through a license agreement with similar terms and conditions. We will incur all development and regulatory costs associated with the products. Based on the guidance in Accounting Standards Codification (ASC) 810, *Consolidation*, we determined that BexCaFe represents a variable interest entity and that we are the primary beneficiary of BexCaFe because the terms of the license give us the power to direct the activities that most significantly impact the entity's economic performance. As a result, we consolidated BexCaFe, a development-stage company with no employees that did not meet the definition of a business, as of the date we signed the license agreement. Upon initial consolidation of BexCaFe, we measured an IPR&D asset at its fair value of $59 million and recorded liabilities totaling $59 million, which included contingent consideration of $49 million based on the fair value of estimated future milestone payments and sales royalties owed under the license agreement. The initial fair value of the contingent payments was calculated based on an income approach, with payments adjusted for probability of success and then discounted to a present value. There is no minimum payout due on the contingent consideration and the maximum payout related to sales royalties is unlimited. Since BexCaFe did not meet the definition of a business, no goodwill was recorded and immediately after initial consolidation, we expensed the IPR&D asset because we concluded that it did not have an alternative future use. This amount is included in asset impairment, restructuring, and other special charges in our consolidated statement of operations for the year ended December 31, 2022.

We paid $10 million to BexCaFe under the terms of this agreement during the year ended December 31, 2022. Contingent consideration liabilities of $49 million are included in other current liabilities and other noncurrent liabilities on our consolidated balance sheet as of December 31, 2022. We will make $13 million of payments to BexCaFe in the first quarter of 2023 in connection with development/regulatory milestones achieved upon U.S. FDA approval of the original new animal drug application for *Bexacat* in December 2022.

Subsequent to the effective date of the license agreement, our consolidated financial statements include the assets, liabilities, operating results and cash flows of BexCaFe. Based on the guidance in ASC 810, income and expense between us and BexCaFe have been eliminated against the income or expense included in the financial statements of BexCaFe. The resulting amounts after the effect of these eliminations were included in our consolidated financial statements for the year ended December 31, 2022 and were not material.

Note 7. 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 3: Basis of Presentation and Note 4: 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 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 as of December 31, 2021.

The program announced in November 2021 included 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 eliminated approximately 380 positions. During the year ended December 31, 2021, activities related to this initiative resulted in charges of approximately $86 million, consisting of severance costs. During the year ended December 31, 2022, we recorded adjustments of $9 million to reduce severance accruals resulting from final negotiations and certain restructured employees filling open positions. Restructuring charges under this program were substantially complete as of December 31, 2022.

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 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 31, 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 as of December 31, 2021.

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

	2022	2021	2020
Restructuring charges (credits):			
Severance and other costs (credits) [1]	$ (9)	$ 110	$ 155
Facility exit costs (credits)	2	—	(3)
Acquisition related charges:			
Transaction and integration costs [2]	105	162	424
Non-cash and other items:			
Asset impairment [3]	60	66	17
Asset write-down [4]	21	284	19
Gain on sale of fixed assets	—	—	(4)
Net periodic benefit income (Note 19)	—	(29)	—
Settlements and other [5]	4	41	15
Total expense	$ 183	$ 634	$ 623

(1) 2022 credits primarily relate to adjustments resulting from the reversal of severance accruals associated with the November 2021 program. 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. 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.

(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) 2022 primarily includes a charge of $59 million related to the expensing of an IPR&D asset with no alternative future use licensed from BexCaFe during the second quarter. See Note 6: Acquisitions, Divestitures and Other Arrangements for further discussion. 2021 amounts represent the impact of adjustments to the fair value of certain IPR&D assets that were subject to product rationalization, including a decision by management to terminate an IPR&D 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. See Note 12: Goodwill and Intangibles for further information.

(4) 2022 primarily includes the finalization of the write-down charge upon the final sale of the Speke manufacturing site. 2021 primarily includes the initial 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, as well as adjustments to values of assets sold in relation to the Shawnee manufacturing site sold on August 1, 2021 and assets classified as held for sale in relation to the Speke manufacturing site. See Note 6: Acquisitions, Divestitures and Other Arrangements for further discussion. Also included are charges recorded to write down assets in Belford Roxo, Brazil; Basel, Switzerland; Cuxhaven, Germany; and Manukau, New Zealand that were classified as held and used to their current fair value. These charges were recorded in connection with announced restructuring programs.

(5) 2022 includes a $2 million measurement period adjustment to the charge associated with the settlement of a liability for future royalty and milestone payments triggered in connection with our acquisition of KindredBio. See Note 6: Acquisitions, Divestitures and Other Arrangements for further discussion. 2021 includes the initial charge associated with the settlement of the liability for future royalty and milestone payments triggered in connection with our acquisition of KindredBio, 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:

	Severance
Balance at December 31, 2020	$ 130
Charges	126
Reserve adjustment	(16)
Cash paid	(111)
Foreign currency translation adjustments	(3)
Balance at December 31, 2021	126
Charges	—
Reserve adjustment	(9)
Cash paid	(79)
Foreign currency translation adjustments	(2)
Balance at December 31, 2022	$ 36

These reserves are included in other current liabilities and other noncurrent liabilities on our consolidated balance sheets based on the timing of when the obligations are expected to be paid, which can vary due to certain country negotiations and regulations. As of December 31, 2022, we expect to pay approximately $29 million over the next 12 months. We believe that the reserves are adequate.

Note 8. 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:

	2022	2021
Finished products	$ 725	$ 598
Work in process	605	565
Raw materials and supplies	266	254
Total	1,596	1,417
Decrease to LIFO cost	(58)	(46)
Inventories	$ 1,538	$ 1,371

Inventories valued under the LIFO method comprised $288 million and $260 million of total inventories at December 31, 2022 and 2021, respectively.

Note 9. Equity

Common Stock Offering

In January 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

In January 2020, we also completed our offering of 11 million, 5.00% TEUs. Total proceeds, net of issuance costs, were $528 million. Each TEU was comprised of a prepaid stock purchase contract (prepaid stock) and a senior amortizing note due February 1, 2023. Subsequent to issuance, each TEU was legally separable into the two components. The prepaid stock was considered a freestanding financial instrument, indexed to Elanco common stock, and met 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 debt on the consolidated balance sheets. Issuance costs related to the amortizing notes are reflected as a reduction of the carrying amount and are 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 had an aggregate principal amount of $79 million bearing interest at 2.75% per year. On each February 1, May 1, August 1, and November 1 until the maturity date, we have paid 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 is 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 automatically settled 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 were 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 for the years ended December 31, 2022, 2021 and 2020. 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. The entire additional 3 million shares are included in diluted weighted average shares outstanding if the applicable market value is at or below $32.00 and the impact is not anti-dilutive.

