

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-Q

Quarterly Report Under Section 13 or 15(d) of the
Securities Exchange Act of 1934
FOR THE QUARTERLY PERIOD ENDED SEPTEMBER 30, 2021
OR

Transition Report Pursuant To Section 13 or 15(d) of the
Securities Exchange Act of 1934
COMMISSION FILE NUMBER 001-38661



Elanco Animal Health Incorporated

(Exact name of Registrant as specified in its charter)

INDIANA
(State or other jurisdiction of
incorporation or organization)

82-5497352
(I.R.S. Employer
Identification No.)

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

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

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, no par value	ELAN	New York Stock Exchange
5.00% Tangible Equity Units	ELAT	New York Stock Exchange

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 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
Non-accelerated filer

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 is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes No

The number of shares of common stock outstanding as of November 1, 2021 were 473,098,643

ELANCO ANIMAL HEALTH INCORPORATED
FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2021
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FORWARD-LOOKING STATEMENTS AND RISK FACTOR SUMMARY

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

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

- heightened competition, including from generics;
- the impact of disruptive innovations and advances in veterinary medical practices, animal health technologies and alternatives to animal-derived protein;
- changes in regulatory restrictions on the use of antibiotics in farm animals;
- our ability to implement our business strategies or achieve targeted cost efficiencies and gross margin improvements;
- consolidation of our customers and distributors;
- an outbreak of infectious disease carried by farm animals;
- the impact on our operations, the supply chain, customer demand, and our liquidity as a result of the COVID-19 global health pandemic;
- the success of our R&D and licensing efforts;
- misuse, off-label or counterfeiting use of our products;
- unanticipated safety, quality or efficacy concerns and the impact of identified concerns associated with our products;
- the impact of weather conditions and the availability of natural resources;
- use of alternative distribution channels and the impact of increased or decreased sales to our channel distributors resulting in fluctuation in our revenues;
- manufacturing problems and capacity imbalances;
- challenges to our intellectual property rights or our alleged violation of rights of others;
- risks related to our presence in foreign markets;
- breaches of our information technology systems;
- our ability to complete acquisitions and successfully integrate the businesses we acquire, including KindredBio and the animal health business of Bayer (Bayer Animal Health);
- the terms, timing or structure of any separation of the microbiome R&D platform, including whether it will be consummated at all, and whether the operational and strategic benefits of such transaction can be achieved, including whether the uncertainty of announcing the separation initiative will have adverse impacts on the employees, customers and suppliers related to the platform;
- the effect of our substantial indebtedness on our business;

- the uncertainties inherent in research relating to product safety and additional analyses of existing safety data;
- actions by regulatory bodies, including as a result of their interpretation of studies on product safety;
- unfavorable publicity resulting from media reports on our products;
- public acceptance of our products;
- fluctuations in our business results due to seasonality and other factors; and
- the impact of litigation, regulatory investigations, and other legal matters.

See Item 1A, "Risk Factors," of Part I of our Annual Report on Form 10-K for the year ended December 31, 2020 filed with the Securities and Exchange Commission (SEC), and Item 1A, "Risk Factors," of Part II of our Quarterly Reports on Form 10-Q for the periods ended June 30, 2021 and March 31, 2021 and Part II of this Quarterly Report on Form 10-Q, 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 quarterly report. If any of these risks materialize, or if any of the 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 quarterly report. 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 quarterly report. Any forward-looking statement made by us in this quarterly report 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. FINANCIAL STATEMENTS

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue	\$ 1,131	\$ 890	\$ 3,652	\$ 2,134
Costs, expenses and other:				
Cost of sales	502	442	1,622	1,071
Research and development	94	88	277	214
Marketing, selling and administrative	342	278	1,075	623
Amortization of intangible assets	141	96	417	197
Asset impairment, restructuring and other special charges	111	262	518	456
Interest expense, net of capitalized interest	60	48	181	89
Other (income) expense, net	11	(115)	8	(162)
	1,261	1,099	4,098	2,488
Loss before income taxes	(130)	(209)	(446)	(354)
Income tax benefit	(26)	(74)	(71)	(117)
Net loss	\$ (104)	\$ (135)	\$ (375)	\$ (237)
Loss per share:				
Basic	\$ (0.21)	\$ (0.29)	\$ (0.77)	\$ (0.56)
Diluted	\$ (0.21)	\$ (0.29)	\$ (0.77)	\$ (0.56)
Weighted average shares outstanding:				
Basic	487.3	462.4	487.1	426.5
Diluted	487.3	462.4	487.1	426.5

See notes to condensed consolidated financial statements.

Elanco Animal Health Incorporated
Condensed Consolidated Statements of Comprehensive Loss (Unaudited)
(In millions)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net loss	\$ (104)	\$ (135)	\$ (375)	\$ (237)
Other comprehensive income (loss):				
Unrealized gain (loss) on derivatives for cash flow hedges, net of taxes	4	(7)	52	(67)
Foreign currency translation	(209)	101	(506)	121
Defined benefit pension and retiree health benefit plans, net of taxes	(6)	(1)	5	(2)
Other comprehensive income (loss), net of taxes	(211)	93	(449)	52
Comprehensive loss	\$ (315)	\$ (42)	\$ (824)	\$ (185)

See notes to condensed consolidated financial statements.

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

	September 30, 2021 (Unaudited)	December 31, 2020
Assets		
<i>Current Assets</i>		
Cash and cash equivalents	\$ 453	\$ 495
Accounts receivable, net of allowances of \$11 (2021) and \$9 (2020)	924	872
Other receivables	158	205
Inventories	1,383	1,578
Prepaid expenses and other	242	256
Restricted cash	—	11
Total current assets	3,160	3,417
<i>Noncurrent Assets</i>		
Goodwill	6,191	6,225
Other intangibles, net	5,816	6,387
Other noncurrent assets	357	348
Property and equipment, net of accumulated depreciation of \$1,050 (2021) and \$1,038 (2020)	1,041	1,316
Total assets	\$ 16,565	\$ 17,693
Liabilities and Equity		
<i>Current Liabilities</i>		
Accounts payable	\$ 436	\$ 501
Employee compensation	159	144
Sales rebates and discounts	316	295
Current portion of long-term debt	61	555
Other current liabilities	390	582
Total current liabilities	1,362	2,077
<i>Noncurrent Liabilities</i>		
Long-term debt	6,273	5,572
Accrued retirement benefits	302	346
Deferred taxes	726	900
Other noncurrent liabilities	220	322
Total liabilities	8,883	9,217
<i>Commitments and Contingencies</i>		
	—	—
<i>Equity</i>		
Preferred stock, no par value, 1,000,000,000 shares authorized; none issued	—	—
Common stock, no par value, 5,000,000,000 shares authorized, 473,033,625 and 471,921,116 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	—	—
Additional paid-in capital	8,680	8,650
Accumulated deficit	(852)	(477)
Accumulated other comprehensive income (loss)	(146)	303
Total equity	7,682	8,476
Total liabilities and equity	\$ 16,565	\$ 17,693

See notes to condensed consolidated financial statements.

Elanco Animal Health Incorporated
Condensed Consolidated Statements of Equity (Unaudited)
(Dollars and shares in millions)

	Common Stock		Additional Paid-in Capital	Retained Earnings (Accumulated Deficit)	Accumulated Other Comprehensive Income (Loss)			Total	Total Equity
	Shares	Amount			Cash Flow Hedge Gain (Loss)	Foreign Currency Translation	Defined Benefit Pension and Retiree Health Benefit Plans		
December 31, 2019	373.0	\$ —	\$ 5,636	\$ 84	\$ —	\$ (199)	\$ 25	\$ (174)	\$ 5,546
Net loss	—	—	—	(49)	—	—	—	—	(49)
Adoption of Accounting Standards Update 2016-13	—	—	—	(1)	—	—	—	—	(1)
Other comprehensive loss, net of tax	—	—	—	—	(39)	(29)	(1)	(69)	(69)
Separation activities ⁽¹⁾	—	—	16	—	—	—	—	—	16
Stock compensation	—	—	11	—	—	—	—	—	11
Issuance of stock under employee stock plans, net	0.8	—	(13)	—	—	—	—	—	(13)
Issuance of common stock, net of issuance costs	25.0	—	768	—	—	—	—	—	768
Issuance of tangible equity units, net of issuance costs	—	—	452	—	—	—	—	—	452
March 31, 2020	398.8	—	6,870	34	(39)	(228)	24	(243)	6,661
Net loss	—	—	—	(53)	—	—	—	—	(53)
Other comprehensive income (loss), net of tax	—	—	—	—	(21)	50	(1)	28	28
Separation activities ⁽¹⁾	—	—	9	—	—	—	—	—	9
Stock compensation	—	—	8	—	—	—	—	—	8
Issuance of stock under employee stock plans, net	0.1	—	(1)	—	—	—	—	—	(1)
June 30, 2020	398.9	—	6,886	(19)	(60)	(178)	23	(215)	6,652
Net loss	—	—	—	(135)	—	—	—	—	(135)
Other comprehensive income (loss), net of tax	—	—	—	—	(7)	101	(1)	93	93
Stock compensation	—	—	11	—	—	—	—	—	11
Issuance of stock under employee stock plans, net	0.1	—	0	—	—	—	—	—	0
Issuance of stock to Bayer for acquisition, net of issuance costs	72.9	—	1,723	—	—	—	—	—	1,723
September 30, 2020	471.9	\$ —	\$ 8,620	\$ (154)	\$ (67)	\$ (77)	\$ 22	\$ (122)	\$ 8,344

(1) Represent amounts associated with transactions between us and Eli Lilly and Company (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.



