News Release

FOR IMMEDIATE RELEASE

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Merck Announces Third-Quarter 2021 Financial Results

- Results Demonstrate Strong Momentum Across Business
- Third-Quarter 2021 Worldwide Sales Were $13.2 Billion, 20% Above Third-Quarter 2020; Excluding the Impact from Foreign Exchange, Sales Grew 19% Reflecting Strong Demand for the Company's Robust Portfolio:
    - KEYTRUDA Sales Grew 22% to $4.5 Billion; Excluding the Impact from Foreign Exchange, Sales Grew 21%
    - GARDASIL/GARDASIL 9 Sales Grew 68% to $2.0 Billion; Excluding the Impact from Foreign Exchange, Sales Grew 63%
    - Animal Health Sales Grew 16% to $1.4 Billion; Excluding the Impact from Foreign Exchange, Sales Grew 14%
- Third-Quarter 2021 GAAP EPS from Continuing Operations Was $1.80; Third-Quarter 2021 Non-GAAP EPS from Continuing Operations Was $1.75
- Bolstered Innovation with Agreement to Acquire Acceleron Pharma, Complementing and Expanding Merck's Cardiovascular Pipeline
- Progressed Regulatory Applications, Secured Multiple Regulatory Approvals, and Saw Advancement of Key Government Recommendations, Including:
    - Submission of Emergency Use Authorization Application to FDA for Molnupiravir, an Investigational Oral Antiviral Medicine for the Treatment of At-Risk Patients with Mild-to-Moderate COVID-19
    - FDA Approval of WELIREG for the Treatment of Adult Patients with Certain Types of Von Hippel-Lindau Disease-Associated Tumors
    - FDA Approval of KEYTRUDA in Combination with Lenvima for the First-Line Treatment of Adult Patients with Advanced Renal Cell Carcinoma

    - FDA Approval of KEYTRUDA in Combination with Chemotherapy, with or Without Bevacizumab, for the Treatment of Certain Patients with Persistent, Recurrent or Metastatic Cervical Cancer
    - U.S. CDC's Advisory Committee on Immunization Practices Vote to Provisionally Recommend Vaccination with a Sequential Regimen of VAXNEUVANCE Followed by PNEUMOVAX 23 as an Option both for Adults 65 Years and Older and for Adults Ages 19 to 64 with Certain Underlying Medical Conditions
- 2021 Financial Outlook:
    - Raises and Narrows Estimated Full-Year 2021 Revenue Range to Be Between $47.4 Billion and $47.9 Billion, Including a Positive Impact from Foreign Exchange of Approximately 1.5%; Now Expects Full-Year 2021 Sales Growth of 14% to 15%
    - Raises and Narrows Full-Year 2021 GAAP EPS to be Between $4.71 and $4.76; Raises and Narrows Full-Year 2021 Non-GAAP EPS to be Between $5.65 and $5.70, Including a Positive Impact from Foreign Exchange of Approximately 2%

KENILWORTH, N.J., Oct. 28, 2021 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced financial results for the third quarter of 2021.

"Merck delivered another strong quarter with positive momentum across our business and meaningful progress across our pipeline. Our teams continued to excel as we focus on evolving our operations, while driving innovations in our labs that exemplify the best of Merck science," said Robert M. Davis, chief executive officer and president, Merck. "We achieved notable clinical milestones in the key areas of oncology and COVID-19, including positive Phase 3 results for molnupiravir. We recently announced our proposed acquisition of Acceleron, which will strengthen our cardiovascular portfolio with complementary, cutting-edge science and an exciting late-stage candidate. Looking ahead, we remain focused on building more momentum, delivering on our mission of saving and improving lives and continuing to expand our portfolio and pipeline for long-term success and sustainable value creation."

Financial Summary – Continuing Operations

Financial information presented in this release reflects Merck's results on a continuing operations basis, which excludes Organon & Co., that was spun-off on June 2, 2021.