On February 1, 2023, holders of our TEUs received 1.5625 shares of our common stock based on the settlement rate for the applicable market value of below $32.00. In total, we issued approximately 17 million shares to holders in connection with this settlement of the prepaid stock purchase contracts.

Note 10. Debt

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

	2022	2021
Incremental Term Facility due 2025	$ 175	$ —
Incremental Term Facility due 2028	494	499
Incremental Term Facility due 2029	249	—
Term Loan B due 2027	3,881	4,118
Revolving Credit Facility [(1)]	—	250
4.272% Senior Notes due 2023	344	750
4.900% Senior Notes due 2028	750	750
TEU Amortizing Notes due 2023	7	34
Unamortized debt issuance costs	(64)	(82)
	5,836	6,319
Less current portion of long-term debt	388	294
Total long-term debt	$ 5,448	$ 6,025

(1) In February 2023, we drew $100 million of net proceeds on our revolving credit facility.

Maturities on the principal amount of debt outstanding as of December 31, 2022 consist of the following:

As of and for the years ending December 31	
2023	$ 401
2024	50
2025	225
2026	50
2027	3,718
2028 and thereafter	1,456
Total obligations and commitments	5,900
Unamortized debt issuance costs	(64)
Total debt	$ 5,836

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

	2022	2021	2020
Interest paid	$ 266	$ 221	$ 131

2022 Financings

In April 2022, we entered into an incremental assumption agreement with Farm Credit Mid-America, PCA (Farm Credit) supplementing and amending our existing credit agreement dated August 1, 2020 relating to our senior secured credit facility. The incremental assumption agreement provides for an incremental term facility with an aggregate principal amount of $250 million maturing on April 19, 2029. The new incremental term facility bears interest at the Secured Overnight Financing Rate (Term SOFR), including a credit spread adjustment, plus 175 basis points and will be payable in quarterly installments of principal and interest with a final balloon payment due on April 19, 2029. The proceeds were used to repay a portion of our outstanding obligations under our revolving credit facility. 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.

In June 2022, we entered into an incremental assumption agreement with Bank of America, N.A. supplementing and amending our existing credit agreement dated August 1, 2020 relating to our senior secured credit facility. The incremental assumption agreement provides for an incremental term facility with an aggregate principal amount of $175 million. The new incremental term facility bears interest at Term SOFR, including a credit spread adjustment, plus 175 basis points and is payable in full on June 30, 2025. The proceeds were used to repay a portion of our outstanding obligations under our revolving credit facility. 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 and revolving credit facility.

2021 Financing

In August 2021, we entered into an incremental assumption agreement with Farm Credit supplementing and amending our existing credit agreement dated August 1, 2020 relating to our senior secured credit facility. The incremental assumption agreement provides for an incremental term facility with an aggregate principal amount of $500 million. 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 proceeds were used to retire our existing Senior Notes due August 27, 2021. 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 and revolving credit facility.

2020 Financings

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.

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. We may draw on our revolving credit facility as a source of liquidity for certain operating activities and for additional flexibility to finance capital investments, business development activities, repayments of debt, and other cash requirements.

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, 2022.

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, 2022.

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 (fully repaid as part of the August 2021 Farm Credit refinancing), $750 million of 4.272% Senior Notes due August 28, 2023 (partially repaid as part of our April 2022 tender offer discussed below), 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, 2022.

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, 2022. The TEU amortizing notes were fully repaid on February 1, 2023. See Note 9: Equity for further information.

Debt Extinguishment

In April 2022, we completed a tender offer and retired $406 million in aggregate principal amount of our 4.272% Senior Notes due August 28, 2023, resulting in a debt extinguishment loss of approximately $17 million recognized in interest expense, net of capitalized interest in the consolidated statements of operations. The repayment was funded with proceeds received from a draw under our revolving credit facility.

In 2022, we repaid indebtedness outstanding under our Term Loan B. We paid $195 million in cash, composed of principal and accrued interest, resulting in a debt extinguishment loss of approximately $3 million recognized in interest expense, net of capitalized interest in the consolidated statements of operations.

In January 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.

In September 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 11. 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 had investments without readily determinable fair values and equity method investments included in other noncurrent assets on the consolidated balance sheets totaling $27 million and $22 million as of December 31, 2022 and 2021, respectively. We recorded net unrealized losses of $8 million and $10 million in other (income) expense, net in the consolidated statements of operations for the years ended December 31, 2022 and 2021, respectively. Unrealized net gains in 2020 were $11 million.

The following table summarizes the fair value information at December 31, 2022 and 2021 for foreign exchange contract assets (liabilities), investments, 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, 2022					
Prepaid expenses and other - foreign exchange contracts not designated as hedging instruments	$ 76	$ —	$ 76	$ —	$ 76
Prepaid expenses and other - forward-starting interest rate contracts designated as cash flow hedges	14	—	14	—	14
Other noncurrent assets - forward-starting interest rate contracts designated as cash flow hedges	10	—	10	—	10
Other noncurrent assets - investments	7	7	—	—	7
Other current liabilities - foreign exchange contracts not designated as hedging instruments	(64)	—	(64)	—	(64)
Long-term debt, including current portion	(5,900)	—	(5,711)	—	(5,711)
December 31, 2021					
Prepaid expenses and other - foreign exchange contracts not designated as hedging instruments	$ 19	$ —	$ 19	$ —	$ 19
Other noncurrent assets - forward-starting interest rate contracts designated as cash flow hedges	8	—	8	—	8
Other noncurrent assets - investments	13	13	—	—	13
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)

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.

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. Further, we do not offset derivative assets and liabilities on the consolidated balance sheets. Our outstanding positions are discussed below.

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, 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. As of December 31, 2022 and 2021, we had outstanding foreign exchange contracts with aggregate notional amounts of $784 million and $1,212 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,		
	2022	2021	2020
Foreign exchange forward contracts [1]	$ (12)	$ (35)	$ (4)

[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 loss will remain in accumulated other comprehensive loss until either the sale or substantial liquidation of the hedged subsidiary.

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,		
	2022	2021	2020
Cross-currency interest rate swap contracts	$ —	$ —	$ 24

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. Our outstanding forward-starting interest rate swaps have maturities ranging between 2023 and 2025 with aggregate notional amounts of $3,050 million and $3,800 million as of December 31, 2022 and 2021, respectively.

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

	For the Year Ended December 31,		
	2022	2021	2020
Forward-starting interest rate swaps, net of tax benefit of $0, $0, and $15, respectively	$ 157	$ 86	$ (61)

During the years ended December 31, 2022, 2021 and 2020, activity on cash flow hedges recorded in other comprehensive income (loss) included gains of $224 million and $86 million and losses of $61 million, respectively, related to mark-to-market adjustments.