Elanco Animal Health Incorporated
Condensed Consolidated Statements of Equity (Unaudited), Continued
(Dollars and shares in millions)

	Common Stock			Retained Earnings (Accumulated Deficit)	Accumulated Other Comprehensive Income (Loss)			Total	Total Equity
	Shares	Amount	Additional Paid-in Capital		Cash Flow Hedge Gain (Loss)	Foreign Currency Translation	Defined Benefit Pension and Retiree Health Benefit Plans		
December 31, 2020	471.9	\$ —	\$ 8,650	\$ (477)	\$ (61)	\$ 360	\$ 4	\$ 303	\$ 8,476
Net loss	—	—	—	(61)	—	—	—	—	(61)
Other comprehensive income (loss), net of tax	—	—	—	—	53	(466)	8	(405)	(405)
Stock compensation	—	—	15	—	—	—	—	—	15
Issuance of stock under employee stock plans, net	1.1	—	(18)	—	—	—	—	—	(18)
March 31, 2021	473.0	—	8,647	(538)	(8)	(106)	12	(102)	8,007
Net loss	—	—	—	(210)	—	—	—	—	(210)
Other comprehensive income (loss), net of tax	—	—	—	—	(5)	169	3	167	167
Stock compensation	—	—	16	—	—	—	—	—	16
June 30, 2021	473.0	—	8,663	(748)	(13)	63	15	65	7,980
Net loss	—	—	—	(104)	—	—	—	—	(104)
Other comprehensive income (loss), net of tax	—	—	—	—	4	(209)	(6)	(211)	(211)
Stock compensation	—	—	17	—	—	—	—	—	17
September 30, 2021	473.0	\$ —	\$ 8,680	\$ (852)	\$ (9)	\$ (146)	\$ 9	\$ (146)	\$ 7,682

See notes to condensed consolidated financial statements.



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

	Nine Months Ended September 30,	
	2021	2020
Cash Flows from Operating Activities		
Net loss	\$ (375)	\$ (237)
Adjustments to reconcile net loss to cash flows from operating activities:		
Depreciation and amortization	542	295
Change in deferred income taxes	(119)	(160)
Stock-based compensation expense	48	31
Asset impairment and write-down charges	334	5
Gain on sale of assets	—	(51)
Loss (gain) on divestitures	2	(170)
Inventory fair value step-up amortization	64	33
Changes in operating assets and liabilities, net of acquisitions	(243)	291
Other non-cash operating activities, net	7	15
Net Cash Provided by Operating Activities	260	52
Cash Flows from Investing Activities		
Net purchases of property and equipment	(60)	(16)
Cash paid for acquisitions, net of cash acquired	(342)	(5,001)
Proceeds from settlement of net investment hedges	—	33
Proceeds from product divestitures	—	435
Purchases of intangible assets	(35)	—
Purchases of software	(11)	(148)
Other investing activities, net	(8)	(8)
Net Cash Used for Investing Activities	(456)	(4,705)
Cash Flows from Financing Activities		
Repayments of borrowings	(555)	(684)
Net proceeds from revolving credit facility	250	—
Proceeds from issuance of long-term debt	500	4,554
Proceeds from issuance of common stock and tangible equity units	—	1,220
Debt issuance costs	(1)	(103)
Other net financing transactions with Lilly	(11)	—
Other financing activities, net	(17)	(15)
Net Cash Provided by Financing Activities	166	4,972
Effect of exchange rate changes on cash and cash equivalents	(23)	7
Net increase (decrease) in cash, cash equivalents and restricted cash	(53)	326
Cash, cash equivalents and restricted cash at January 1	506	345
Cash, cash equivalents and restricted cash at September 30	\$ 453	\$ 671
	September 30,	
	2021	2020
Cash and cash equivalents	\$ 453	\$ 660
Restricted cash	—	11
Cash, cash equivalents and restricted cash at September 30	\$ 453	\$ 671

See notes to condensed consolidated financial statements.

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

Note 1. Basis of Presentation and Summary of Significant Accounting Policies

Elanco Animal Health Incorporated (Elanco Parent) and its subsidiaries (collectively, Elanco, the Company, we, us, or our) is a premier animal health company that innovates, develops, manufactures and markets products for pets and farm animals.

Elanco was originally a wholly owned subsidiary of Eli Lilly and Company (Lilly). Elanco Parent, formed as the ultimate parent company of substantially all of the animal health businesses of Lilly, completed an initial public offering (IPO) in September 2018 and Lilly completed the disposition of all of its ownership interest in Elanco in March 2019.

We have prepared the accompanying unaudited condensed consolidated financial statements in accordance with the United States (U.S.) Securities and Exchange Commission (SEC) requirements for interim reporting. As permitted under those rules, certain information and footnote disclosures normally included in annual financial statements prepared in accordance with generally accepted accounting principles in the U.S. (GAAP) have been condensed or omitted. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with our consolidated and combined financial statements and accompanying notes for the year ended December 31, 2020 included in our Annual Report on Form 10-K filed with the SEC on March 1, 2021. In addition, results for interim periods should not be considered indicative of results for any other interim period or for the full year ending December 31, 2021 or any other future period.

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. 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.

The significant accounting policies set forth in Note 4 to the consolidated and combined financial statements in our Annual Report on Form 10-K for the year ended December 31, 2020 appropriately represent, in all material respects, the current status of our accounting policies, except as it relates to the adoption of the standard that was effective January 1, 2021 as described in Note 2: Implementation of New Financial Accounting Pronouncements.

On August 1, 2020 and August 27, 2021 we completed the acquisitions of Bayer Animal Health and KindredBio, respectively. See Note 4: Acquisitions and Divestitures for additional information.

Note 2. Implementation of New Financial Accounting Pronouncements

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

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

The following table provides a brief description of an accounting standard that is applicable to us but has not yet been adopted:

Standard	Description	Effective Date	Effect on the financial statements or other significant matters
ASU 2020-04, <i>Reference rate reform (Topic 848) - Facilitation of the Effects of Reference Rate Reform on Financial Reporting</i> ; ASU 2021-01, <i>Reference Rate Reform (Topic 848): Scope</i>	ASU 2020-04 provides optional expedients and exceptions for applying GAAP to contracts, hedging relationships, and other transactions affected by reference rate reform if certain criteria are met. ASU 2021-01 clarifies the scope of Topic 848 so that derivatives affected by the discounting transition are explicitly eligible for certain optional expedients and exceptions.	These standards were effective as of March 12, 2020 through December 31, 2022 and adoption is permitted at any time during the period on a prospective basis.	We are currently in the process of evaluating the impact of the London Interbank Offered Rate (LIBOR) on our existing contracts and may elect optional expedients in future periods as reference rate reform activities occur. We do not expect that these updates will have a material impact on our consolidated financial statements.

Note 3. Revenue

Our sales rebates are based on specific agreements. The most significant of our sales rebate 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 United Kingdom (U.K.). As of September 30, 2021 and 2020, the aggregate liability for sales rebates for these countries represented approximately 72% and 74%, respectively, of our total liability.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Beginning balance	\$ 303	\$ 164	\$ 295	\$ 211
Bayer Animal Health at acquisition	—	78	—	78
Reduction of revenue	163	145	516	316
Payments	(150)	(108)	(495)	(326)
Ending balance	\$ 316	\$ 279	\$ 316	\$ 279

Adjustments to revenue recognized as a result of changes in estimates for the judgments described above during the three and nine months ended September 30, 2021 and 2020 for product shipped in previous periods were not material.

Actual global product returns were approximately 2% and less than 1% of net revenue for the three months ended September 30, 2021 and 2020, respectively. Actual global product returns were approximately 1% of net revenue for the nine months ended September 30, 2021 and 2020.

Disaggregation of Revenue

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Pet Health	\$ 527	\$ 401	\$ 1,857	\$ 861
Farm Animal	583	473	1,728	1,222
Contract Manufacturing ⁽¹⁾	21	16	67	51
Revenue	\$ 1,131	\$ 890	\$ 3,652	\$ 2,134

⁽¹⁾ Represents revenue from arrangements in which we act as a contract manufacturer, including supply agreements associated with divestitures of products related to the acquisition of Bayer Animal Health.

Note 4. Acquisitions and Divestitures

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 our condensed consolidated financial statements from the dates of acquisition.

KindredBio Acquisition

On August 27, 2021, we acquired KindredBio, a publicly traded biopharmaceutical company that develops innovative biologics focused on saving and improving the lives of pets. The acquisition further accelerates our pet health expansion, particularly by expanding our presence in dermatology. In connection with the merger agreement, we acquired all outstanding stock of KindredBio for \$9.25 per share, or an aggregate cash purchase consideration of \$444 million. We utilized our revolving credit facility and cash on hand to finance the acquisition. Refer to Note 8: Debt for further details.

During the three months ended June 30, 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 the \$26 million liability was settled upon the closing of our acquisition of KindredBio. Refer to Note 5: Asset Impairment, Restructuring and Other Special Charges for further discussion.

We incurred transaction costs in connection with the KindredBio acquisition of \$4 million and \$6 million during the three and nine months ended September 30, 2021, respectively. 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 our condensed consolidated statements of operations.

Revenue and loss from KindredBio included in our condensed consolidated statements of operations since the date of acquisition for the three and nine months ended September 30, 2021 were immaterial.

The valuation of assets acquired and liabilities assumed has not yet been finalized as of September 30, 2021. The purchase price allocation is preliminary and subject to change, including the valuation of property and equipment, intangible assets, income taxes and goodwill. The amounts recognized will be finalized as the information necessary to complete the analysis is obtained, but no later than one year after the acquisition date.

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

Estimated Fair Value at August 27, 2021

Cash and cash equivalents	\$	31
Other net working capital		1
Property and equipment		26
Intangible assets, primarily acquired in-process research and development		352
Deferred income taxes		(22)
Total identifiable net assets		388
Goodwill		30
Settlement of liability related to previous license agreement		26
Total consideration transferred	\$	444

Property and equipment is mostly composed of land, buildings, equipment (including laboratory equipment, furniture and fixtures, and computer equipment), and construction in progress. The fair value of property and equipment is currently equal to its net book value at the time of the acquisition, as we are in the process of gathering information to complete our fair value assessment.

The preliminary estimated fair values of acquired in-process research and development (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 fair value of acquired IPR&D as of September 30, 2021 is based on preliminary assumptions which are subject to change as we complete our valuation procedures.

The goodwill recognized from this acquisition is attributable primarily to KindredBio's assembled workforce. 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 \$93 million during the nine months ended September 30, 2021 and 2020, respectively. Transaction costs for the three months ended September 30, 2020 were \$35 million. Transaction costs were primarily associated with financial advisory, legal and other professional services related to the acquisition and are reflected within asset impairment, restructuring and other special charges in our condensed consolidated statements of operations.

The amount of revenue attributable to Bayer Animal Health included in our condensed consolidated statements of operations for the three and nine months ended September 30, 2021 is \$421 million and \$1,509 million, respectively. Bayer Animal Health revenues were \$196 million for both the three and nine months ended September 30, 2020. 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		<u>3,649</u>
Goodwill		3,129
Total consideration transferred	\$	<u><u>6,778</u></u>

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 decrease to working capital accounts and other non-current assets and liabilities of \$14 million, and an increase to goodwill of \$207 million.

