

NEWS RELEASE

Merck Announces Second-Quarter 2021 Financial Results

7/29/2021

- Second-Quarter 2021 Worldwide Sales from Continuing Operations (Excluding Organon) Were \$11.4 Billion, 22% Above Second-Quarter 2020; Excluding the Impact from Foreign Exchange, Sales Grew 19% Reflecting Ongoing Recovery from the COVID-19 Pandemic and Strong Underlying Demand Across the Company's Portfolio of Innovative Products:
 - KEYTRUDA Sales Grew 23% to \$4.2 Billion; Excluding the Impact from Foreign Exchange, Sales Grew 20%
 - GARDASIL/GARDASIL 9 Sales Grew 88% to \$1.2 Billion; Excluding the Impact from Foreign Exchange, Sales Grew 78%
 - Animal Health Sales Grew 34% to \$1.5 Billion; Excluding the Impact from Foreign Exchange, Sales Grew 27%
- Second-Quarter 2021 GAAP EPS from Continuing Operations Was \$0.48; Second-Quarter 2021 Non-GAAP EPS from Continuing Operations Was \$1.31
- Progressed Pipeline and Secured Multiple Regulatory Approvals, Including FDA Approval of VAXNEUVANCE, Merck's 15-Valent Pneumococcal Conjugate Vaccine, for Adults; FDA Approvals for Neoadjuvant/Adjuvant KEYTRUDA in Combination With Chemotherapy for High-Risk Early-Stage Triple-Negative Breast Cancer (KEYNOTE-522) and KEYTRUDA in Combination with Lenvima for the Treatment of Certain Patients With Advanced Endometrial Carcinoma (KEYNOTE-775/Study 309)
- Completed the Spinoff of Organon on June 2; Received Cash Distribution of Approximately \$9 Billion
- 2021 Continuing Operations Financial Outlook:
 - Expects Full-Year 2021 Sales Growth of 12% to 14%; Narrows and Raises Estimated Full-Year 2021 Revenue Range to be Between \$46.4 Billion and \$47.4 Billion, Including a Positive Impact from Foreign Exchange of Less Than 2%
 - Expects Full-Year 2021 GAAP EPS to be Between \$4.24 and \$4.34; Expects Full-Year 2021 Non-GAAP EPS

to be Between \$5.47 and \$5.57, Including a Positive Impact from Foreign Exchange of Approximately 2%

KENILWORTH, N.J.--(BUSINESS WIRE)-- Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced financial results for the second quarter of 2021.

This press release features multimedia. View the full release here:

<https://www.businesswire.com/news/home/20210729005307/en/>

“We are encouraged by the strong momentum of our underlying business led by our key growth drivers as the impact of the pandemic on our performance lessens,” said Rob Davis, chief executive officer and president, Merck. “We are confident that we will deliver sustained long-term growth and value creation enabled by our strengthening discovery research engine and by working with increased speed, urgency and agility to accelerate the delivery of our innovations to the patients who depend on them.”

Financial Summary – Continuing Operations

The businesses that were contributed to Organon & Co. (Organon) in the spinoff are now accounted for as discontinued operations. Financial information presented in this release reflects Merck’s results on a continuing operations basis, which excludes Organon. Prior periods have been recast to conform to this presentation. The Company previously filed a Form 8-K on June 21, 2021, which included historical financial information recast to reflect Organon as discontinued operations.

	Second Quarter			
	2021	2020	Change	Change Ex-Exchange
\$ in millions, except EPS amounts				
Sales	\$11,402	\$9,353	22%	19%
GAAP net income ¹	1,213	2,341	-48%	-47%
Non-GAAP net income that excludes certain items ^{1,2*}	3,321	2,586	28%	27%
GAAP EPS	0.48	0.92	-48%	-48%
Non-GAAP EPS that excludes certain items ^{2*}	1.31	1.02	28%	27%

*Refer to table on page 11.

GAAP (generally accepted accounting principles) earnings per share assuming dilution (EPS) was \$0.48 for the second quarter of 2021. GAAP EPS for the second quarter of 2021 includes a \$1.7 billion charge for the acquisition of Pandion Therapeutics, Inc. (Pandion). Non-GAAP EPS of \$1.31 for the second quarter of 2021 excludes acquisition- and divestiture-related costs, restructuring costs, income and losses from investments in equity securities, the charge related to Pandion and certain other items. Year-to-date results can be found in the attached tables.