In April 2022 and September 2022, we took advantage of market opportunities to restructure our interest rate swap portfolio. We unwound the existing swaps and simultaneously entered into new agreements with the same notional amounts and covering the same tenors. As a result, we received cash settlements of $207 million. These gains were initially recognized in accumulated other comprehensive loss and are reclassified to interest expense, net of capitalized interest over the period during which the related interest payments are made.

During the year ended December 31, 2022, we reclassified $49 million of gains relating to our terminated interest rate swaps from accumulated other comprehensive loss to interest expense, net of capitalized interest. Additionally, as a result of the April 2022 interest rate swap settlement, other comprehensive income (loss) for the year ended December 31, 2022 included a $17 million reclassification of a stranded tax benefit from accumulated other comprehensive loss to income tax expense (benefit), based on our policy to reclassify income tax effects from accumulated other comprehensive loss using the portfolio approach. Other than the reclassification of the stranded tax benefit, there was no tax effect recorded in relation to our cash flow hedges for the years ended December 31, 2022 and 2021 after the application of the U.S. valuation allowance. See Note 16: Income Taxes for further discussion.

During the years ended December 31, 2022, 2021 and 2020, we reclassified $15 million, $28 million and $7 million, respectively, of net losses into interest expense. Over the next 12 months, we expect to reclassify a gain of $105 million, which includes $89 million relating to the interest rate swap settlements, to interest expense, net of capitalized interest.

Note 12. Goodwill and Intangibles

Goodwill

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

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
KindredBio measurement period adjustments		3
Goodwill associated with Speke divestiture		(3)
Foreign currency translation adjustments		(179)
Balance as of December 31, 2022	$	5,993

Goodwill is recorded as the difference, if any, between the aggregate consideration paid for an acquisition and the fair value of the net tangible and intangible assets acquired. Goodwill is not amortized, but is reviewed for impairment at least annually and when certain qualitative impairment indicators are present. When required, a comparison of fair value to the carrying amount of our single reporting unit is performed to determine the amount of any impairment. We begin by assessing qualitative factors to determine whether it is more likely than not that the fair value of our single reporting unit is less than its carrying value. Based on that qualitative assessment, if we conclude that it is more likely than not that the fair value of our single reporting unit is less than its carrying value, we conduct a quantitative goodwill impairment test, which involves comparing the estimated fair value of our single reporting unit to its carrying value, including goodwill. We estimate the fair value of our single reporting unit using an income approach. If the carrying value of the reporting unit exceeds its estimated fair value, we recognize an impairment loss for the difference.

During the third quarter of 2022, a significant change in our market capitalization relative to our book value, among other factors, triggered the need for an impairment review. However, no impairment existed with respect to our goodwill because the estimated fair value of our single reporting unit exceeded the carrying amount by more than 20%. Given the general worldwide economic conditions, we reevaluated our impairment testing from a qualitative perspective as December 31, 2022, which did not result in a change to our previous conclusion that no impairment exists.

No impairments have occurred with respect to the carrying value of goodwill for the years ended December 31, 2022, 2021 and 2020. Since a significant portion of our goodwill is denominated in foreign currencies, changes to our goodwill balance can occur over time due to changes in foreign exchange rates. See Note 6: Acquisitions, Divestitures and Other Arrangements for further discussion related to goodwill resulting from recent business combinations and changes in the carrying amount of goodwill.

Other Intangibles

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

Description	2022 Carrying Amount, Gross	2022 Accumulated Amortization	2022 Carrying Amount, Net	2021 Carrying Amount, Gross	2021 Accumulated Amortization	2021 Carrying Amount, Net
Finite-lived intangible assets:						
Marketed products	$ 6,561	$ (2,275)	$ 4,286	$ 6,828	$ (1,837)	$ 4,991
Software	310	(135)	175	285	(77)	208
Other	47	(31)	16	47	(28)	19
Total finite-lived intangible assets	6,918	(2,441)	4,477	7,160	(1,942)	5,218
Indefinite-lived intangible assets:						
Acquired in-process research and development	365	—	365	369	—	369
Other intangible assets	$ 7,283	$ (2,441)	$ 4,842	$ 7,529	$ (1,942)	$ 5,587

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. For the years ended December 31, 2022, 2021 and 2020, depreciation expense included software amortization of $65 million, $52 million, and $35 million, respectively.

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 capitalized R&D costs, 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.

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 those 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 recorded in relation to our other intangible assets were as follows:

	2022	2021	2020
Asset impairment, restructuring and other special charges	$ 60	$ 66	$ 17

During 2022, we recorded impairment charges comprised of $59 million for acquired IPR&D and $1 million for an other finite-lived intangible asset. The charge for acquired IPR&D primarily related to the expensing of an IPR&D asset with no alternative future use licensed from BexCaFe during the second quarter of 2022. See Note 6: Acquisitions, Divestitures and Other Arrangements for further discussion. The charge recorded for the other finite-lived intangible asset resulted from the termination of a license, development and commercialization agreement during the fourth quarter of 2022. As a result of the termination of the arrangement, the related technology had no alternative future use.

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 were 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.

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, 2022, the remaining weighted-average amortization periods for finite-lived intangible assets were as follows:

	Weighted Average Life (Years)
Marketed products	9
Software	5
Other	5

The estimated amortization expense for each of the next five years associated with our finite-lived intangible assets as of December 31, 2022 is as follows:

	2023	2024	2025	2026	2027
Estimated amortization expense	$ 512	$ 510	$ 491	$ 488	$ 456

Note 13. 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 carrying 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:

	2022	2021
Land	$ 40	$ 42
Buildings	578	543
Equipment	941	1,354
Construction in progress	163	157
	1,722	2,096
Less accumulated depreciation	(723)	(1,041)
Property and equipment, net	$ 999	$ 1,055

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

	2022	2021
United States	$ 554	$ 557
Germany	224	211
United Kingdom	3	59
France	52	54
Other foreign countries	166	174
Property and equipment, net	$ 999	$ 1,055

Depreciation expense related to property and equipment was as follows:

	2022	2021	2020
Depreciation expense	$ 89	$ 108	$ 122

Note 14. 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:

	2022	2021	2020
Lease cost			
Operating lease cost	$ 45	$ 43	$ 38
Short-term lease cost	1	1	1
Variable lease cost	5	4	3
Total lease cost	$ 51	$ 48	$ 42
Other information			
Operating cash outflows from operating leases	$ 33	$ 40	$ 36
Right-of-use assets obtained in exchange for new operating lease liabilities	32	36	138
Weighted-average remaining lease term - operating leases	7 years	7 years	8 years
Weighted-average discount rate - operating leases	4.0 %	3.8 %	3.8 %

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

Asset/Liability	Balance Sheet Classification	December 31, 2022	December 31, 2021
Right-of-use assets	Other noncurrent assets	$ 141	$ 161
Current operating lease liabilities	Other current liabilities	31	34
Non-current operating lease liabilities	Other noncurrent liabilities	111	127

As of December 31, 2022, the annual minimum lease payments for our operating lease liabilities were as follows:

2023	$	36
2024		28
2025		22
2026		17
2027		11
2028 and thereafter		50
Total lease payments		164
Less imputed interest		(22)
Total	$	142

Lease contracts that have been executed but have not yet commenced are excluded from the tables above. As of December 31, 2022, we have a lease commitment that has not yet commenced for our new corporate headquarters in Indianapolis, Indiana. Total minimum lease payments are estimated to be approximately $378 million over a term of 25 years, excluding extensions. The increase in estimated minimum lease payments in comparison to the prior year estimate of $310 million is primarily due to higher expected costs. Final lease payments may vary depending on the actual cost of certain construction activities. Lease commencement is expected in 2025.