Inventories comprised of \$311 million, \$81 million, \$95 million in finished products, work in process, and raw materials, respectively. The estimate of fair value of finished products was determined based on net realizable value adjusted for the costs to complete the sales process, a reasonable profit allowance from the sales process, and estimated holding costs. The estimate of fair value of work in process was determined based on net realizable value adjusted for costs to complete the manufacturing process, costs of the sales process, a reasonable profit allowance for the remaining manufacturing and sales process effort, and an estimate of holding costs. The fair value of raw materials was determined to approximate book value. The net fair value step-up adjustment to inventories of \$152 million has been amortized to cost of sales as the inventory is sold to customers. As of September 30, 2021, the fair value step-up adjustment has been fully amortized.

Property and equipment is mostly composed of land, buildings, equipment (including machinery, furniture and fixtures, and computer equipment), and construction in progress. The estimated fair value of real property was

determined using the sales comparison data valuation technique and personal property was determined using the direct replacement cost method. The estimated fair value of property and equipment located at the Shawnee, Kansas site was determined using the income approach.

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

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

Accrued retirement benefits primarily relate to certain Bayer Animal Health international subsidiaries that have underfunded defined benefit pension plans. We have recorded the fair value of these plans using assumptions and accounting policies similar to those disclosed in Note 19: Retirement Benefits to the consolidated and combined financial statements in our Annual Report on Form 10-K for the year ended December 31, 2020. 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 as if the acquisition of Bayer Animal Health had occurred on January 1, 2020:

	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2020
Revenue	\$ 1,069	\$ 3,308
Loss before income taxes	(227)	(392)

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 acquisition been completed on January 1, 2020, 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 property and equipment, intangibles and inventory; interest expense and amortization of debt issuance costs for the debt issuance to finance the acquisition of Bayer Animal Health. The unaudited supplemental pro forma financial information includes transaction charges associated with the acquisition. There are no material, nonrecurring pro forma adjustments directly attributable to the acquisition included in the reported pro forma revenue and loss before income taxes.

Divestitures

Shawnee and Speke divestitures

In the second quarter of 2021, as part of our strategy to optimize our manufacturing footprint, we announced an agreement with TriRx Pharmaceuticals (TriRx) to sell our manufacturing sites in Shawnee and Speke, U.K. (Speke), including the planned transfer of approximately 600 employees. In connection with these arrangements, we also entered into long-term manufacturing and supply agreements, under which TriRx will manufacture existing Elanco products at both sites upon the closing of the transactions. During the nine months ended September 30, 2021, we recorded a \$271 million pre-tax charge to reduce the carrying value of the disposal groups to an amount equal to fair value less costs to sell in asset impairment, restructuring, and other special charges in our condensed consolidated statements of operations. Our fair value less costs to sell assessment includes the fair value of the favorable manufacturing and supply agreements, estimated using a combined income and market approach which incorporated Level 3 inputs. On August 1, 2021, we completed the sale of our Shawnee site and expect to receive gross cash proceeds of \$51 million over a period of three years based on the terms of the agreement. This activity is considered non-cash investing activity within our condensed consolidated statements of cash flows for the nine months ended September 30, 2021. We expect to close the Speke transaction in the first quarter of 2022; therefore, the related assets are classified as held for sale as of September 30, 2021. See Note 5: Asset Impairment, Restructuring and Other Special Charges for further information.

Elanco and Bayer Animal Health product divestitures

In connection with advancing our efforts to secure the necessary regulatory clearances for our acquisition of Bayer Animal Health, we signed agreements in 2020 to divest the rights to manufacture and commercialize certain legacy Elanco products. In 2020, we signed agreements to divest the worldwide rights to *Osumnia*[™] 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 nine months ended September 30, 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 the nine months ended September 30, 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 our condensed consolidated statements of operations. The related assets met the assets held for sale criteria as of December 31, 2020.

To allow the Bayer Animal Health acquisition to close on a timely basis, we signed agreements to divest the rights to the legacy Bayer Animal Health products *Drontal* and *Profender* within the U.K. and European Economic Area as well as other IPR&D. We completed the transactions, which were accounted for as asset divestitures, in August 2020. *Drontal*, *Profender*, and the IPR&D rights were acquired as part of the Bayer Animal Health acquisition. The related assets were classified as held for sale on the balance sheet as of the acquisition date and measured at fair value at the time of the acquisition; therefore, no gains were recognized on the sales. During the three months ended September 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 three and nine months ended September 30, 2020, we received gross cash proceeds of \$435 million and recognized pre-tax gains of \$156 million (net of transaction costs of \$13 million) relating to the product divestitures described above. Pre-tax gains were included in other (income) expense, net in our condensed consolidated statements of operations.

Assets Held For Sale

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

	September 30, 2021	December 31, 2020
Inventories	\$ 38	\$ 2
Other intangibles, net	—	4
Property and equipment, net	55	—
Deferred tax asset	—	1
Total assets held for sale	\$ 93	\$ 7

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

Microbiome R&D platform carve-out

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

Note 5. 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. Restructuring activities primarily include charges associated with facility rationalization and workforce reductions. In connection with our recent acquisitions, including the acquisitions of Bayer Animal Health and KindredBio, 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 asset 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 1: Basis of Presentation and Summary of Significant Accounting Policies for discussion regarding estimates and assumptions.

Components of asset impairment, restructuring and other special charges are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Restructuring charges:				
Severance and other costs ⁽¹⁾	\$ (2)	\$ 130	\$ 26	\$ 131
Facility exit costs ⁽¹⁾	—	—	—	1
Acquisition related charges:				
Transaction and integration costs ⁽²⁾	30	131	141	318
Non-cash and other items:				
Asset impairment ⁽³⁾	50	—	63	4
Asset write-down ⁽⁴⁾	6	1	275	3
Gain on sale of fixed assets ⁽⁵⁾	—	—	—	(4)
Settlements and other ⁽⁶⁾	27	—	13	3
Total expense	\$ 111	\$ 262	\$ 518	\$ 456

⁽¹⁾ For the nine months ended September 30, 2021, these charges primarily related to a restructuring program announced and initiated in January 2021. These costs were partially offset by the reversal of severance accruals associated with the January 2021 and September 2020 programs during the period. See below for further details.

For the three and nine months ended September 30, 2020, these charges primarily related to a restructuring program announced and initiated in September 2020. See below for further details.

⁽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⁾ Asset impairment charges for the three and nine months ended September 30, 2021 related to adjustments to the fair value of IPR&D assets that were subject to product rationalization. The asset impairment charge during the three months ended September 30, 2021 reflects a decision by management to terminate an IPR&D project and fully impair the related asset, which is associated with a farm animal parasiticide. The decision was prompted by unfavorable efficacy results observed during the quarter.

Asset impairment charges for the nine months ended September 30, 2020 related to the impairment of an IPR&D asset resulting from product rationalization and a reassessment of geographic viability.

⁽⁴⁾ Asset write-down expenses for the nine months ended September 30, 2021 include 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 future sale of the Speke manufacturing site during the three months ended September 30, 2021. See Note 4: Acquisitions and Divestitures for further discussion. Other charges for the nine months ended September 30, 2021 include adjustments 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 the January 2021 and September 2020 restructuring programs.

Asset write-down expenses for the three and nine months ended September 30, 2020 resulted from adjustments recorded to write down assets classified as held and used to their current fair value. These charges primarily related to fixed assets in Wusi, China in connection with the announced 2019 program to streamline operations.

⁽⁵⁾ Represents a gain on the disposal from the sale of an R&D facility in Prince Edward Island, Canada.

⁽⁶⁾ Settlements and other expenses for the three and nine months ended September 30, 2021 include a charge associated with the settlement of a liability for future royalty and milestone payments triggered in connection with our acquisition of KindredBio as discussed further in Note 4: Acquisitions and Divestitures, accounting and advisory fees related to the sale of our manufacturing site in Shawnee, and an \$8 million charge related to a litigation settlement for a matter that originated prior to our acquisition of Bayer Animal Health, partially offset by net curtailment and settlement gains from the remeasurement of our pension benefit obligation as a result of workforce reductions in connection with our September 2020 and January 2021 restructuring programs. See Note 13: Retirement Benefits for further information. The amount for the nine months ended September 30, 2021 also includes the gain recorded on the divestiture of an early-stage IPR&D asset acquired as part of the Bayer Animal Health acquisition.

Settlements and other expenses for the three and nine months ended September 30, 2020 relate to a non-recurring litigation settlement for a matter that originated prior to our separation from Lilly.

In January 2021, we announced a restructuring aligned with our ongoing efforts to improve operating efficiencies. The proposed actions focused on streamlining processes and delivering increased efficiency in functional areas, while improving the productivity of our investments in innovation. As part of the restructuring plan, we closed our R&D sites in Manukau, New Zealand and Cuxhaven, Germany. We have also reduced duplication and optimized structures in U.S. operations, marketing, manufacturing and quality central functions, and administrative areas. The restructuring resulted in the elimination of approximately 330 positions around the world. Activities related to this initiative resulted in favorable adjustments of \$1 million and charges of \$44 million during the three and nine months ended September 30, 2021, respectively. The favorable adjustments reflect a change in estimate resulting from ongoing negotiations. Initiatives under this program are expected to be substantially completed by the end of 2021.

In September 2020, following the closing of the Bayer Animal Health acquisition, we implemented a restructuring program designed to reduce duplication, drive efficiency and optimize our footprint in key geographies. As part of the restructuring plan, we have eliminated approximately 900 positions across 40 countries, primarily in the commercial and marketing functions, but also in R&D, manufacturing and quality, and back office support functions. During the three and nine months ended September 30, 2021 we recorded favorable adjustments of \$1 million and \$15 million, respectively, as a change in estimate related to this initiative, which reflects adjustments to severance accruals resulting from favorable negotiations and certain restructured employees filling open positions. Initiatives under this program are expected to be substantially completed by the end of 2021.