	Third Quarter			
$ in millions, except EPS amounts	**2021**	**2020**	**Change**	**Change Ex-Exchange**
Sales	$13,154	$10,929	20%	19%
GAAP net income from continuing operations[1]	4,567	2,324	97%	94%
Non-GAAP net income that excludes certain items[1,2]*	4,439	3,486	27%	26%
GAAP EPS from continuing operations	1.80	0.92	96%	93%
Non-GAAP EPS that excludes certain items[2]*	1.75	1.37	28%	26%

*Refer to table on page 13.

GAAP (generally accepted accounting principles) earnings per share assuming dilution (EPS) was $1.80 for the third quarter of 2021. Non-GAAP EPS of $1.75 for the third quarter of 2021 excludes acquisition- and divestiture-related costs, restructuring costs, income and losses from investments in equity securities and certain other items. Year-to-date results can be found in the attached tables.

Strong Performance Across the Business

Merck achieved strong performance across its key pillars of Oncology, Vaccines, and Animal Health, led by highly innovative products, including KEYTRUDA (pembrolizumab), Lynparza (olaparib), Lenvima (lenvatinib), GARDASIL [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant], GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant) and the BRAVECTO (fluralaner) line of products. In addition, BRIDION (sugammadex) injection 100 mg/mL saw strong growth in the quarter. The company continues to benefit from strong underlying demand for its products, as well as broad commercial scale and improved patient access to its innovative medicines across the globe.

[1] Net income from continuing operations attributable to Merck & Co., Inc.

[2] Merck is providing certain 2021 and 2020 non-GAAP information that excludes certain items because of the nature of these items and the impact they have on the analysis of underlying business performance and trends. Management believes that providing this information enhances investors' understanding of the company's results and permits investors to understand how management assesses performance. Management uses these measures internally for planning and forecasting purposes and to measure the performance of the company along with other metrics. In addition, senior management's annual compensation is derived in part using non-GAAP pretax income. This information should be considered in addition to, but not as a substitute for or superior to, information prepared in accordance with GAAP. For a description of the non-GAAP adjustments, see Table 2a attached to this release.

Merck Reported Positive Phase 3 Results for Molnupiravir, an Investigational Oral Antiviral COVID-19 Treatment

Merck and Ridgeback Biotherapeutics announced positive results from the interim analysis of the Phase 3 MOVe-OUT trial of investigational oral antiviral therapeutic molnupiravir (MK-4482/EIDD-2801) in at-risk, non-hospitalized adult patients with mild-to-moderate COVID-19. The company announced on Oct. 11, 2021, the submission of an application for Emergency Use Authorization (EUA) to the U.S. Food and Drug Administration (FDA) based on these findings and plans to submit marketing applications to other regulatory bodies worldwide. If authorized or approved, Merck anticipates that molnupiravir can become an important treatment as part of the global effort to fight the COVID-19 pandemic. On Oct. 14, 2021, the FDA announced a Nov. 30, 2021, meeting of its Antimicrobial Drugs Advisory Committee to discuss the available data supporting the use of molnupiravir to treat at-risk adults with mild-to-moderate COVID-19. On Oct. 25, 2021, the European Medicines Agency (EMA) initiated a rolling review for molnupiravir for the treatment of COVID-19 in adults. Merck plans to work with the EMA's Committee for Medicinal Products for Human Use (CHMP) to complete the rolling review process to facilitate initiating the formal review of the Marketing Authorization Application.

Merck is committed to providing timely access to molnupiravir globally, if it is authorized or approved, and plans to implement a tiered pricing approach based on World Bank country income criteria to reflect countries' relative ability to finance their pandemic response and health systems. Merck has entered into non-exclusive voluntary licensing agreements with established generic manufacturers in India for molnupiravir. Additionally, Merck and the Medicines Patent Pool (MPP) jointly announced the signing of a voluntary licensing agreement to facilitate access to generic molnupiravir, upon local regulatory authorization. These agreements will help expand access to molnupiravir in more than 100 low- and middle-income countries.

Merck has entered into supply and purchase commitments for molnupiravir with several governments worldwide, including Australia, New Zealand, South Korea, the U.K. and the U.S., pending regulatory authorization, and is currently in discussions with other governments. The company expects to produce 10 million courses of treatment by the end of 2021, with at least 20 million additional courses expected to be produced in 2022.