Oncology Program Highlights

Merck continued to advance development programs across its oncology portfolio, anticipating greater than 90 potential new indications by 2028, including notable progress for KEYTRUDA (pembrolizumab), the company's anti-PD-1 therapy; Lynparza (olaparib), an oral poly ADP ribose polymerase (PARP) inhibitor, being co-developed and co-commercialized with AstraZeneca; and Lenvima (lenvatinib mesylate), an orally available tyrosine kinase inhibitor, being co-developed and co-commercialized with Eisai Co., Ltd. (Eisai).

- Merck announced the following regulatory milestones:
 - U.S. Food and Drug Administration (FDA) **approval** of KEYTRUDA in combination with chemotherapy as pre-operative (neoadjuvant) treatment and then continuing as a single-agent (adjuvant) treatment after surgery in high-risk early-stage triple-negative breast cancer (TNBC) based on results from the pivotal Phase 3 KEYNOTE-522 trial. These results were presented during a European Society for Medical Oncology Virtual Plenary session on July 15.
 - FDA **approval** of KEYTRUDA in combination with trastuzumab and chemotherapy for the first-line treatment of patients with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma based on results from the ongoing Phase 3 KEYNOTE-811 trial. This is the first time an anti-PD-1 therapy has been approved in combination with anti-HER2 therapy and chemotherapy as a first-line treatment for these patients. This accelerated approval is contingent upon verification of clinical benefit in confirmatory trials.
 - FDA **approval** of KEYTRUDA as monotherapy for the treatment of patients with locally advanced cutaneous squamous cell carcinoma (cSCC) that is not curable by surgery or radiation. This approval was based on results from the Phase 2 KEYNOTE-629 trial.
 - FDA **approval** of KEYTRUDA in combination with Lenvima for the treatment of certain patients with advanced endometrial carcinoma that is not 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 approval was based on results from the confirmatory pivotal Phase 3 KEYNOTE-775/Study 309 trial.
 - FDA **priority review** for KEYTRUDA in combination with Lenvima for the first-line treatment of patients with advanced renal cell carcinoma (RCC) based on results from the pivotal Phase 3 CLEAR study (KEYNOTE-581/Study 307). The Prescription Drug User Fee Act (PDUFA) or target action date is Aug. 26.
 - The FDA Oncologic Drugs Advisory Committee **voted against** maintaining accelerated approval of KEYTRUDA for the third-line treatment of certain patients with gastric cancer. Merck announced a **voluntary withdrawal** of the accelerated approval indication for KEYTRUDA for the treatment of patients with recurrent locally advanced or metastatic gastric or GEJ adenocarcinoma with disease progression on or after platinum-containing chemotherapy and at least one other prior line of therapy. As agreed with the FDA, Merck will initiate the withdrawal in Jan. 2022.
 - European Commission (EC) **approval** of KEYTRUDA in combination with platinum- and fluoropyrimidine-

based chemotherapy for the first-line treatment of certain patients with locally advanced unresectable or metastatic carcinoma of the esophagus or HER2-negative GEJ adenocarcinoma in adults whose tumors express PD-L1 (CPS \geq 10), based on the Phase 3 KEYNOTE-590 trial.