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

	Facility exit costs	Severance	Total
Balance at December 31, 2019	\$ 5	\$ 16	\$ 21
Charges	1	132	133
Reserve adjustments	—	(1)	(1)
Cash paid	(1)	(15)	(16)
Balance at September 30, 2020	<u>\$ 5</u>	<u>\$ 132</u>	<u>\$ 137</u>
Balance at December 31, 2020	\$ —	\$ 130	\$ 130
Charges	—	41	41
Reserve adjustments	—	(15)	(15)
Cash paid	—	(95)	(95)
Balance at September 30, 2021	<u>\$ —</u>	<u>\$ 61</u>	<u>\$ 61</u>

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

Note 6. 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 consisted of the following:

	September 30, 2021	December 31, 2020
Finished products	\$ 595	\$ 772
Work in process	576	625
Raw materials and supplies	255	210
Total	1,426	1,607
Decrease to LIFO cost	(43)	(29)
Inventories	<u>\$ 1,383</u>	<u>\$ 1,578</u>

Note 7. Equity

Common Stock Offering

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

Tangible Equity Unit (TEU) Offering

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

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

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

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

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

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

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

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

Note 8. Debt

Long-term debt consisted of the following:

	September 30, 2021	December 31, 2020
Incremental Term Facility	\$ 500	\$ —
Term Loan B	4,129	4,164
Revolving Credit Facility	250	—
3.912% Senior Notes due 2021	—	500
4.272% Senior Notes due 2023	750	750
4.900% Senior Notes due 2028	750	750
TEU Amortizing Notes	40	60
Other obligations	—	1
Unamortized debt issuance costs	(85)	(98)
	6,334	6,127
Less current portion of long-term debt	61	555
Total long-term debt	<u>\$ 6,273</u>	<u>\$ 5,572</u>

Farm Credit Agreement

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

Bayer Animal Health Related Financing

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

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. In February 2021, we drew down \$150 million on the revolving credit facility for working capital needs. We subsequently repaid \$100 million in March 2021 and the remaining \$50 million in April 2021. In August 2021, we drew down \$350 million on the revolving credit facility to partially fund the acquisition of KindredBio. We subsequently repaid \$100 million in September 2021.

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 September 30, 2021.

The second financial maintenance covenant for the revolving credit facility requires us to maintain a ratio of pro forma adjusted EBITDA to cash interest expense of no less than 2.00 to 1.00, tested as of the end of each fiscal quarter. We were in compliance with all covenants under the credit facility as of September 30, 2021.

Senior Notes

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

The indenture that governs the Senior Notes contains covenants that limit our, and certain of our subsidiaries' ability, to incur liens or engage in sale-leaseback transactions. The indenture also contains restrictions on our ability to consolidate, merge or sell substantially all of our assets, in addition, to other customary terms. We were in compliance with all such covenants under the indenture governing the Senior Notes as of September 30, 2021.

TEU Amortizing Notes

On January 22, 2020, we issued \$550 million in TEUs. We offered 11 million, 5.00% TEUs at the stated amount of \$50 per unit, comprised of prepaid stock purchase contracts and a senior amortizing note due February 1, 2023 (the mandatory settlement date). Total cash of \$528 million was received, comprised of \$452 million of prepaid stock purchase contracts and \$76 million of senior amortizing notes, net of issuance costs. During the three and nine months ended September 30, 2021, we paid \$7 million and \$21 million, respectively, representing partial payment of principal and interest on the TEU amortizing notes. See Note 7: Equity for further information.

Debt Extinguishment

On January 31, 2020, we repaid indebtedness outstanding under our previous 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 our condensed consolidated statements of operations for the nine months ended September 30, 2020), primarily related to the write-off of deferred debt issuance costs.

On September 25, 2020, we made a repayment of principal of \$100 million on the indebtedness outstanding under our Term Loan B. 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 condensed consolidated statements of operations for the three and nine months ended September 30, 2020), primarily related to the write-off of deferred debt issuance costs.

Note 9. Financial Instruments and Fair Value

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

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

We had investments without readily determinable fair values and equity method investments included in other noncurrent assets on our condensed consolidated balance sheets totaling \$21 million and \$24 million as of September 30, 2021 and December 31, 2020, respectively. Unrealized net gains and losses on our investments for the three and nine months ended September 30, 2021 and 2020 were immaterial.

The following table summarizes the fair value information at September 30, 2021 and December 31, 2020 for foreign exchange contract assets (liabilities), investments, contingent consideration liabilities, and cash flow hedge assets (liabilities) measured at fair value on a recurring basis in the respective balance sheet line items, as well as long-term debt (including TEU amortizing notes) for which fair value is disclosed on a recurring basis:

Financial statement line item	Carrying Amount	Fair Value Measurements Using			Fair Value
		Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	
September 30, 2021					
Prepaid expenses and other - foreign exchange contracts not designated as hedging instruments	\$ 30	\$ —	\$ 30	\$ —	\$ 30
Other noncurrent assets - investments	15	15	—	—	15
Other current liabilities - foreign exchange contracts not designated as hedging instruments	(30)	—	(30)	—	(30)
Other current liabilities - contingent consideration	(1)	—	—	(1)	(1)
Other noncurrent liabilities - forward-starting interest rate contracts designated as cash flow hedges	(24)	—	(24)	—	(24)
Long-term debt, including current portion	(6,419)	—	(6,551)	—	(6,551)
December 31, 2020					
Prepaid expenses and other - foreign exchange contracts not designated as hedging instruments	\$ 36	\$ —	\$ 36	\$ —	\$ 36
Other noncurrent assets - investments	9	9	—	—	9
Other current liabilities - foreign exchange contracts not designated as hedging instruments	(36)	—	(36)	—	(36)
Other noncurrent liabilities - contingent consideration	(1)	—	—	(1)	(1)
Other noncurrent liabilities - forward-starting interest rate contracts designated as cash flow hedges	(76)	—	(76)	—	(76)
Long-term debt, including current portion	(6,225)	—	(6,420)	—	(6,420)

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

Contingent consideration liabilities as of September 30, 2021 and December 31, 2020 related to contingent consideration associated with the acquisitions of Aratana Therapeutics, Inc. (Aratana) and Prevtec Microbia Inc. (Prevtec) during 2019. For Aratana, we will pay up to \$12 million in contingent value rights that are dependent on the achievement of a specified milestone by December 31, 2021 as outlined in the merger agreement. For Prevtec, based on the terms of the purchase agreement, we will pay up to \$16 million contingent upon the achievement of specific *Coliprotec* sales milestones by December 31, 2021. The fair value of both contingent consideration liabilities was estimated using the Monte Carlo simulation model and Level 3 inputs including historical revenue, discount rate, asset volatility, and revenue volatility.

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.

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 British pound, Canadian dollar, Euro, Japanese yen, Swiss franc (CHF), 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 condensed consolidated statements of operations. Forward contracts generally have maturities not exceeding 12 months. At September 30, 2021 and December 31, 2020, we had outstanding foreign exchange contracts with aggregate notional amounts of \$1,417 million and \$1,391 million, respectively.

The amounts of net gain (loss) on derivative instruments not designated as hedging instruments, recorded in other (income) expense, net are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Foreign exchange forward contracts ⁽¹⁾	\$ (2)	\$ (2)	\$ (29)	\$ 19

⁽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 (NIH) 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 nine months ended September 30, 2020 we fully liquidated our cross currency interest rate swaps for a cash benefit of \$35 million (including \$2 million in interest). Notwithstanding settlement, gains and losses within accumulated other comprehensive income (loss) will remain in accumulated other comprehensive income (loss) until either the sale or substantial liquidation of the hedged subsidiary.

Gains on the NIH, recognized within interest expense, net of capitalized interest, are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Cross-currency interest rate swap contracts	\$ —	\$ —	\$ —	\$ 6

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 accumulated other comprehensive income (loss), are as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Cross-currency interest rate swap contracts	\$ —	\$ —	\$ —	\$ 24

Separately, in March 2020, as a means of mitigating variability in cash flows associated with the anticipated Term Loan B issuance, we executed forward-starting interest rate swaps with a \$4.1 billion notional amount, which are designated as cash flow hedges and have maturity dates ranging between 2022 and 2025. These instruments effectively convert floating-rate debt to fixed-rate debt. The cash flow hedges are recorded at fair value on our condensed consolidated balance sheets, while changes in the fair value of the hedge 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. Amounts recorded in accumulated other comprehensive income (loss) are recognized in earnings in interest expense, net of capitalized interest when the hedged transaction affects earnings (i.e., as interest payments are accrued on the Term Loan B).

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Forward-starting interest rate swaps, net of tax benefit of \$0, \$2, \$0 and \$20, respectively	\$ 4	\$ (7)	\$ 52	\$ (67)

There was no tax effect for the three and nine months ended September 30, 2021 after the application of the U.S. valuation allowance. See Note 10: Income Taxes for further discussion. Over the next 12 months we expect to reclassify \$26 million from accumulated other comprehensive income (loss) to interest expense, net of capitalized interest due to the amortization of net losses on the interest rate swaps. During the three and nine months ended September 30, 2021, we reclassified \$8 million and \$22 million, respectively, of net losses into interest expense.

Note 10. Income Taxes

<i>Income Tax Benefit</i>	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Income tax benefit	\$ (26)	\$ (74)	\$ (71)	\$ (117)
Effective tax rate	20.0 %	35.4 %	15.9 %	32.9 %

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

For the three and nine months ended September 30, 2021, we recognized an income tax benefit of \$26 million and \$71 million, respectively. For the three months ended September 30, 2021, our effective tax rate of 20.0% differs from the statutory income tax rate primarily due to preliminary accounting for the acquisition of KindredBio, which caused a partial release of the U.S. federal valuation allowance, as well as profits being located in jurisdictions with higher statutory tax rates. For the nine months ended September 30, 2021, our effective tax rate of 15.9% differs from the statutory income tax rate primarily because the U.S. federal and state jurisdictions are currently generating losses that are subject to valuation allowances.

For the three and nine months ended September 30, 2020, we recognized an income tax benefit of \$74 million and \$117 million, respectively. For the three and nine months ended September 30, 2020, our effective tax rate of 35.4% and 32.9%, respectively, differs from the statutory income tax rate primarily due to the release of foreign valuation allowances as a result of gains on divestitures. Additionally, the state tax benefit is a result of U.S. pre-tax losses and the foreign tax benefit is due to losses in jurisdictions with tax rates higher than U.S. statutory rates.