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 statement 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 15. 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 20 million. As of December 31, 2022, the aggregate number of remaining shares available for future grant was approximately 12.2 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, 2022, 2021 or 2020. 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:

	2022	2021	2020
Total stock-based compensation expense [1]	$ 59	$ 66	$ 47
Related tax benefit	(3)	(11)	(8)

[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)	2022	2021	2020
Granted units	1.3	1.1	1.3
Weighted-average fair value	$ 28.17	$ 33.57	$ 27.44

Changes in the nonvested portion of RSUs for 2022 are summarized below:

(Shares in millions)	Shares	Weighted-Average Grant Date Fair Value
Nonvested units at January 1, 2022	2.2	$ 30.87
Granted	1.3	28.17
Vested	(1.1)	30.51
Forfeited	(0.4)	30.39
Nonvested units at December 31, 2022	2.0	29.40

The fair market value of RSUs vesting in 2022, 2021 and 2020 was $29 million, $30 million and $33 million, respectively.

As of December 31, 2022, the total remaining unrecognized stock-based compensation expense related to nonvested RSUs was $24 million, which is expected to be amortized over a weighted-average remaining requisite service period of 16 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, 2022 is summarized below:

(Shares in millions)	Shares	Weighted-Average Grant Date Fair Value
Nonvested awards at January 1, 2022	1.0	$ 30.53
Granted	0.5	28.94
Vested	(1.0)	33.45
Forfeited	0.0	31.40
Nonvested awards at December 31, 2022	0.5	28.94

The fair market value of PAs vesting in 2022, 2021 and 2020 was $23 million, $22 million and $2 million, respectively.

As of December 31, 2022, the total remaining unrecognized stock-based compensation expense related to nonvested PAs was $6 million, which is expected to be amortized over a weighted-average remaining requisite service period of 12 months.

Stock Option Program

Stock options represent the right to purchase shares of our common stock within a specified period of time at a specified price. The exercise price for a stock option will be not less than 100% of the fair market value of the common stock on the date of the grant.

We account for our employee stock options under the fair value method of accounting using a Black-Scholes-Merton valuation model to measure stock option expense at the date of grant. The corresponding expense is generally amortized on a straight-line basis over the vesting term.

Stock options were granted in 2022 to our officers, management and board members at exercise prices equal to the fair market value of our stock at the date of the grant. Options fully vest three years from the grant date and have a term of 10 years. No stock options were granted in 2021 and 2020.

The Black-Scholes-Merton model incorporates a number of valuation assumptions, which are noted in the following table, shown at their weighted-average values for the year ended December 31:

	2022
Expected dividend yield [1]	— %
Risk-free interest rate [2]	1.59 %
Expected stock price volatility [3]	36.5 %
Expected term [4] (years)	6

[1] We have never declared nor paid any dividends on our common stock, and we do not anticipate paying dividends on our common stock for the foreseeable future.

[2] Determined using the term-matched, zero-coupon risk-free rate from the Treasury Constant Maturity yield curve, continuously compounded

[3] Determined using a leverage-adjusted historical volatility of peer companies

[4] Determined using SEC safe harbor approach, based on a 3-year cliff vesting schedule and 10-year contractual term.

Stock option activity during the year ended December 31, 2022 is summarized below:

(Shares in millions)	Shares of Common Stock Attributable to Options	Weighted-Average Exercise Price of Options	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value[1]
Outstanding at January 1, 2022	0.3	$ 31.61		
Granted	0.5	28.94		
Exercised	—	—		
Forfeited or expired	—	—		
Outstanding at December 31, 2022	0.8	$ 30.11	7.7	$ —
Exercisable at December 31, 2022	0.3	31.61	5.8	—

(1) Market price of underlying Elanco common stock less exercise price. Options do not have an intrinsic value unless the market price exceeds the exercise price.

As of December 31, 2022, there was approximately $2 million of unrecognized compensation costs related to nonvested stock options, which is expected to amortize over an expected remaining weighted-average period of 18 months.

Note 16. Income Taxes

Our income tax provision for the years ended December 31, 2022, 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 by the Internal Revenue Service of tax years 2016 to 2018 began in 2019 and is ongoing. It is possible that the examination of these tax years could conclude within the next 12 months. Final resolution of certain matters is dependent upon several factors, including the potential for formal administrative proceedings.

Effective January 1, 2022, the Tax Cuts and Jobs Act of 2017 (2017 Tax Act) requires the capitalization of research and development (R&D) costs for tax purposes, which can be amortized over five years and 15 years for domestic and foreign costs, respectively. The implementation of this provision in 2022 resulted in the capitalization of $161 million in costs, of which $154 million will be amortized over five years and $7 million will be amortized over 15 years.

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. The tax benefit from an uncertain tax position is recognized 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.

The composition of loss before income tax expense (benefit) is as follows:

	2022	2021	2020
Federal	$ (350)	$ (341)	$ (491)
Foreign	278	(230)	(186)
Loss before income taxes	$ (72)	$ (571)	$ (677)

The composition of income tax expense (benefit) is as follows:

	2022	2021	2020
Current:			
Federal	$ 11	$ —	$ (36)
Foreign	51	59	54
State	1	1	(7)
Total current tax expense	63	60	11
Deferred:			
Federal	(20)	(11)	(6)
Foreign	(36)	(136)	(116)
State	(1)	(1)	8
Total deferred tax benefit	(57)	(148)	(114)
Income tax expense (benefit)	$ 6	$ (88)	$ (103)

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

	2022	2021
Deferred tax assets:		
Compensation and benefits	$ 32	$ 58
Accruals and reserves	54	41
Tax credit carryovers	53	53
Tax loss carryovers	329	311
Business interest deduction limitation	120	55
Inventories	30	18
Restructuring and other reserves	13	31
R&D capitalized assets	42	—
Operating lease liabilities	34	42
Other assets	13	34
Total gross deferred tax assets	720	643
Valuation allowances	(228)	(182)
Total deferred tax assets	492	461
Deferred tax liabilities:		
Right-of-use assets	(34)	(42)
Intangibles	(920)	(995)
Property and equipment	(70)	(80)
Cash flow hedge deferred gain	(42)	—
Other liabilities	(6)	—
Total deferred tax liabilities	(1,072)	(1,117)
Deferred tax liabilities - net	$ (580)	$ (656)

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, 2022, 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 $8 million and if unused, will begin to expire in 2036. The U.S. federal credits total $30 million and if unused, will begin to expire in 2029. The state credits total $15 million and if unused, will begin to expire in 2023. 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, 2022, we have net operating loss carryovers for foreign, U.S. federal and state income tax purposes of $329 million. $112 million will expire between 2023 and 2041, and $217 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.