Planned Acquisition of Acceleron Bolsters Innovation and Broadens Cardiovascular Pipeline

Merck announced a definitive agreement and tender offer to acquire Acceleron Pharma Inc. (Acceleron). The planned acquisition complements and strengthens Merck's cardiovascular

pipeline with Acceleron's lead therapeutic candidate, sotatercept, a potentially first-in-class therapy in Phase 3 clinical trials for the treatment of pulmonary arterial hypertension. Merck commenced a tender offer on Oct. 12, 2021, and upon successful completion of the tender offer and receipt of necessary regulatory approvals, Merck, through a subsidiary, will acquire Acceleron for $180 per share in cash for an approximate total equity value of $11.5 billion. The transaction is expected to close in the fourth quarter of 2021.

Oncology Program Highlights

Merck continued to advance development programs across its oncology portfolio, anticipating more than 90 potential new indications by 2028, including notable progress for KEYTRUDA, the company's anti-PD-1 therapy; Lynparza, an oral poly (ADP-ribose) polymerase (PARP) inhibitor being co-developed and co-commercialized with AstraZeneca; Lenvima, an orally available tyrosine kinase inhibitor (TKI) being co-developed and co-commercialized with Eisai Co., Ltd. (Eisai); and WELIREG (belzutifan), an oral hypoxia-inducible factor-2 alpha inhibitor (HIF-2α).

- Merck announced the following regulatory milestones:
  - FDA approval of WELIREG for the treatment of adult patients with von Hippel-Lindau disease who require therapy for associated renal cell carcinoma (RCC), central nervous hemangioblastomas, or pancreatic neuroendocrine tumors, not requiring immediate surgery based on the open label Study 004 trial. WELIREG is the first HIF-2α inhibitor therapy approved in the U.S. and is currently being evaluated in three Phase 3 studies as monotherapy and in combination with other novel therapies.
  - FDA approval of KEYTRUDA in combination with Lenvima for the first-line treatment of adult patients with advanced RCC. The approval was based on results from the pivotal Phase 3 CLEAR study (KEYNOTE-581/Study 307).
  - FDA approval of KEYTRUDA in combination with chemotherapy, with or without bevacizumab, for the treatment of patients with persistent, recurrent or metastatic cervical cancer whose tumors express PD-L1 (Combined Positive Score [CPS] ≥1) as determined by an FDA-approved test, based on results from the Phase 3 KEYNOTE-826 trial.
  - FDA priority review for a new supplemental Biologics License Application (sBLA) for KEYTRUDA for the adjuvant treatment of patients with RCC at intermediate-high or high risk of recurrence following nephrectomy (surgical removal of a kidney), or following nephrectomy and resection of metastatic lesions. This sBLA was based on data that

demonstrated a statistically significant and clinically meaningful improvement in disease-free survival compared to placebo from the pivotal Phase 3 KEYNOTE-564 trial. The Prescription Drug User Fee Act (PDUFA) date is Dec. 10, 2021.

- FDA priority review for a new sBLA for KEYTRUDA for the adjuvant treatment of adult and pediatric patients (12 years and older) with STAGE IIB or IIC melanoma following complete resection, based on results from the Phase 3 KEYNOTE-716 trial that showed a statistically significant and clinically meaningful improvement in recurrence-free survival compared to placebo. The PDUFA date is Dec. 4, 2021.
- FDA review of a new sBLA seeking approval for KEYTRUDA as a single agent for the treatment of patients with advanced endometrial carcinoma (EC) that is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior systemic therapy in any setting and are not candidates for curative surgery or radiation. The application is based on overall response data from Cohorts D and K of the KEYNOTE-158 trial. The PDUFA date is March 28, 2022.
- Positive opinion from the CHMP of the EMA for KEYTRUDA in combination with chemotherapy for the treatment of locally recurrent unresectable or metastatic triple-negative breast cancer (TNBC) in adults whose tumors express PD-L1 (CPS ≥10) and who have not received prior chemotherapy for metastatic disease. The positive opinion is based on progression-free survival and overall survival (OS) results from the Phase 3 KEYNOTE-355 trial.
- European Commission approval of KEYTRUDA, in combination with chemotherapy, for the first-line treatment of locally recurrent unresectable or metastatic TNBC in adults whose tumors express PD-L1 (CPS ≥10) and who have not received prior chemotherapy for metastatic disease.
- Positive opinions from the CHMP of the EMA recommending approval of the combination of KEYTRUDA plus Lenvima for two different indications: advanced RCC and advanced or recurrent EC. The positive opinions are based on data from two pivotal Phase 3 trials: CLEAR (KEYNOTE-581/Study 307) evaluating the combination in adult patients with advanced RCC and KEYNOTE-775/Study 309 evaluating the combination in certain patients with advanced or recurrent EC.
- National Medical Products Administration approval in China of KEYTRUDA in combination with platinum- and fluoropyrimidine-based chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic carcinoma of the esophagus or gastroesophageal junction. This new indication was granted approval