Note 11. Commitments and Contingencies

Legal Matters

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

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

Claims seeking actual damages, injunctive relief, and/or restitution for allegedly deceptive marketing have been made against Elanco Animal Health Inc. and Bayer HealthCare LLC, along with other Elanco and Bayer entities, arising out of the use of *Seresto*[™], a non-prescription flea and tick collar for cats and dogs. During the nine months ended September 30, 2021, putative class action lawsuits were filed in state and federal courts in the U.S. alleging that the *Seresto* collars contain pesticides and other ingredients that can cause serious injury and death to cats and/or dogs wearing the product. The cases mention the existence of incident reports involving humans, but no plaintiff has claimed personal harm from the product. One plaintiff filed a petition before the Judicial Panel on Multidistrict Litigation (JPML). The hearing on the JPML petition took place on July 29, 2021, and a decision was reached to consolidate and transfer all pending lawsuits to the federal court in the Northern District of Illinois. We continue to receive information with respect to potential litigation costs, and we will be taking appropriate steps to defend these class action lawsuits.

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

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

We are party to various other legal actions in the normal course of business. In determining whether a pending matter is significant for financial reporting and disclosure purposes, we consider both quantitative and qualitative factors in order to assess materiality. We accrue for liability claims to the extent that it is probable we will incur a loss and we can formulate a reasonable estimate of the costs. As of September 30, 2021 and December 31, 2020, we had no material liabilities established related to litigation as there were no significant claims which were probable and estimable. We are not currently subject to a significant claim other than the lawsuits noted above.

Regulatory Matters

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

Note 12. Geographic Information

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

Our products include *Baycox*[™], *Cydectin*[™], *Denagard*[™], *Maxiban*[™], *Optaflexx*[™], *Rumensin*[™], *Tylan*[™], and other products for livestock and poultry, as well as *Advantage*[™], *Advantix*[™], *Advocate*[™] (collectively referred to as the *Advantage Family*), *Credelio*[™], *Duramune*[™], *Galliprant*[™], *Interceptor*^{™ Plus}, *Seresto*, *Trifexis*[™], and other products for pets.

We have a single customer that accounted for 11% and 12% of revenue for the three months ended September 30, 2021 and 2020, respectively, and 9% and 12% of revenue for the nine months ended September 30, 2021 and 2020, respectively. Product sales with this customer resulted in accounts receivable of \$80 million and \$87 million as of September 30, 2021 and December 31, 2020, respectively.

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

Selected geographic area information was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue				
United States	\$ 507	\$ 422	\$ 1,621	\$ 970
International	624	468	2,031	1,164
Revenue	\$ 1,131	\$ 890	\$ 3,652	\$ 2,134

Note 13. Retirement Benefits

The following table summarizes net periodic benefit cost (income) relating to our defined benefit pension plans:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Service cost	\$ 4	\$ 3	\$ 14	\$ 8
Interest cost	1	—	2	1
Expected return on plan assets	(2)	(2)	(5)	(4)
Amortization of prior service cost	(1)	(2)	(5)	(6)
Amortization of net actuarial loss	—	1	1	2
Net curtailments and settlements (Note 5)	(9)	—	(26)	—
Net periodic benefit cost (income)	\$ (7)	\$ —	\$ (19)	\$ 1

The components of net periodic benefit cost other than service cost and net curtailments and settlements are included in other (income) expense, net in our condensed consolidated statements of operations. Net curtailments and settlements are included in asset impairment, restructuring and other special charges, in our condensed consolidated statements of operations.

Note 14. Loss Per Share

We compute basic loss per share by dividing net loss available to common shareholders by the actual weighted average number of common shares outstanding for the reporting period. Elanco has variable common stock equivalents relating to certain equity awards in stock-based compensation arrangements and the TEU prepaid stock purchase contracts (see Note 7: 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 loss per share.

Basic and diluted loss per share are calculated as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net loss available to common shareholders	\$ (104)	\$ (135)	\$ (375)	\$ (237)
Determination of shares:				
Weighted average common shares outstanding	487.3	462.4	487.1	426.5
Assumed conversion of dilutive common stock equivalents ⁽¹⁾	—	—	—	—
Diluted weighted average shares outstanding	487.3	462.4	487.1	426.5
Loss per share ⁽²⁾				
Basic	\$ (0.21)	\$ (0.29)	\$ (0.77)	\$ (0.56)
Diluted	\$ (0.21)	\$ (0.29)	\$ (0.77)	\$ (0.56)

⁽¹⁾ During the three and nine months ended September 30, 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 three months ended September 30, 2021 and 2020, approximately 1.7 million and 1.6 million, respectively, of potential common shares were excluded from the calculation of diluted earnings per share because their effect was anti-dilutive. For the nine months ended September 30, 2021 and 2020, approximately 1.6 million and 1.9 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, loss per share may not recalculate precisely based on the amounts presented within this table.

Note 15. Transactions and Agreements with Bayer

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

For regulatory purposes in certain jurisdictions, consideration was required to be paid locally at closing in addition to amounts paid globally for the acquisition. Pursuant to the stock and asset purchase agreement, Bayer has provided a refund for payment amounts duplicated in these regions. The total amount paid to and received from Bayer during the nine months ended September 30, 2021 for these local country asset purchases was approximately \$16 million. All local country asset purchases have been completed as of September 30, 2021.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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 condensed consolidated financial statements and accompanying footnotes in Item 1 of Part I of this Quarterly Report on Form 10-Q. Certain statements in this Item 2 of Part I of this Quarterly Report on Form 10-Q constitute forward-looking statements. Various risks and uncertainties, including those discussed in "Forward-Looking Statements" of this Quarterly Report on Form 10-Q, in Item 1A, "Risk Factors" of Part II of this Quarterly Report on Form 10-Q, and in Item 1A, "Risk Factors" of Part I of our Annual Report on Form 10-K for the year ended December 31, 2020, may cause our actual results, financial position, and cash generated from operations to differ materially from these forward-looking statements. Further, due to the seasonality of our pet health sales, interim results are not necessarily an appropriate base from which to project annual results.

Overview

Founded in 1954, Elanco is a premier animal health company that innovates, develops, manufactures and markets products for pets and farm animals. Headquartered in Greenfield, Indiana, we are one of the largest animal health companies in the world, with pro forma combined revenue of Elanco and Bayer Animal Health of approximately \$4.4 billion for the year ended December 31, 2020.

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 4: Acquisitions and Divestitures to the condensed 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.

On August 27, 2021, we acquired KindredBio, a biopharmaceutical company that develops innovative biologics focused on saving and improving the lives of pets. We had previously signed an agreement with KindredBio in the second quarter of 2021 to acquire exclusive global rights to KIND-030, a monoclonal antibody that is being developed for the treatment and prevention of canine parvovirus. The acquisition of KindredBio further accelerates our pet health expansion, particularly by expanding our presence in dermatology. See Note 4: Acquisitions and Divestitures to the condensed 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 October 5, 2021, we announced our intention to carve out our microbiome R&D platform, aiming to create a privately funded, independent, biopharmaceutical company focused on developing solutions for animal and human health. We are exploring structures with both strategic and financial sponsors, and may retain a minority stake in this new entity. The potential carve-out is expected to be completed by the end of the first quarter of 2022.

We offer a diverse portfolio of approximately 190 brands that make us a trusted partner to veterinarians and farm animal producers in more than 90 countries. Our products are generally sold worldwide to third-party distributors, retailers, and directly to farm animal producers and veterinarians. With the acquisition of Bayer Animal Health, we have expanded our presence in retail and e-commerce channels in order to meet pet owners where they want to purchase.

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. In 2020, we renamed our four primary product categories by replacing "food animal" and "companion animal" with "farm animal" and "pet health," respectively, to better reflect the terminology used by our customers. We advance our vision with the following offering of portfolio solutions:

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 *Seressto* and *Advantage*, *Advantix*, *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 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) and swine production. In poultry, our *Maxiban* product, is a valuable offering for the control and prevention of intestinal disease.

A summary of our 2021 revenue and net loss compared with the same period in 2020 is as follows:

(Dollars in millions)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue	\$ 1,131	\$ 890	\$ 3,652	\$ 2,134
Net loss	(104)	(135)	(375)	(237)

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

Key Trends and Conditions Affecting Our Results of Operations

Industry Trends

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

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.

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

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

Factors Affecting Our Results of Operations

COVID-19 Pandemic

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

Operations

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

In late 2020 and early 2021, vaccines effective in combating COVID-19 were authorized for use by health agencies in certain countries and regions in which we operate (including the U.S., U.K., European Union, Canada and Mexico) and began to be administered. As a result, certain countries and regions in which we operate lifted travel bans and eased restrictions put in place to contain the virus. However, some countries and regions reinstated travel bans and restrictions in connection with the resurgence of COVID-19 cases due to the Delta variant. In addition, the availability of COVID-19 vaccines, their continued effectiveness and the need for and availability of boosters are difficult to predict, and vaccination levels vary across jurisdictions. The pace and shape of the COVID-19 recovery as well as the impact and extent of COVID-19 variants or potential resurgences is not presently known. As a result, it is possible the COVID-19 pandemic, particularly in light of variant strains of the virus, could further impact our operations and the operations of our customers, suppliers and vendors as a result of quarantines, facility closures, illnesses, and travel and logistics restrictions.

Supply

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

Demand

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

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

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

Our Acquisition of Bayer Animal Health and KindredBio

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

Product Development and New Product Launches

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

Competition

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

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.

Productivity

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

Prior to the acquisition of Bayer Animal Health, our acquisitions within the last six years added in the aggregate \$1.4 billion in revenue, 4,600 full-time employees, 12 manufacturing and eight R&D sites. The 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. In addition, from 2015 to 2020, changing market demand for antibiotics and other headwinds, such as competition with generics and competitor innovation, affected some of our highest gross margin products, resulting in a change to our product mix and driving operating margin lower. In response, we implemented a number of initiatives across the manufacturing, R&D and selling, general and administrative (SG&A) functions. Our manufacturing cost savings strategies included improving manufacturing processes and headcount through lean manufacturing (minimizing waste while maintaining productivity), closing and selling manufacturing sites, consolidating our CMO network, strategically insourcing certain projects, and pursuing cost savings opportunities with respect to raw materials via a new procurement process. Additional cost savings have resulted from reducing the number of R&D sites, SG&A savings from sales force consolidation, and reducing discretionary and other general and administrative (G&A) operating expense.

Seasonality

The results of our pet health business may fluctuate due to seasonality. For example, based upon historical results, approximately 70% and 60% of total annual revenue contributed by our higher-margin parasiticide products *Seresto* and *Advantage Family*, respectively, has occurred during the first half of the year, which is reflective of the flea and tick season in the Northern Hemisphere. Therefore, a period-to-period comparison of our historical results may not be meaningful and fluctuations in total revenue for our pet health products are not necessarily an indication of future performance.