Movements in the valuation allowance are summarized as follows:

	2022	2021
January 1	$ (182)	$ (100)
Increase	(49)	(88)
Release	3	6
December 31	$ (228)	$ (182)

The increase in the valuation allowance during 2022 was primarily attributable to the likelihood of not realizing the benefit of U.S. federal and state deferred tax assets because of U.S. pre-tax losses. The total net increase in the valuation allowance recorded in income tax expense (benefit) in the consolidated statements of operations was $80 million, $76 million and $72 million in 2022, 2021 and 2020, respectively with the remaining change in balance primarily recorded through accumulated other comprehensive loss.

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 deemed 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 required to be made. 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:

	2022	2021	2020
Cash payments of income taxes	$ 93	$ 151	$ 97

Income taxes receivable included in prepaid expenses and other on our consolidated balance sheets as of December 31 were as follows:

	2022	2021	2020
Income taxes receivable	$ 180	$ 130	$ 116

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:

	2022	2021	2020
Income tax benefit at the U.S. federal statutory tax rate	$ (15)	$ (120)	$ (143)
Add (deduct):			
Taxation of international operations	(27)	(16)	(15)
State taxes	(11)	(8)	(10)
Income tax credits	(13)	(14)	(24)
Non-deductible employee compensation	7	4	1
Other permanent adjustments	(2)	(8)	23
Change in uncertain tax positions	3	(2)	(7)
Change in valuation allowance	80	76	72
Brazil receivable	(16)	—	—
Income tax expense (benefit)	$ 6	$ (88)	$ (103)

The Brazil receivable is attributable to an income tax refund claim resulting from a Brazil Supreme Court decision rendered in 2022 that determined certain Brazil state value-added tax (VAT) incentives were not subject to federal tax.

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

	2022	2021	2020
Beginning balance at January 1	$ 6	$ 3	$ 8
Additions based on tax positions related to the current year	3	—	—
Changes for tax positions of prior years	—	(1)	(2)
Additions related to acquisition	7	4	—
Settlements	—	—	(3)
Ending balance at December 31	$ 16	$ 6	$ 3

The total amount of unrecognized tax benefits that, if recognized, would affect tax expense was $2 million, $6 million, and $3 million at December 31, 2022, 2021, and 2020, respectively. Additions related to acquisition represent unrecognized tax benefits related to the 2021 KindredBio acquisition that were recorded on the opening balance sheet.

We recognize both accrued interest and penalties related to unrecognized tax benefits in income tax expense (benefit). Interest and penalties related to income tax matters were not material for the years ended December 31, 2022, 2021 and 2020.

Note 17. Commitments and Contingencies

Legal Matters

We are party to various legal actions that arise in the normal course of business. The most significant matters are described below. Loss contingency provisions are recorded when it is deemed probable that we will incur a loss and we can formulate a reasonable estimate of that loss. For the litigation matters discussed below for which a loss is reasonably possible, we are unable to estimate the possible loss or range of loss, if any. The process of resolving these matters is inherently uncertain and may develop over an extended period of time; therefore, at this time, the

ultimate resolutions cannot be predicted. As of December 31, 2022 and 2021, we had no material liabilities established related to litigation as there were no significant claims which were probable and estimable.

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. On August 17, 2022, the Court issued an order granting our motion to dismiss the case without prejudice. On October 14, 2022, the plaintiffs filed a motion for leave to amend the complaint. We filed an opposition to the plaintiffs' motion on December 7, 2022. We believe the claims made in the case are meritless, and we intend to vigorously defend our position.

On October 16, 2020, a shareholder class action lawsuit captioned *Saffron 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 and entities. 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. From February 2021 to August 2022, this case was stayed in deference to *Hunter v. Elanco Animal Health Inc*. On October 24, 2022, we filed a motion to dismiss. The plaintiffs filed their opposition to the motion to dismiss on December 23, 2022. We believe the claims made in the case are meritless, and we intend to vigorously defend our position.

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 federal courts in the U.S. alleging that the *Seresto* collars contain pesticides 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. In August 2021, the lawsuits were consolidated by the Judicial Panel on Multidistrict Litigation, and the cases were transferred to the Northern District of Illinois. We are vigorously defending these lawsuits. In January 2023, an international lawsuit seeking damages for alleged negligence, breach of statutory regulations, breach of statutory duties, and deceptive marketing was filed against Elanco among other parties, arising out of the use of *Seresto* and *Foresto*™, a flea and tick collar for cats and dogs that is marketed and sold in Europe and in Israel. We intend to defend our position vigorously.

Further, in March 2021, a U.S. House of Representatives 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. On June 15, 2022, the subcommittee held a hearing at which our CEO testified. During and after the hearing, the subcommittee chair repeated his request that Elanco voluntarily recall the collars and also requested that the Environmental Protection Agency (EPA) commence administrative proceedings that would allow the EPA to remove *Seresto* from the market.

Seresto is a pesticide registered with the 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*. 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.

In the third quarter of 2019, Tevra Brands, LLC (Tevra) filed a complaint in the U.S. District Court of the Northern District of California, alleging that Bayer Animal Health (acquired by us in August 2020) had been involved in unlawful exclusive dealing and tying of its flea and tick products *Advantage*, *Advantix*, and *Seresto* and maintained a monopoly in the market. The complaint was amended in March 2020 and then dismissed in September 2020 with leave to amend. A second amended complaint was filed in March 2021 and realleges claims of unlawful exclusive dealing related to *Advantage* and *Advantix* and monopoly maintenance. A motion to dismiss the second amended complaint was denied in January 2022. Tevra's demands include both actual and treble damages. We intend to defend our position vigorously.

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. At this stage, we are unable to estimate the range of any potential loss associated with this matter.