based on OS findings from the pivotal Phase 3 KEYNOTE-590 trial. KEYTRUDA is now approved for eight indications across five different types of cancer in China.

  - Pharmaceuticals and Medical Devices Agency approval in Japan of two KEYTRUDA indications. KEYTRUDA was approved for the treatment of patients with PD-L1-positive, hormone receptor-negative and human epidermal growth factor receptor 2-negative, inoperable or recurrent breast cancer based on the results of the Phase 3 KEYNOTE-355 trial and for the treatment of patients with unresectable, advanced or recurrent MSI-H colorectal cancer, based on the results of the Phase 3 KEYNOTE-177 trial. With these approvals, KEYTRUDA has 15 authorized uses in Japan, including indications in nine tumor types as well as MSI-H tumors.

- Merck provided additional data presentations and updates including:
  - Final OS results from the pivotal Phase 3 KEYNOTE-355 trial were presented at the European Society for Medical Oncology (ESMO) Congress 2021 demonstrating a 27% reduction in risk of death for patients with metastatic TNBC whose tumors expressed PD-L1 (CPS ≥10) using first-line treatment of KEYTRUDA in combination with chemotherapy (paclitaxel, nab-paclitaxel or gemcitabine/carboplatin) as compared to chemotherapy alone.
  - Positive results from the Phase 3 PROpel trial demonstrating superior radiographic progression-free survival with Lynparza in combination with abiraterone and prednisone versus abiraterone plus prednisone as a first-line treatment for men with metastatic castration-resistant prostate cancer with or without homologous recombination repair gene mutations.

Other Highlights

Vaccines

- Merck announced positive topline results from the pivotal Phase 3 PNEU-PED (V114-029) study evaluating the immunogenicity, safety and tolerability of VAXNEUVANCE (Pneumococcal 15-valent Conjugate Vaccine) in healthy infants enrolled between 42-90 days of age.
- Merck announced that the CHMP of the EMA has recommended the approval of VAXNEUVANCE for active immunization for the prevention of invasive disease and pneumonia caused by *Streptococcus pneumoniae* in individuals 18 years of age and older. The CHMP recommendation will now be reviewed by the European Commission for marketing authorization in the EU, and a final decision is expected by the end of the year.

- Merck announced the U.S. Centers for Disease Control and Prevention's (CDC's) Advisory Committee on Immunization Practices (ACIP) voted to provisionally recommend vaccination either with a sequential regimen of VAXNEUVANCE followed by PNEUMOVAX 23 (Pneumococcal Vaccine Polyvalent), or with a single dose of 20-valent pneumococcal conjugate vaccine, for both adults 65 years and older and for adults ages 19 to 64 with certain underlying medical conditions or other risk factors. Final recommendations are subject to review by the director of the CDC and the Department of Health and Human Services, and will become official when published in the CDC's *Morbidity and Mortality Weekly Report (MMWR).*