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. During the nine months ended September 30, 2021 and 2020, approximately 51% and 52%, respectively, of our revenue was denominated in foreign currencies. As we operate in multiple foreign currencies, including the Euro, British pound, Swiss franc, Brazilian real, Australian dollar, Japanese yen, Canadian dollar, Chinese yuan, and other currencies, changes in those currencies relative to the U.S. dollar impact our revenue, cost of sales and expenses, and consequently, net income. These fluctuations may also affect the ability to buy and sell our products between markets impacted by significant exchange rate variances. Currency movements increased revenue by 2% during the nine months ended September 30, 2021 and decreased revenue by 1% during the nine months ended September 30, 2020.

Our Relationship with Lilly and Additional Standalone Costs

All operations-focused TSAs that went into effect after our 2018 separation from Lilly were exited as planned during the first half of 2021. We are nearly complete with investments in expanding our own administrative

functions, including, but not limited to, information technology, facilities management, distribution, human resources, and manufacturing, to replace services previously provided by Lilly. Because of initial stand-up costs and overlaps with services previously provided by Lilly, we have incurred and expect to continue to incur certain temporary, duplicative expenses in connection with the separation. We have also incurred costs related to the build out of processes and systems to support finance and global supply and logistics, among others. At the present time, we expect minimal additional costs to be incurred and we anticipate that total costs incurred will be between \$325 million and \$335 million, net of completed and planned real estate dispositions and employee benefit changes, of which a portion will be capitalized and the remainder will be expensed.

Asset Impairment, Restructuring and Other Special Charges

During the nine months ended September 30, 2021 and 2020 we incurred charges related to asset impairment, restructuring and other special charges, including in connection with the productivity initiatives described above under "Factors Affecting Our Results of Operations - Productivity," and integration of acquired businesses. These charges include: severance costs resulting from actions taken to reduce our costs; asset impairment charges and write-downs primarily related to competitive pressures for certain pet health products; 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, as we stand our organization up as an independent company.

For more information on these charges, see Note 5: Asset Impairment, Restructuring and Other Special Charges to the condensed consolidated financial statements.

Results of Operations

The following discussion and analysis of our results of operations should be read along with our condensed consolidated financial statements and the notes thereto.

(Dollars in millions)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2021	2020	% Change	2021	2020	% Change
Revenue	\$ 1,131	\$ 890	27 %	\$ 3,652	\$ 2,134	71 %
Costs, expenses and other:						
Cost of sales	502	442	14 %	1,622	1,071	51 %
% of revenue	44 %	50 %	(6) %	44 %	50 %	(6) %
Research and development	94	88	7 %	277	214	29 %
% of revenue	8 %	10 %	(2) %	8 %	10 %	(2) %
Marketing, selling and administrative	342	278	23 %	1,075	623	73 %
% of revenue	30 %	31 %	(1) %	29 %	29 %	— %
Amortization of intangible assets	141	96	47 %	417	197	112 %
% of revenue	12 %	11 %	2 %	11 %	9 %	2 %
Asset impairment, restructuring and other special charges	111	262	(58) %	518	456	14 %
Interest expense, net of capitalized interest	60	48	25 %	181	89	103 %
Other (income) expense, net	11	(115)	NM	8	(162)	NM
Loss before income taxes	(130)	(209)	38 %	(446)	(354)	(26) %
% of revenue	(11)%	(23)%	12 %	(12)%	(17)%	5 %
Income tax benefit	(26)	(74)	(65) %	(71)	(117)	(39) %
Net loss	\$ (104)	\$ (135)	23 %	\$ (375)	\$ (237)	(58) %

Certain amounts and percentages may reflect rounding adjustments.

NM - Not meaningful

Disaggregated Revenue

On a global basis, our revenue by product category for the three months ended September 30 is summarized as follows:

(Dollars in millions)	Revenue		% of Total Revenue		Increase (Decrease)		
	2021	2020	2021	2020	\$ Change	% Change	CER ⁽¹⁾
Pet Health	\$ 527	\$ 401	47 %	45 %	\$ 126	31 %	30 %
Farm Animal	583	473	52 %	53 %	110	23 %	22 %
Subtotal	1,110	874	98 %	98 %	236	27 %	26 %
Contract Manufacturing ⁽²⁾	21	16	2 %	2 %	5	31 %	31 %
Total	\$ 1,131	\$ 890	100 %	100 %	241	27 %	26 %

⁽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⁾ Represents revenue from arrangements in which we act as a contract manufacturer, including supply agreements associated with divestitures of products related to the acquisition of Bayer Animal Health.

Total revenue increased \$241 million to \$1,131 million, comprised of \$710 million from the legacy Elanco portfolio and \$421 million from the legacy Bayer Animal Health portfolio. This 27% increase reflects a 24% increase in volume, a 2% increase in price, and a 1% favorable impact from foreign exchange rates.

The detailed change in revenue by product category was as follows:

- Pet Health revenue increased by \$126 million, or 31%, for the quarter, driven by an increase in revenue as a result of the addition of Bayer Animal Health product revenue of \$247 million in the quarter as compared to \$113 million in the prior year. The decrease in the legacy Elanco business was driven by declines in older generation parasiticides and the impact of divestitures, partially offset by volume increases for newer generation parasiticide and pain products, as well as price growth. Current period growth in the Bayer Animal Health business was mostly attributable to the inclusion of a full quarter of revenue in comparison to a partial quarter in the prior year, as well as price growth.
- Farm Animal revenue increased by \$110 million, or 23%, for the quarter, driven by an increase in revenue as a result of the addition of Bayer Animal Health product revenue of \$157 million in the quarter as compared to \$77 million in the prior year. Legacy Elanco revenue increased as a result of a favorable comparison to the prior year, which included lower levels of demand due to the impact of the COVID-19 pandemic on global protein markets, as well as volume growth in global cattle and U.S. swine, improvement in international poultry and aqua, and revenue from new products launched in 2021. Current period revenue was negatively impacted by generic competition and lower levels of producer demand in China's swine market due to herd liquidation. Current period growth in the Bayer Animal Health business was mostly attributable to the inclusion of a full quarter of revenue in comparison to a partial quarter in the prior year, as well as price growth.
- Contract Manufacturing revenue was \$21 million, and represented 2% of total revenue. Contract manufacturing revenue for the period includes \$17 million resulting from the acquisition of Bayer Animal Health.

On a global basis, our revenue by product category for the nine months ended September 30 is summarized as follows:

(Dollars in millions)	Revenue		% of Total Revenue		Increase (Decrease)		
	2021	2020	2021	2020	\$ Change	% Change	CER ⁽¹⁾
Pet Health	\$ 1,857	\$ 861	51 %	40 %	\$ 996	116 %	114 %
Farm Animal	1,728	1,222	47 %	57 %	506	41 %	39 %
Subtotal	3,585	2,083	98 %	98 %	1,502	72 %	70 %
Contract Manufacturing ⁽²⁾	67	51	2 %	2 %	16	31 %	31 %
Total	\$ 3,652	\$ 2,134	100 %	100 %	1,518	71 %	69 %

⁽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⁾ Represents revenue from arrangements in which we act as a contract manufacturer, including supply agreements associated with divestitures of products related to the acquisition of Bayer Animal Health.

Total revenue increased \$1,518 million to \$3,652 million, comprised of \$2,143 million from the legacy Elanco portfolio and \$1,509 million from the legacy Bayer Animal Health portfolio. This 71% increase reflects a 67% increase in volume, a 2% increase in price, and a 2% favorable impact from foreign exchange rates.

The detailed change in revenue by product category was as follows:

- Pet Health revenue increased by \$996 million, or 116%, for the period, driven by an increase in revenue as a result of the addition of Bayer Animal Health product revenue of \$964 million in the period as compared to \$113 million in the prior year. The increase in the legacy Elanco business was driven by a favorable comparison to the prior year, during which we reduced channel inventory levels with our distributors during the first half of the year and experienced reduced demand for veterinary products, primarily in U.S. vaccines and international markets, due to the COVID-19 pandemic. Current period growth in the legacy Elanco business was attributable to higher volume in newer generation parasiticide and pain products and price growth led by U.S. vaccines, partially offset by declines in older generation parasiticides and the impact of divestitures.
- Farm Animal revenue increased by \$506 million, or 41%, for the period, driven by an increase in revenue as a result of the addition of Bayer Animal Health product revenue of \$488 million in the period as compared to \$77 million in the prior year. Legacy Elanco revenue increased as a result of a favorable comparison to the prior year, which included lower levels of demand due to the impact of the COVID-19 pandemic on global protein markets and actions taken across brands to reduce channel inventory levels in the first half of the year due to the pandemic. In the current period, revenue increases due to price growth, volume growth in global cattle and U.S. swine, improvement in international poultry and aqua, and revenue from new products launched in 2021 were partially offset by lower levels of demand in certain markets due to the negative impact of the COVID-19 pandemic on poultry and aqua consumption, production, and profitability, generic competition, and lower levels of producer demand in China's swine market due to herd liquidation.
- Contract Manufacturing revenue was \$67 million, and represented 2% of total revenue. Contract manufacturing revenue for the period includes \$57 million resulting from the acquisition of Bayer Animal Health.

Cost of Sales

(Dollars in millions)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2021	2020	% Change	2021	2020	% Change
Cost of sales	\$ 502	\$ 442	14 %	\$ 1,622	\$ 1,071	51 %
% of revenue	44 %	50 %		44 %	50 %	

Cost of sales increased 14% for the three months ended September 30, 2021, primarily due to increased sales. Cost of sales during the three months ended September 30, 2021 was approximately 44% of revenue, compared to 50% in the prior year. This decrease is due to the inclusion of a full quarter of Bayer Animal Health products, which have higher margins, as well as lower amortization of the inventory fair value adjustment associated with the Bayer Animal Health acquisition, continued improvements in manufacturing productivity and increases in price, partially offset by product mix.

Cost of sales increased 51% for the nine months ended September 30, 2021, primarily due to increased sales and higher amortization of the inventory fair value adjustment associated with the Bayer Animal Health acquisition. Cost of sales during the nine months ended September 30, 2021 was approximately 44% of revenue, compared to 50% in the prior year. This decrease is due to the inclusion of Bayer Animal Health products, which have higher margins, as well as continued improvements in manufacturing productivity and increases in price, partially offset by higher amortization of the inventory fair value adjustment.