Other Matters

Corporate Headquarters

The land for our new corporate headquarters is located in a Tax Increment Finance District, and the project is, in part, funded through Tax Incremental Financing (TIF) through an incentive agreement between us and the City of Indianapolis. The agreement provides for an estimated total incentive of $64 million to be funded by the City of Indianapolis in connection with the future tax increment revenue generated from the developed property. In December 2021, as part of a funding and development agreement entered into between us and the developer, we made a commitment to use the expected TIF proceeds towards the cost of developing and constructing the headquarters. In exchange, the developer reimbursed us up to the $64 million commitment in 2021. During the year ended December 31, 2022, we refunded approximately $15 million of the TIF proceeds to the developer. As a result, it is our expectation that our future lease payments will be reduced. The remaining accrued incentive is included in other noncurrent liabilities on our consolidated balance sheets and will be amortized over the lease term beginning on the commencement date and offset future rent expense.

Note 18. 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 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, Catosal, Clynav, Cydectin Denagard, Maxiban, Rumensin*, *Pulmotil* and other products for livestock, poultry and aquaculture, as well as *Advantage, Advantix, Advocate* (collectively referred to as the *Advantage Family), Credelio, TruCan*, *Galliprant, Interceptor Plus, Seresto, Trifexis* and other products for pets.

We have a single customer that accounted for 11%, 10% and 11% of revenue for the years ended December 31, 2022, 2021 and 2020, respectively. The product sales resulted in accounts receivable with this customer of $73 million and $74 million as of December 31, 2022 and 2021, 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:

	2022	2021	2020
United States	$ 1,965	$ 2,124	$ 1,475
International	2,446	2,640	1,796
Revenue	$ 4,411	$ 4,764	$ 3,271

Note 19. Retirement Benefits

Pension Plans

We sponsor various defined benefit pension plans, which cover certain employees worldwide. Our plans in Switzerland and Germany represent approximately 91% 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 recorded on the consolidated balance sheets at December 31 for our defined benefit pension plans, which were as follows:

	2022	2021
Change in benefit obligation:		
Benefit obligation at beginning of year	$ 462	$ 560
Service cost	14	18
Interest cost	4	2
Actuarial gain	(123)	(25)
Benefits paid	(12)	(4)
Plan amendments	(1)	—
Curtailment gain	—	(19)
Settlements	(1)	(38)
Foreign currency exchange rate changes and other adjustments	(19)	(32)
Benefit obligation at end of year	324	462

Change in plan assets:		
Fair value of plan assets at beginning of year	207	234
Actual return on plan assets	(26)	13
Employer contribution	12	12
Benefits paid	(12)	(4)
Settlements	(1)	(38)
Foreign currency exchange rate changes and other adjustments	(5)	(10)
Fair value of plan assets at end of year	175	207
Funded status	(148)	(255)
Unrecognized net actuarial (gain) loss	(82)	13
Unrecognized prior service cost	(30)	(34)
Net amount recognized	$ (260)	$ (276)
Amounts recognized in the consolidated balance sheet consisted of:		
Other noncurrent assets	$ 2	$ —
Other current liabilities	—	(1)
Accrued retirement benefits	(150)	(254)
Accumulated other comprehensive income before income taxes	(112)	(21)
Net amount recognized	$ (260)	$ (276)

The unrecognized net actuarial (gain) 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, 2022.

We do not expect any plan assets to be returned to us in 2023.

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

(Percentages)	2022	2021	2020
Discount rate for benefit obligation	3.4 %	1.1 %	0.6 %
Discount rate for net benefit costs	1.1	0.6	0.6
Rate of compensation increase for benefit obligation	3.0	2.7	3.1
Rate of compensation increase for net benefit costs	2.7	3.1	2.3
Expected return on plan assets for net benefit costs	3.1	2.9	3.2

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, 2022 and 2021 resulted in higher discount rates as compared to their prior years.

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:

	2023	2024	2025	2026	2027	2027-2031
Benefit payments	$ 12	$ 13	$ 14	$ 14	$ 16	$ 85

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

	2022	2021
Projected benefit obligation	$ 301	$ 455
Fair value of plan assets	150	200

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

	2022	2021
Accumulated benefit obligation	$ 289	$ 441
Fair value of plan assets	146	200

The total accumulated benefit obligation for our defined benefit pension plans was $314 million and $446 million at December 31, 2022 and 2021, respectively.

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

	2022	2021	2020
Service cost	$ 14	$ 18	$ 14
Interest cost	4	2	2
Expected return on plan assets	(6)	(6)	(6)
Amortization of prior service cost	(5)	(6)	(8)
Amortization of net actuarial loss	1	2	3
Net curtailments and settlements (Note 7)	—	(29)	—
Net pension expense (benefit)	$ 8	$ (19)	$ 5

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 7: Asset Impairment, Restructuring and Other Special Charges for further information.

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

	2022	2021	2020
Actuarial gain (loss) arising during period	$ 92	$ 29	$ (18)
Prior year service cost during the year	1	—	—
Amortization of prior service cost, including settlements, in net loss	(5)	(36)	(8)
Amortization of net actuarial loss, including curtailments, in net loss	1	22	3
Foreign currency exchange rate changes and other	1	—	1
Total other comprehensive income (loss) during period	$ 90	$ 15	$ (22)

We recognized $11 million of income tax expense in other comprehensive income (loss) related to our defined benefit plans during the year ended December 31, 2022. Amounts recognized in 2021 and 2020 were immaterial.

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 87% 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 35% fixed-income securities, 30% equity securities, a share of 22% in real estate and 13% 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: 51% fixed-income securities, 26% equity securities and 23% 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, 2022 by asset category are as follows:

Asset Class	Total	Fair Value Measurements Using: 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	$ 49	$ 47	$ —	$ —	$ 2
Fixed income:					
Developed markets	64	63	—	—	1
Emerging markets	9	9	—	—	—
Real estate	23	17	6	—	—
Other	30	25	5	—	—
Total	$ 175	$ 161	$ 11	$ —	$ 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, 2022.

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

Asset Class	Total	Fair Value Measurements Using: 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.

Contributions of $11 million to these pension plans are expected in 2023.

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 $34 million, $39 million and $35 million for the years ended December 31, 2022, 2021 and 2020, 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:

	2022	2021
Bayer-Pensionskasse	$ 2	$ 3
Rheinische-Pensionskasse	1	1
Total	$ 3	$ 4

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, 2021 and 2020 indicated total assets of $10,818 million and $11,476 million, respectively; total actuarial present value of accumulated plan benefits of $10,328 million and $10,950 million, respectively; and total contributions for all participating employers of $128 million and $134 million, respectively. Our plan contributions in 2022 and 2021 did not exceed 5% of the total contributions.