Infectious Diseases

- Merck announced top-line results from two pivotal Phase 3 trials of the investigational, once-daily oral fixed dose combination pill of doravirine/islatravir in adults with HIV-1 infection who are virologically suppressed on different antiretroviral therapy regimens (ILLUMINATE SWITCH A) or bictegravir/emtricitabine/tenofovir (ILLUMINATE SWITCH B).
- Merck anticipates the initiation of a phased resupply of ZERBAXA (ceftolozane and tazobactam) for injection beginning with the U.S. in the fourth quarter of 2021 following a voluntary recall in 2020. Additionally, the FDA has accepted for review two supplemental New Drug Applications for ZERBAXA in pediatric complicated urinary tract infections and complicated intra-abdominal infections with PDUFA dates of April 21, 2022, and May 2, 2022, respectively.

Third-Quarter Revenue Performance

The following table reflects sales of the company's top pharmaceutical products, as well as sales of Animal Health products.

$ in millions	Third Quarter			
	2021	2020	Change	Change Ex-Exchange
Total Sales	$13,154	$10,929	20%	19%
Pharmaceutical	11,496	9,714	18%	17%
KEYTRUDA	4,534	3,715	22%	21%
GARDASIL / GARDASIL 9	1,993	1,187	68%	63%
JANUVIA / JANUMET	1,339	1,327	1%	0%
PROQUAD, M-M-R II and VARIVAX	661	576	15%	14%
BRIDION	369	320	16%	15%
PNEUMOVAX 23	277	375	-26%	-26%
Lynparza*	246	196	25%	25%
ROTATEQ	227	210	8%	7%
SIMPONI	203	209	-3%	-5%
ISENTRESS / ISENTRESS HD	189	205	-8%	-7%
Lenvima*	188	142	32%	30%
Animal Health	1,417	1,220	16%	14%
Livestock	864	758	14%	12%
Companion Animals	553	462	20%	18%
Other Revenues**	241	(5)	>100%	>100%

*Alliance revenue for this product represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs.

**Other revenues are comprised primarily of third-party manufacturing sales and miscellaneous corporate revenues, including revenue-hedging activities. Other revenues in the third quarter of 2021 include $135 million related to the receipt of a milestone payment for an out-licensed product.

Pharmaceutical Revenue

Third-quarter pharmaceutical sales increased 18% to $11.5 billion, compared to the third quarter of 2020. Excluding the favorable effect of foreign exchange, sales grew by 17%, reflecting strength in the company's oncology and vaccine businesses.

Growth in oncology was largely driven by higher sales of KEYTRUDA, which rose 22% to $4.5 billion in the quarter. Global sales growth of KEYTRUDA reflects continued strong momentum from the non-small-cell lung cancer indications as well as uptake in other indications, including RCC, head and neck squamous cell carcinoma, TNBC and MSI-H cancers. Also contributing to higher sales in oncology was a 25% increase in Lynparza alliance revenue, primarily reflecting continued uptake in the United States and Europe, as well as a 32% increase in Lenvima alliance revenue, driven primarily by higher demand in the United States and China.

Growth in vaccines for the third quarter was primarily driven by higher combined sales of GARDASIL and GARDASIL 9, vaccines to prevent certain cancers and other diseases caused by HPV. Third-quarter 2021 GARDASIL/GARDASIL 9 sales grew 68% to $2.0 billion, primarily driven by strong global demand, particularly in China, which also benefitted from increased supply, as well as in the United States, which also benefitted from the timing of public sector purchases.

Combined sales of pediatric vaccines VARIVAX (Varicella Virus Vaccine Live), a vaccine to help prevent chickenpox; PROQUAD (Measles, Mumps, Rubella and Varicella Virus Vaccine Live), a combination vaccine to help protect against measles, mumps, rubella and varicella; and M-M-R II (Measles, Mumps and Rubella Virus Vaccine Live), a vaccine to help prevent measles, mumps and rubella, also contributed to higher sales in vaccines, increasing by 15% to $661 million primarily driven by the ongoing recovery of wellness visits in the United States.

Vaccine performance was negatively affected by lower sales of PNEUMOVAX 23, a vaccine to help prevent pneumococcal disease, which declined 26% to $277 million primarily driven by lower demand in the United States reflecting prioritization of the COVID-19 vaccine.