Research and development

(Dollars in millions)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2021	2020	% Change	2021	2020	% Change
Research and development	\$ 94	\$ 88	7 %	\$ 277	\$ 214	29 %
% of revenue	8 %	10 %		8 %	10 %	

R&D expenses increased 7% for the three months ended September 30, 2021 and 29% for the nine months ended September 30, 2021, primarily due to the inclusion of the Bayer Animal Health and KindredBio businesses. As a percent of revenue, research and development was 8% compared to 10% in the prior year for both periods, primarily due to the rationalization of R&D projects, personnel and site operations in the current year following the acquisition of Bayer Animal Health.

Marketing, selling and administrative

(Dollars in millions)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2021	2020	% Change	2021	2020	% Change
Marketing, selling and administrative	\$ 342	\$ 278	23 %	\$ 1,075	\$ 623	73 %
% of revenue	30 %	31 %		29 %	29 %	

Marketing, selling and administrative expenses for the three months ended September 30, 2021 were 30% of revenue, as compared to 31% in the prior year. Expenses increased 23% over prior year, primarily as a result of the acquisition of Bayer Animal Health, increased market research costs and promotional spend for direct-to-consumer and digital advertising, increased information technology spending, increased legal costs, and increases in legacy Elanco compensation and benefits due to the addition of employees to perform activities that were previously covered by the TSAs with Lilly that were exited during the first half of 2021. These increases were partially offset by disciplined cost management across the business.

Marketing, selling and administrative expenses as a percentage of revenue were 29% of revenue for the nine months ended September 30, 2021, and 2020. Expenses increased 73% over prior year, primarily as a result of the acquisition of Bayer Animal Health, increased promotional spend for direct-to-consumer and digital advertising, increased information technology spending, increases in legal and administrative costs, and increases in legacy Elanco compensation and benefits due to the addition of employees to perform activities that were previously covered by the TSAs with Lilly that were exited during the first half of 2021. These increases were partially offset by disciplined cost management across the business.

Amortization of intangible assets

(Dollars in millions)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2021	2020	% Change	2021	2020	% Change
Amortization of intangible assets	\$ 141	\$ 96	47 %	\$ 417	\$ 197	112 %

Amortization of intangible assets increased for the three and nine months ended September 30, 2021, primarily due to the addition of amortization of intangible assets recorded from the acquisition of Bayer Animal Health.

Asset impairment, restructuring and other special charges

(Dollars in millions)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2021	2020	% Change	2021	2020	% Change
Asset impairment, restructuring and other special charges	\$ 111	\$ 262	(58) %	\$ 518	\$ 456	14 %

Asset impairment, restructuring and other special charges decreased \$151 million for the three months ended September 30, 2021 as compared to the prior year. During the three months ended September 30, 2021, we recorded a \$26 million charge to establish a liability for future royalty and milestone payments relating to our canine parvovirus license agreement with KindredBio, \$4 million of costs in relation to the acquisition of KindredBio, \$16 million of costs associated with the implementation of new systems, programs, and processes in connection with the acquisition of the animal health business of Bayer, adjustments of \$6 million to previous write-downs of assets at our Shawnee and Speke sites that were classified as held for sale in the second quarter, an \$8 million charge related to a litigation settlement for a matter that originated prior to our acquisition of Bayer Animal Health, and a \$50 million impairment charge for an IPR&D asset that was subject to product rationalization due to observed efficacy results. These costs were partially offset by \$9 million of pension curtailment gains recorded during the period. During the three months ended September 30, 2020, we recorded \$130 million of charges for severance associated with a restructuring program announced during the period, \$91 million of transaction and integration costs directly related to business acquisitions, including the acquisition of the animal health business of Bayer, and \$40 million of costs associated with the implementation of new systems, programs, and processes due to our separation from Lilly.

Asset impairment, restructuring and other special charges increased \$62 million for the nine months ended September 30, 2021 as compared to the prior year. During the nine months ended September 30, 2021, we recorded a \$271 million charge to write down assets at our Shawnee and Speke sites that were classified as held for sale to an amount equal to estimated fair value less costs to sell, \$41 million of severance associated with a restructuring program announced during the period, \$63 million of impairment charges for intangible assets that were subject to product rationalization, \$50 million of integration costs for the Bayer Animal Health acquisition, \$59 million of costs associated with the implementation of new systems, programs, and processes due to our separation from Lilly, a \$26 million charge to establish a liability for future royalty and milestone payments relating to our canine parvovirus license agreement with KindredBio, \$7 million of costs incurred in relation to the acquisition of KindredBio, \$24 million of costs associated with the implementation of new systems, programs, and processes in connection with the acquisition of the animal health business of Bayer, and an \$8 million charge related to a litigation settlement for a matter that originated prior to our acquisition of Bayer Animal Health. These costs were partially offset by \$26 million of pension curtailment gains as well as a \$16 million reversal of severance accruals during the period due primarily to favorable negotiations. During the nine months ended September 30, 2020, charges primarily consisted of \$130 million of severance associated with a restructuring program announced in September 2020, \$4 million of impairment charges for intangible assets that were subject to product rationalization, \$219 million of transaction and integration costs directly related to business acquisitions, including the acquisition of the animal health business of Bayer, and \$100 million of costs associated with the implementation of new systems, programs, and processes due to our separation from Lilly.

For additional information regarding our asset impairment, restructuring and other special charges, see Note 5: Asset Impairment, Restructuring and Other Special Charges to the condensed consolidated financial statements.

Interest expense, net of capitalized interest

(Dollars in millions)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2021	2020	% Change	2021	2020	% Change
Interest expense, net of capitalized interest	\$ 60	\$ 48	25 %	\$ 181	\$ 89	103 %

Interest expense, net of capitalized interest, increased for the three and nine months ended September 30, 2021, primarily due to interest associated with the Term Loan B entered into August 1, 2020 and used to finance the Bayer Animal Health acquisition and additional debt used to finance the KindredBio acquisition.

Other (income) expense, net

(Dollars in millions)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2021	2020	% Change	2021	2020	% Change
Other (income) expense, net	\$ 11	\$ (115)	NM	\$ 8	\$ (162)	NM

Other expense recorded during the three months ended September 30, 2021 primarily consisted of mark-to-market adjustments on equity investments and foreign exchange losses, partially offset by certain components of net periodic benefit income. See Note 13: Retirement Benefits to the condensed consolidated financial statements for further discussion related to net periodic benefit income recorded during the period. Other income recorded during the three months ended September 30, 2020 was primarily composed of gains recorded on the divestitures of certain products.

Other expense recorded during the nine months ended September 30, 2021 primarily consisted of mark-to-market adjustments on equity investments, losses recorded in relation to divestitures, and foreign exchange losses, partially offset by certain components of net periodic benefit income, an up-front payment received in relation to an asset assignment agreement, and up-front payments received, milestones earned, and equity issued to us in relation to a license agreement. Other income recorded during the nine months ended September 30, 2020 was primarily composed of gains recorded on the divestitures of certain products and a \$46 million gain on the sale of land and buildings in New South Wales, Australia.

Income tax benefit

(Dollars in millions)	Three Months Ended September 30,			Nine Months Ended September 30,		
	2021	2020	% Change	2021	2020	% Change
Income tax benefit	\$ (26)	\$ (74)	(65) %	\$ (71)	\$ (117)	(39) %
Effective tax rate	20.0 %	35.4 %		15.9 %	32.9 %	

Income tax benefit decreased for the three months ended September 30, 2021, primarily due to a decrease in pre-tax loss. The effective tax rate decreased for the three months ended September 30, 2021, primarily as a result of the preliminary accounting for KindredBio, which caused a partial release of the U.S. federal valuation allowance, and the impact of profits located in jurisdictions with higher statutory tax rates. The income tax benefit and effective tax rate decreased for the nine months ended September 30, 2021 primarily due to the fact that U.S. federal and state jurisdictions are currently generating losses that are subject to valuation allowances. See Note 10: Income Taxes to the condensed consolidated financial statements.

Liquidity and Capital Resources

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

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

Our ability to meet future funding requirements may be impacted by macroeconomic, business and financial volatility. As markets change, we will continue to monitor our liquidity position. However, a challenging economic environment or an economic downturn may impact our liquidity or ability to obtain future financing. See "Item 1A. Risk Factors - We may not be able to generate sufficient cash to service all of our indebtedness and may be forced to take other actions to satisfy our obligations under our indebtedness, which may not be successful" in Part I of our Annual Report on Form 10-K for the year ended December 31, 2020.

Cash Flows

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

(Dollars in millions) Net cash provided by (used for):	Nine Months Ended September 30,		
	2021	2020	\$ Change
Operating activities	\$ 260	\$ 52	\$ 208
Investing activities	(456)	(4,705)	4,249
Financing activities	166	4,972	(4,806)
Effect of exchange-rate changes on cash and cash equivalents	(23)	7	(30)
Net increase (decrease) in cash, cash equivalents and restricted cash	\$ (53)	\$ 326	\$ (379)

Operating activities

Our cash provided by operating activities increased by \$208 million, to \$260 million for the nine months ended September 30, 2021 from \$52 million for the nine months ended September 30, 2020. While we incurred a higher net loss year over year, the exclusion of non-cash items during the nine months ended September 30, 2021 more than offset the impact of this higher net loss and the decrease in cash due to changes in operating assets and liabilities, particularly accounts payable and other liabilities, as compared to the nine months ended September 30, 2020. Cash provided by operating activities during the nine months ended September 30, 2021 as compared to September 30, 2020 reflects the impact of the acquisition of Bayer Animal Health on our results, a favorable comparison to the prior year due to the channel inventory reduction in the first half of 2020, and the overall recovery observed in the current year after the COVID-19 global health pandemic impacted the global economy for much of 2020. In the past, we have extended our payment terms for distributors on occasion. Although we presently have no plans to do so in the future, it is possible that we will need to extend payment terms in certain situations as a result of the COVID-19 global health pandemic, competitive pressures and the need for certain inventory levels at our channel distributors to avoid supply disruptions. If so, such extensions of customer payment terms could result in additional uses of our cash flow.

Investing activities

Our cash used for investing activities decreased \$4,249 million, to \$456 million for the nine months ended September 30, 2021 from \$4,705 million for the nine months ended September 30, 2020. The decrease was primarily driven by lower cash paid for acquisitions. During the nine months ended September 30, 2021, cash paid for acquisitions was comprised of \$444 million of cash consideration paid to acquire KindredBio, partially offset by cash acquired from KindredBio and the impact of the finalization of the working capital adjustment related to the acquisition of Bayer Animal Health. Cash used for investing activities during the nine months ended September 30, 2020 was composed of \$5,170 million of cash consideration paid to acquire Bayer Animal Health, partially offset by

cash acquired from Bayer Animal Health and proceeds from product divestitures and the settlement of net investment hedges.