The Rheinische-Pensionskasse financial statements for the years ended December 31, 2021 and 2020 indicated total assets of $1,054 million and $1,026 million, respectively; total actuarial present value of accumulated plan benefits of $1,002 million and $972 million, respectively; and total contributions for all participating employers of $52 million each year. Our plan contributions in 2022 and 2021 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 20. 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. We also had variable common stock equivalents related to the TEU prepaid stock purchase contracts (see Note 9: 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 loss per share are calculated as follows:

	2022	2021	2020
Net loss available to common shareholders	$ (78)	$ (483)	$ (574)
Determination of shares:			
Weighted average common shares outstanding	488.3	487.2	441.4
Assumed conversion of dilutive common stock equivalents [1]	—	—	—
Diluted weighted average shares outstanding	488.3	487.2	441.4
Loss per share [2]			
Basic	$ (0.16)	$ (0.99)	$ (1.30)
Diluted	$ (0.16)	$ (0.99)	$ (1.30)

(1) During the years ended December 31, 2022, 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, 2022, 2021 and 2020, approximately 3.3 million, 3.2 million and 4.1 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 21. Selected Quarterly Data (unaudited)

In connection with the corrections discussed in Note 2: Revisions of Previously Issued Consolidated Financial Statements, we revised our unaudited interim consolidated financial statements for the affected prior periods as follows:

Condensed Consolidated Statements of Operations

	Three Months Ended March 31, 2022			Three Months Ended June 30, 2022			Three Months Ended September 30, 2022		
	As Reported	Revisions	As Revised	As Reported	Revisions	As Revised	As Reported	Revisions	As Revised
Revenue	$ 1,225	$ 1	$ 1,226	$ 1,177	$ (2)	$ 1,175	$ 1,028	$ (2)	$ 1,026
Marketing, selling and administrative	320	2	322	343	—	343	298	—	298
Asset impairment, restructuring and other special charges	46	(6)	40	86	—	86	26	—	26
Other (income) expense, net	9	—	9	—	(6)	(6)	8	—	8
Income (loss) before income taxes	71	4	75	(18)	4	(14)	(42)	(2)	(44)
Income tax expense (benefit)	23	1	24	4	(8)	(4)	7	14	21
Net income (loss)	48	3	51	(22)	12	(10)	(49)	(16)	(65)
Earnings (loss) per share:									
Basic	$ 0.10	—	$ 0.10	$ (0.04)	0.02	$ (0.02)	$ (0.10)	(0.03)	$ (0.13)
Diluted	$ 0.10	—	$ 0.10	$ (0.04)	0.02	$ (0.02)	$ (0.10)	(0.03)	$ (0.13)
Weighted average shares outstanding:									
Basic	488.0	488.0	488.0	488.4	488.4	488.4	488.4	488.4	488.4
Diluted	492.2	492.2	492.2	488.4	488.4	488.4	488.4	488.4	488.4

Amounts presented may not recalculate in total due to rounding.

	Three Months Ended March 31, 2021			Three Months Ended June 30, 2021		
	As Reported	Revisions	As Revised	As Reported	Revisions	As Revised
Revenue	$ 1,242	$ 1	$ 1,243	$ 1,279	$ (1)	$ 1,278
Cost of sales	569	(3)	566	551	—	551
Marketing, selling and administrative	348	1	349	385	—	385
Asset impairment, restructuring and other special charges	108	—	108	299	6	305
Interest expense, net of capitalized interest	61	—	61	60	—	60
Income (loss) before income taxes	(80)	3	(77)	(236)	(7)	(243)
Income tax expense (benefit)	(19)	6	(13)	(26)	(11)	(37)
Net income (loss)	(61)	(3)	(64)	(210)	4	(206)
Earnings (loss) per share:						
Basic	$ (0.12)	(0.01)	$ (0.13)	$ (0.43)	0.01	$ (0.42)
Diluted	$ (0.12)	(0.01)	$ (0.13)	$ (0.43)	0.01	$ (0.42)
Weighted average shares outstanding:						
Basic	486.7	486.7	486.7	487.3	487.3	487.3
Diluted	486.7	486.7	486.7	487.3	487.3	487.3

Amounts presented may not recalculate in total due to rounding.

	Three Months Ended September 30, 2021			Three Months Ended December 31, 2021		
	As Reported	Revisions	As Revised	As Reported	Revisions	As Revised
Revenue	$ 1,131	$ —	$ 1,131	$ 1,113	$ (1)	$ 1,112
Marketing, selling and administrative	342	—	342	329	(2)	327
Income (loss) before income taxes	(130)	—	(130)	(121)	1	(120)
Income tax expense (benefit)	(26)	4	(22)	(24)	9	(15)
Net loss	(104)	(4)	(108)	(97)	(8)	(105)
Loss per share:						
Basic	$ (0.21)	(0.01)	$ (0.22)	$ (0.20)	(0.02)	$ (0.22)
Diluted	$ (0.21)	(0.01)	$ (0.22)	$ (0.20)	(0.02)	$ (0.22)
Weighted average shares outstanding:						
Basic	487.3	487.3	487.3	487.4	487.4	487.4
Diluted	487.3	487.3	487.3	487.4	487.4	487.4

Amounts presented may not recalculate in total due to rounding.

Condensed Consolidated Statements of Cash Flows

	Three Months Ended March 31, 2022			Six Months Ended June 30, 2022			Nine Months Ended September 30, 2022		
	As Reported	Revisions	As Revised	As Reported	Revisions	As Revised	As Reported	Revisions	As Revised
Net income (loss)	$ 48	$ 3	$ 51	$ 26	$ 15	$ 41	$ (23)	$ (1)	$ (24)
Deferred income taxes	(11)	4	(7)	(40)	6	(34)	(36)	8	(28)
Asset impairment and write-down charges	28	(6)	22	87	(6)	81	87	(6)	81
Changes in operating assets and liabilities	(331)	(1)	(332)	(369)	(15)	(384)	(384)	(1)	(385)

Year-to-date amounts presented in the table above may not equal the sum of quarter-to-date amounts due to rounding.

	Three Months Ended March 31, 2021			Six Months Ended June 30, 2021			Nine Months Ended September 30, 2021		
	As Reported	Revisions	As Revised	As Reported	Revisions	As Revised	As Reported	Revisions	As Revised
Net loss	$ (61)	$ (3)	$ (64)	$ (271)	$ —	$ (271)	$ (375)	$ (3)	$ (378)
Deferred income taxes	(32)	4	(28)	(114)	(6)	(120)	(119)	(3)	(122)
Asset impairment and write-down charges	9	—	9	278	6	284	334	6	340
Changes in operating assets and liabilities	(183)	(1)	(184)	(190)	—	(190)	(243)	—	(243)

Year-to-date amounts presented in the table above may not equal the sum of quarter-to-date amounts due to rounding.

Note 22. Related Party Agreements and Transactions

Transactions and Agreements with Bayer

While Bayer is no longer considered a related party, we 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 from August 2020 to December 2020. Those 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 provided a refund for payment amounts duplicated in these regions. The total amount paid to and received from Bayer in 2021 and 2020 for those local country asset purchases was approximately $16 million and $633 million, respectively. All local country asset purchases were completed as of December 31, 2021.