Performance in hospital acute care reflects the suspension of sales of ZERBAXA for injection, a combination cephalosporin antibacterial and beta-lactamase inhibitor for the treatment of adults with certain bacterial infections, following a product recall in the fourth quarter of 2020. This unfavorability was partially offset by higher demand globally for BRIDION injection 100 mg/mL, a medicine for the reversal of neuromuscular blockade induced by rocuronium bromide or vecuronium bromide in adults and pediatric patients aged 2 years and older undergoing surgery, which increased 16% to $369 million due in part to the ongoing COVID-19 pandemic recovery, and growth in DIFICID (fidaxomicin), a macrolide antibacterial drug for treatment of *Clostridioides difficile*-associated diarrhea in adults and pediatric patients aged 6 months and older, in the United States.

Animal Health Revenue

Animal Health sales totaled $1.4 billion for the third quarter of 2021, an increase of 16% compared with the third quarter of 2020. Excluding the favorable effect from foreign exchange, Animal Health sales increased 14%, reflecting growth across geographies and species, including the biopharmaceutical portfolio and the Animal Health Intelligence portfolio. Sales growth in livestock was primarily driven by higher demand globally for ruminant products, including Animal Health Intelligence products. Sales growth in companion animal was primarily driven by the BRAVECTO parasiticide line of products, as well as vaccines.

Third-Quarter Expense, EPS and Related Information

The tables below present selected expense information.

$ in millions **Third-Quarter 2021**	**GAAP**	**Acquisition- and Divestiture-Related Costs**[3]	**Restructuring Costs**	**(Income) Loss from Investments in Equity Securities**	**Certain Other Items**	**Non-GAAP**[2]
Cost of sales	$3,450	$346	$48	$-	$-	$3,056
Selling, general and administrative	2,336	61	5	-	-	2,270
Research and development	2,445	48	8	-	(87)	2,476
Restructuring costs	107	-	107	-	-	-
Other (income) expense, net	(450)	(10)	-	(684)	-	244
Third-Quarter 2020						
Cost of sales	$3,013	$403	$38	$-	$-	$2,572
Selling, general and administrative	2,060	25	15	-	-	2,020
Research and development	3,349	19	19	-	1,082	2,229
Restructuring costs	113	-	113	-	-	-
Other (income) expense, net	(312)	-	-	(346)	(1)	35

GAAP Expense, EPS and Related Information

Gross margin was 73.8% for the third quarter of 2021 compared to 72.4% for the third quarter of 2020. The increase primarily reflects the favorable effects of product mix and lower acquisition- and divestiture-related costs, partially offset by higher manufacturing costs.

Selling, general and administrative expenses were $2.3 billion in the third quarter of 2021, an increase of 13% compared to the third quarter of 2020. The increase primarily reflects higher administrative costs, increased promotional expenses in support of the company's growth pillars, higher acquisition- and divestiture-related costs, as well as the unfavorable effects of foreign exchange.

Research and development expenses were $2.4 billion in the third quarter of 2021 compared with $3.3 billion in the third quarter of 2020. The decrease was primarily driven by lower upfront payments related to collaborations and license agreements, partially offset by

[3] Includes expenses for the amortization of intangible assets and purchase accounting adjustments to inventories, intangible asset impairment charges and expense or income related to changes in the estimated fair value measurement of liabilities for contingent consideration. Also includes integration, transaction and certain other costs related to acquisitions and divestitures.

higher oncology and COVID-19 clinical development spending, as well as increased investment in discovery research and early drug development.

Other (income) expense, net, was $450 million of income in the third quarter of 2021 compared to $312 million of income in the third quarter of 2020, primarily reflecting higher income from investments in equity securities, net, partially offset by higher pension settlement costs.

The effective income tax rate was 13.2% for the third quarter of 2021, reflecting the beneficial impact of the settlement of a foreign tax matter.

GAAP EPS was $1.80 for the third quarter of 2021 compared with $0.92 for the third quarter of 2020.