Financing activities

Our cash provided by financing activities decreased \$4,806 million, to \$166 million for the nine months ended September 30, 2021 from \$4,972 million for the nine months ended September 30, 2020. Cash provided by financing activities during the nine months ended September 30, 2021 primarily reflected the repayment of indebtedness outstanding under our Senior Notes, proceeds from our borrowings under our new debt financing arrangement with Farm Credit, and net proceeds from our revolving credit facility. Cash provided by financing activities during the nine months ended September 30, 2020, reflected proceeds from our borrowings under the term loan B and revolving credit facility and issuances of common stock and TEUs to finance the acquisition of Bayer Animal Health during the period, partially offset by the repayment of indebtedness outstanding under our credit facilities.

Description of Indebtedness

For a complete description of our description of our debt and available credit facilities as of September 30, 2021 and December 31, 2020, see Note 8: Debt to the condensed consolidated financial statements.

Off Balance-Sheet Arrangements

Other than the commitments and contingencies disclosed in Note 11: Commitments and Contingencies, we had no off-balance sheet arrangements that have, or are reasonably likely to have, a current or future material effect on our financial condition, results of operations, or liquidity.

Contractual Obligations

Our contractual obligations and commitments as of September 30, 2021 are primarily comprised of long-term debt obligations, including principal repayments and interest payments, operating leases, and purchase obligations. Our long-term debt obligations are comprised of our expected principal and interest obligations and our interest rate swaps. Purchase obligations consist of open purchase orders as of September 30, 2021 and contractual payment obligations with significant vendors which are noncancelable and are not contingent. These obligations are primarily short-term in nature.

Critical Accounting Policies

The preparation of financial statements in accordance with 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. Such policies are summarized in Item 7, "Management's Discussion & Analysis of Results of Financial Condition and Results of Operations," of our Annual Report on Form 10-K for the year ended December 31, 2020. There have been no significant changes in the application of our critical accounting policies during the nine months ended September 30, 2021.

ITEM 3. 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 decrease our net income by approximately \$18 million for the nine months ended September 30, 2021.

We generally identify hyperinflationary markets as those markets whose cumulative inflation rate over a three-year period exceeds 100%. We have concluded that our Argentina subsidiary is operating in a hyperinflationary market. As a result, beginning in the second quarter of 2018, the functional currency of our Argentina subsidiary changed from the local currency to the U.S. dollar. During the nine months ended September 30, 2021, sales in Argentina represented less than 1% of our consolidated sales. Assets held in Argentina as of September 30, 2021 represented less than 1% of our consolidated assets. While the hyperinflationary conditions did not have a material impact on our business during the nine months ended September 30, 2021, in the future, we may incur larger currency devaluations, which could have a material adverse impact on our results of operations.

Interest Risk

Borrowings under our Incremental Term Facility, Term Loan B, and revolving credit facility are exposed to interest rate fluctuations based on LIBOR. As of September 30, 2021, we held certain interest rate swap agreements with a notional value of approximately \$4.1 billion that have the economic effect of modifying the variable-interest obligations associated with the Term Loan B, so that a portion of the variable-rate interest payable becomes fixed. During the nine months ended September 30, 2021, we recorded a gain of \$52 million, net of taxes on these interest rate swaps in other comprehensive income (loss). The gain is primarily attributable to an increase in the U.S. Treasury yield curve during the first half of 2021. See Note 9: Financial Instruments and Fair Value to the condensed consolidated financial statements for further information.

Recently Issued Accounting Pronouncements

For discussion of our new accounting standards, see Note 2: Implementation of New Financial Accounting Pronouncements to the condensed consolidated financial statements.

ITEM 4. CONTROLS AND PROCEDURES

(a) *Evaluation of Disclosure Controls and Procedures.* Under applicable SEC regulations, management of a reporting company, with the participation of the principal executive officer and principal financial officer, must periodically evaluate the company's "disclosure controls and procedures," which are defined generally as controls and other procedures of a reporting company designed to ensure that information required to be disclosed by the reporting company in its periodic reports filed with the SEC (such as this Form 10-Q) is recorded, processed, summarized, and reported on a timely basis.

Our management, with the participation of Jeffrey N. Simmons, president and chief executive officer, and Todd S. Young, executive vice president and chief financial officer, evaluated our disclosure controls and procedures as of September 30, 2021. Based on this evaluation, the chief executive officer and the chief financial officer concluded that the disclosure controls and procedures are effective.

(b) *Changes in Internal Controls.* As of September 30, 2021, management is in the process of integrating the internal controls of the acquired Bayer Animal Health business into our existing operations as part of planned integration activities. In addition, we have transitioned from a Lilly solutions center to a newly established Elanco solutions center and substantially completed the implementation of our new Enterprise Resource Planning (ERP) system during the first quarter of 2021. Other than the controls enhanced or implemented to integrate the Bayer Animal Health business and certain control processes that were updated to reflect our ERP implementation, there has been no change in our internal control over financial reporting during the quarter ended September 30, 2021.

that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. As additional transformation activities occur, we will continue to monitor and evaluate our internal control over financial reporting. Further, we have not experienced any material impact to our internal controls over financial reporting despite our accounting, finance, and legal employees working remotely due to the COVID-19 pandemic. We are continually monitoring and assessing COVID-19 on our internal controls to minimize the impact on their design and operating effectiveness.

PART II

ITEM 1. LEGAL PROCEEDINGS

See Note 11: Commitments and Contingencies to the condensed consolidated financial statements for a summary of our legal proceedings, which is incorporated herein by reference.

ITEM 1A. RISK FACTORS

Other than the revisions set forth below, there have been no material changes from the risk factors disclosed in Part I of our Annual Report on Form 10-K for the year ended December 31, 2020.

The following risk factors have been changed from the risk factors that were previously disclosed:

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

Unanticipated safety, quality or efficacy concerns arise from time to time with respect to animal health products, whether or not scientifically or clinically supported, potentially leading to product recalls, withdrawals or suspended or declining sales, as well as product liability and other claims. Regulatory actions based on these types of safety, quality or efficacy concerns could impact all, or a significant portion, of a product's sales.

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

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

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 investigation, 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 recently filed against us allege, in part, that we and certain of our executives made materially false and/or misleading statements and/or failed to disclose certain facts about our supply chain,

inventory, revenue, projections and our relationships with third party distributors and revenue attributable to those distributors. We intend to vigorously defend the claims made in these lawsuits, however, the ultimate resolution cannot be predicted and the claims raised in these lawsuits may result in further legal matters or actions against us, including, but not limited to, government enforcement actions or additional private litigation. In addition, changes in the interpretations of laws and regulations to which we are subject, or in legal standards in one or more of the jurisdictions in which we operate, could increase our exposure to liability. For example, in the U.S., attempts have been made to allow damages for emotional distress and pain and suffering in connection with the loss of, or injury to, a pet. If such attempts were successful, our exposure with respect to product liability claims could increase materially.

Also, on July 1, 2021, we received a subpoena from the U.S. Securities and Exchange Commission (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.

We have identified the following additional risk factors:

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, such as the acquisition of KindredBio and proposed carve-out of our microbiome R&D platform.

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

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

- the inability to realize the anticipated value from various assets of the target company;
- the inability to combine the businesses of the acquired company with ours in a manner that permits us to achieve the cost savings or other synergies anticipated as a result of the transaction or to achieve such cost savings or other anticipated synergies in a timely manner, which could result in us not realizing some anticipated benefits of the transaction in the time frame anticipated, or at all;
- loss of key employees;
- potential unknown liabilities and unforeseen increased expenses, delays or unfavorable conditions in connection with the closing of the transaction and the subsequent integration; and
- performance shortfalls at our or the target company as a result of the diversion of management's attention from ongoing business activities as a result of completing the transaction and integrating the companies' operations.

In the case of our recent announcement regarding our intention to carve-out our microbiome R&D platform, the terms, timing and structure of any such separation of this platform, or whether the separation can be completed at all, remain uncertain, as is our ability to achieve any operational and strategic benefits from the separation. In the

meantime, the uncertainty of announcing the separation initiative may adversely impact employees, customers and suppliers related to the microbiome R&D platform.

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

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

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

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

- weather conditions and the availability of natural resources;
- increased or decreased inventory levels at our channel distributors;
- timing of customer orders and deliveries;
- competitive changes, such as price changes or new product introductions that we or our competitors may make;
- timing of marketing programs and events; and
- availability of veterinarians to use our products, as there are seasonal impacts, due to veterinarian vacations or training events that limit their ability to serve their customers that result in the use of our products.

For more detailed information on some of the above-listed factors that can cause fluctuations in our operating results, see "Our business may be negatively affected by weather conditions and the availability of natural resources" and "Increased or decreased inventory levels at our channel distributors can lead to fluctuations in our revenues and variations in our payment terms extended to our distributors can impact our cash flows" in Part I - Item 1A. Risk Factors of our Annual Report on Form 10-K for the year ended December 31, 2020.

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.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

(none)

ITEM 3. DEFAULTS UPON SENIOR SECURITIES

(none)

ITEM 4. MINE SAFETY DISCLOSURES

(none)

ITEM 5. OTHER INFORMATION

(none)

ITEM 6. 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
10.1	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).
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	Cover Page Interactive Data File (formatted as Inline XBRL document and included in Exhibit 101)

Signatures

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

ELANCO ANIMAL HEALTH INCORPORATED

(Registrant)

Date: November 5, 2021

/s/ Jeffrey N. Simmons

Jeffrey N. Simmons

President and Chief Executive Officer

Date: November 5, 2021

/s/ Todd S. Young

Todd S. Young

Executive Vice President, Chief Financial Officer

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Elanco Animal Health Incorporated, an Indiana corporation (the "Company"), does hereby certify that, to the best of their knowledge:

The Quarterly Report on Form 10-Q for the quarter ended September 30, 2021 (the "Form 10-Q") of the Company fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934 and information contained in the Form 10-Q fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 5, 2021

/s/ Jeffrey N. Simmons

Jeffrey N. Simmons
President and Chief Executive Officer

Date: November 5, 2021

/s/ Todd S. Young

Todd S. Young
Executive Vice President and Chief Financial Officer