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 were ineffective due to the material weakness in internal control over financial reporting described below. Notwithstanding this material weakness, management concluded that the consolidated financial statements included in this report present fairly, in all material respects, our financial condition, results of operations and cash flows for the periods covered by this report and our external auditors have issued an unqualified opinion on our consolidated financial statements as of and for the year ended December 31, 2022.

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). In connection with the audit of our financial statements for the fiscal year ended December 31, 2022, we identified a material weakness related to the ineffective review of the annual income tax provision, including the valuation allowance related to deferred tax assets. This resulted in the immaterial revisions to our previously-reported financial results for the years ended December 31, 2021 and 2020, as detailed within this report.

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, 2022 and has issued an adverse report thereon as stated in their report which is included herein.

Remediation of Material Weakness

As discussed above, the material weakness related to the ineffective review of the annual income tax provision was identified in connection with the audit of our financial statements for the fiscal year ended December 31, 2022. We are in the process of identifying all issues contributing to this material weakness and developing a remediation plan.

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, 2022 other than the identification of the material weakness discussed above.

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, 2022, 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, because of the effect of the material weakness described below on the achievement of the objectives of the control criteria, Elanco Animal Health Incorporated (the Company) has not maintained effective internal control over financial reporting as of December 31, 2022, based on the COSO criteria.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management's assessment. Management has identified a material weakness related to the ineffective review of the annual income tax provision, including the valuation allowance related to deferred tax assets.

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, 2022 and 2021, the related consolidated statements of operations, comprehensive loss, equity and cash flows for each of the three years in the period ended December 31, 2022, and the related notes. This material weakness was considered in determining the nature, timing and extent of audit tests applied in our audit of the 2022 consolidated financial statements, and this report does not affect our report dated March 1, 2023, which 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
March 1, 2023

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, 2022 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, 2022, 2021 and 2020
- Consolidated Statements of Comprehensive Loss—Years Ended December 31, 2022, 2021 and 2020
- Consolidated Balance Sheets—December 31, 2022 and 2021
- Consolidated Statements of Equity—Years Ended December 31, 2022, 2021 and 2020
- Consolidated Statements of Cash Flows—Years Ended December 31, 2022, 2021 and 2020

- 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
2.2	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 May 18, 2022 (incorporated by reference to Exhibit 3.1 of the Quarterly Report on Form 10-Q filed with the SEC on August 8, 2022).
3.2	Amended and Restated Bylaws of Elanco Animal Health Incorporated, effective May 18, 2022 (incorporated by reference to Exhibit 3.1 of the Current Report on Form 8-K filed with the SEC on May 19, 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	Description of Securities (filed herewith)
10.1	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).
10.2	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).
10.3	Incremental Assumption Agreement, dated April 19, 2022, 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 April 20, 2022)
10.4	Incremental Assumption Agreement, dated June 28, 2022 by and among Elanco Animal Health Incorporated, Elanco US Inc., the subsidiary loan parties party thereto, Bank of America, N.A., as incremental term lender, each other person party thereto 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 June 29, 2022)
10.5	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)*
10.6	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)*
10.7	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).*
10.8	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).*
10.9	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).*
10.10	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)*
10.11	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)*
10.12	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)*

10.13	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).*
10.14	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).*
10.15	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).*
10.16	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)
10.17	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)*
10.18	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).*
10.19	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).*
10.20	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)*
10.21	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).*
10.22	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).*
10.23	Elanco Animal Health Incorporated Amended and Restated Corporate Bonus Plan (filed herewith).*
10.24	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).*
10.25	Form of Elanco Animal Health Incorporated Restricted Stock Unit Award Agreement for executives with respect to annual awards (filed herewith).*
10.26	Form of Elanco Animal Health Incorporated Performance-Based Award Agreement for executives with respect to annual awards (filed herewith).*
10.27	Form of Elanco Animal Health Incorporated Nonqualified Stock Option Award Agreement for executives with respect to annual awards (filed herewith).*
10.28	Elanco Animal Health Incorporated Amended and Restated Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the SEC on May 19, 2022).*
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, 2022, 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 Section 13 or 15(d) 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: March 1, 2023

/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: March 1, 2023
/s/ Todd S. Young Todd S. Young Executive Vice President, Chief Financial Officer (principal financial officer)	Date: March 1, 2023
/s/ James M. Meer James M. Meer Senior Vice President, Chief Accounting Officer (principal accounting officer)	Date: March 1, 2023
/s/ R. David Hoover R. David Hoover Chairman of the Board	Date: March 1, 2023
/s/ Kapila Kapur Anand Kapila Kapur Anand Director	Date: March 1, 2023
/s/ John P. Bilbrey John P. Bilbrey Director	Date: March 1, 2023
/s/ William F. Doyle William F. Doyle Director	Date March 1, 2023

/s/ Art A. Garcia — Date: March 1, 2023

Art A. Garcia
Director

/s/ Michael J. Harrington — Date: March 1, 2023

Michael J. Harrington
Director

/s/ Paul Herendeen — Date: March 1, 2023

Paul Herendeen
Director

/s/ Deborah T. Kochevar — Date: March 1, 2023

Deborah T. Kochevar
Director

/s/ Lawrence E. Kurzius — Date: March 1, 2023

Lawrence E. Kurzius
Director

/s/ Kirk McDonald — Date: March 1, 2023

Kirk McDonald
Director

/s/ Denise Scots-Knight Ph.D. — Date: March 1, 2023

Denise Scots-Knight Ph.D.
Director

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Securities Information

Common Stock

Listed on the New York Stock Exchange – trading symbol ELAN.

Shareholders of Record

Number of shares outstanding at the record date: 492,047,948

Corporate Information

Corporate Office
Elanco Animal Health
2500 Innovation Way
Greenfield, IN 46140 USA
1 (877) 352-6261

Elanco Contacts

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Head, Global Corporate Communications
1 (317) 989-7011
colleen.dekker@elancoah.com

Katy Grissom
Head, Investor Relations
1 (317) 273-9284
kathryn.grissom@elancoah.com

Marcela Kirberger
Executive Vice President, General Counsel and Corporate Secretary
1 (317) 381-1153
marcela.kirberger@elancoah.com

Transfer Agent and Registrar

Communications concerning shareholder address changes, stock transfer, changes of ownership, lost stock certificates, payment of dividends, dividend check replacements, duplicate mailings or other account services should be directed to the following:

Shareholder correspondence should be mailed to:

Computershare
C/O: Shareholder Services
P.O. Box 43078
Providence, RI 02940-3078

Overnight correspondence should be sent to:

Computershare
C/O: Shareholder Services
150 Royall Street Suite 101
Canton, MA 02021

1 (800) 736-3001

1 (781) 575-3100

webqueries@computershare.com

www.computershare.com/investor

For additional information visit **elanco.com**

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