Non-GAAP Expense, EPS and Related Information

Non-GAAP gross margin was 76.8% for the third quarter of 2021 compared to 76.5% for the third quarter of 2020. The increase in non-GAAP gross margin primarily reflects the favorable effect of product mix, partially offset by higher manufacturing costs.

Non-GAAP selling, general and administrative expenses were $2.3 billion in the third quarter of 2021, an increase of 12% compared to the third quarter of 2020. The increase primarily reflects higher administrative costs, increased promotional expenses in support of the company's growth pillars, as well as the unfavorable effects of foreign exchange.

Non-GAAP R&D expenses were $2.5 billion in the third quarter of 2021, an 11% increase compared to the third quarter of 2020. The increase primarily reflects higher oncology and COVID-19 clinical development spending, as well as increased investment in discovery research and early drug development.

Non-GAAP other (income) expense, net, was $244 million of expense in the third quarter of 2021 compared to $35 million of expense in the third quarter of 2020, primarily reflecting higher pension settlement costs.

The non-GAAP effective income tax rate was 13.0% for the third quarter of 2021, reflecting the beneficial impact of the settlement of a foreign tax matter.

Non-GAAP EPS was $1.75 for the third quarter of 2021 compared with $1.37 for the third quarter of 2020.

A reconciliation of GAAP to non-GAAP net income and EPS is provided in the table that follows.

$ in millions, except EPS amounts	Third Quarter	
	2021	**2020**
EPS		
GAAP EPS	$1.80	$0.92
Difference	(0.05)	0.45
Non-GAAP EPS that excludes items listed below[2]	$1.75	$1.37
Net Income		
GAAP net income[1]	$4,567	$2,324
Difference	(128)	1,162
Non-GAAP net income that excludes items listed below[1,2]	$4,439	$3,486
Decrease (Increase) in Net Income Due to Excluded Items:		
Acquisition- and divestiture-related costs[3]	$445	$447
Restructuring costs	168	185
(Income) loss from investments in equity securities	(684)	(346)
Charges for acquisitions and collaborations[4]	-	1,082
Other	(87)	(1)
Net decrease (increase) in income before taxes	(158)	1,367
Income tax (benefit) expense[5]	30	(205)
Decrease (increase) in net income	$(128)	$1,162

Financial Outlook

Merck continues to experience strong global underlying demand across its business. Consequently, Merck is raising and narrowing its full-year estimated ranges for revenue and EPS. At mid-October 2021 exchange ranges, Merck now expects sales growth of 14% to 15% in 2021, with full-year 2021 revenue estimated to be between $47.4 billion and $47.9 billion, including a positive impact from foreign exchange of approximately 1.5%.

Merck continues to believe that the global health systems and patients have largely adapted to the impacts of the COVID-19 pandemic, and, that while certain negative effects will persist, the trend will continue to improve. Merck continues to estimate that the pandemic will have a net unfavorable impact to 2021 revenues of less than 3%, all of which relates to the pharmaceutical segment.

[4] 2020 includes $832 million related to the Seagen collaborations.
[5] Includes the estimated tax impact on the reconciling items. In addition, the amount for 2020 includes a tax cost of $67 million, representing an adjustment to the tax benefits recorded in conjunction with the 2015 acquisition of Cubist Pharmaceuticals, Inc.

Merck is raising and narrowing its full-year 2021 GAAP EPS range to be between $4.71 and $4.76.

Merck is raising and narrowing its non-GAAP EPS range and now expects full-year 2021 to be between $5.65 and $5.70, including a positive impact from foreign exchange of approximately 2%. The non-GAAP range excludes acquisition- and divestiture-related costs, costs related to restructuring programs, income and losses from investments in equity securities, and certain other items. Neither the sales nor the EPS ranges provided above include the impact of the potential launch of Merck's COVID-19 antiviral drug candidate, molnupiravir.

The following table summarizes the company's full-year 2021 financial guidance.

	GAAP	**Non-GAAP**[2]
Revenue	$47.4 to $47.9 billion	$47.4 to $47.9 billion*
Operating expenses	Lower than 2020 by a mid-single digit rate	Higher than 2020 by a high-single digit rate
Effective tax rate	14.5% to 15.0%	14.0% to 14.5%
EPS**	$4.71 to $4.76	$5.65 to $5.70

*The company does not have any non-GAAP adjustments to revenue.
**EPS guidance for 2021 assumes a share count (assuming dilution) of approximately 2.54 billion shares.

A reconciliation of anticipated 2021 GAAP EPS to non-GAAP EPS and the items excluded from non-GAAP EPS are provided in the table below.

$ in millions, except EPS amounts	**Full-Year 2021**
GAAP EPS	$4.71 to $4.76
Difference	$0.94
Non-GAAP EPS that excludes items listed below[2]	$5.65 to $5.70
Acquisition- and divestiture-related costs	$2,100
Restructuring costs	700
(Income) loss from investments in equity securities	(2,000)
Charge for the discontinuation of COVID-19 development programs	225
Charge for the acquisition of Pandion Therapeutics	1,704
Other	(29)
Net decrease (increase) in income before taxes	2,700
Income tax (benefit) expense[6]	(310)
Decrease (increase) in net income	$2,390

Earnings Conference Call

Investors, journalists and the general public may access a live audio webcast of the call today at 8:00 a.m. EDT on Merck's website at https://investors.merck.com/events-and-

[6] Includes the estimated tax impact on the reconciling items, as well as a $207 million net tax benefit related to the settlement of certain federal income tax matters.

presentations/default.aspx. Institutional investors and analysts can participate in the call by dialing (833) 353-0277 or (469) 886-1947 and using ID code number 6768456. Members of the media are invited to monitor the call by dialing (833) 353-0277 or (469) 886-1947 and using ID code number 6768456. Journalists who wish to ask questions are requested to contact a member of Merck's Media Relations team at the conclusion of the call.

About Merck

For over 130 years, Merck, known as MSD outside of the United States and Canada, has been inventing for life, bringing forward medicines and vaccines for many of the world's most challenging diseases in pursuit of our mission to save and improve lives. We demonstrate our commitment to patients and population health by increasing access to health care through far-reaching policies, programs and partnerships. Today, Merck continues to be at the forefront of research to prevent and treat diseases that threaten people and animals – including cancer, infectious diseases such as HIV and Ebola, and emerging animal diseases – as we aspire to be the premier research-intensive biopharmaceutical company in the world. For more information, visit www.merck.com and connect with us on Twitter, Facebook, Instagram, YouTube and LinkedIn.

Forward-Looking Statement of Merck & Co., Inc., Kenilworth, N.J., USA

This news release of Merck & Co., Inc., Kenilworth, N.J., USA (the "company") includes "forward-looking statements" within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. These statements are based upon the current beliefs and expectations of the company's management and are subject to significant risks and uncertainties. There can be no guarantees with respect to pipeline products, including if the Acceleron acquisition is consummated, Acceleron's pipeline products, that the products will receive the necessary regulatory approvals or that they will prove to be commercially successful. If underlying assumptions prove inaccurate or risks or uncertainties materialize, actual results may differ materially from those set forth in the forward-looking statements.

Risks and uncertainties include but are not limited to, general industry conditions and competition; uncertainties as to the timing of the offer and subsequent merger with Acceleron; uncertainties as to how many of Acceleron's stockholders will tender their shares in the offer; the risk that competing offers or acquisition proposals will be made; the possibility that various conditions to the consummation of the merger and the offer contemplated thereby may not be satisfied or waived; the effects of disruption from the transactions contemplated by the merger

agreement and the impact of the announcement and pendency of the transactions on Acceleron's business; the risk that stockholder litigation in connection with the offer or the merger may result in significant costs of defense, indemnification and liability; general economic factors, including interest rate and currency exchange rate fluctuations; the impact of the global outbreak of novel coronavirus disease (COVID-19); the impact of pharmaceutical industry regulation and health care legislation in the United States and internationally; global trends toward health care cost containment; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approval; the company's ability to accurately predict future market conditions; manufacturing difficulties or delays; financial instability of international economies and sovereign risk; dependence on the effectiveness of the company's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

The company undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in the company's 2020 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).

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