- Chinese National Medical Products Administration **approval** of Lynparza as monotherapy for the treatment of adult patients with germline or somatic BRCA-mutated metastatic castration-resistant prostate cancer who have progressed following prior treatment that included a new hormonal agent (abiraterone, enzalutamide), based on data from the Phase 3 PROfound trial.
- Merck provided additional data presentations including:
 - Positive top-line overall survival (OS) **results** for the Phase 3 KEYNOTE-355 study evaluating KEYTRUDA in combination with chemotherapy in patients with untreated metastatic triple-negative breast cancer whose tumors expressed PD-L1 (CPS \geq 10). Data will be submitted to global health authorities and will be presented at an upcoming medical meeting.
 - **Results** from the pivotal Phase 3 KEYNOTE-564 trial for the adjuvant treatment of certain patients with RCC at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting. In the study, KEYTRUDA given after surgery demonstrated a statistically significant and clinically meaningful reduction in the risk of disease recurrence or death compared to placebo. Results are being submitted to global regulatory authorities and the trial will continue to evaluate OS, a key secondary endpoint.
 - **Results** from the pivotal Phase 3 KEYNOTE-826 trial investigating KEYTRUDA in combination with chemotherapy with or without bevacizumab, confirming the trial met its dual primary endpoints of OS and progression-free survival (PFS) in the first-line treatment of patients with persistent, recurrent or metastatic cervical cancer regardless of PD-L1 status. Results will be presented at an upcoming medical meeting and will be submitted to regulatory authorities.
 - Initial **results** presented by Merck and AstraZeneca from the Phase 3 OlympiA trial at the 2021 ASCO Annual Meeting, in which Lynparza demonstrated a statistically significant improvement in its primary endpoint of invasive disease-free survival versus placebo in the adjuvant treatment of patients with germline BRCA1/2 mutations and HER2-negative early breast cancer. Results will be submitted to global regulatory authorities and the trial will continue to assess OS as a secondary endpoint.

Vaccines Highlights

- Merck announced the FDA **approval** of VAXNEUVANCE (15-valent Pneumococcal Conjugate Vaccine) for active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F in adults 18 years of age and older.
- Merck presented new data from the pivotal Phase 3 PNEU-AGE study of VAXNEUVANCE compared with a 13-valent pneumococcal conjugate vaccine in adults 50 years of age and older at the European Congress of Clinical Microbiology & Infectious Diseases (ECCMID) 2021.
- Merck **announced** VAXNEUVANCE met its primary immunogenicity and safety endpoints in two trials from its

Phase 3 pediatric clinical program. Plans are on track for submission of a supplemental regulatory licensure application to the FDA for use in children before the end of the year.

HIV Highlight

- Merck **announced** results from an ongoing Phase 2a clinical trial evaluating the safety, tolerability and pharmacokinetics of six monthly oral doses, over 24 weeks, of islatravir, the company's investigational nucleoside reverse transcriptase translocation inhibitor, versus placebo for pre-exposure prophylaxis (PrEP) of HIV-1 infection in adults at low risk of contracting HIV-1. These data, which support the safety profile of an oral islatravir PrEP regimen through 24 weeks versus placebo, were shared as a late-breaking oral presentation during the virtual 11th International AIDS Society Conference on HIV Science.

Other Highlights

- The EC **granted** marketing authorization in the European Union for Verquvo (vericiguat) for the treatment of symptomatic chronic heart failure in adult patients with reduced ejection fraction who are stabilized after a recent decompensation event requiring intravenous therapy. Verquvo is being jointly developed by Merck and Bayer AG.
- BRIDION (sugammadex) Injection 100 mg/mL was approved by the FDA for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in pediatric patients aged 2 years and older undergoing surgery.
- The FDA has informed Merck of its decision to extend the goal date for the company's New Drug Application for gefapixant, an investigational, orally administered, selective P2X3 receptor antagonist, for the treatment of refractory chronic cough or unexplained chronic cough in adults, to provide time for a full review of the submission. The extended PDUFA action date is March 21, 2022.

COVID-19 Highlights

- In April, Merck and Ridgeback Biotherapeutics LP **announced** top-line data from the Phase 2 portion of the Phase 2/3 trials studying molnupiravir (MK-4482), which showed that it inhibits the replication of multiple RNA viruses including SARS-CoV-2, the causative agent of COVID-19. Data were **presented** at ECCMID in July. Molnupiravir is now being evaluated in a Phase 3 clinical trial, the MOVE-OUT study, for the treatment of non-hospitalized patients with laboratory-confirmed COVID-19 and at least one risk factor associated with poor disease outcomes.
- In April, Merck **announced** that the company entered into non-exclusive voluntary licensing agreements for molnupiravir with established Indian generic manufacturers. Merck entered into these agreements to accelerate availability of molnupiravir in India and in other low- and middle-income countries following approvals or emergency authorization by local regulatory agencies.
- In June, Merck **announced** it entered into a procurement agreement with the United States government for

molnupiravir.

Second-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	Second Quarter			Change Ex-Exchange
	2021	2020	Change	
Total Sales	\$11,402	\$9,353	22%	19%
Pharmaceutical	9,980	8,178	22%	18%
KEYTRUDA	4,176	3,388	23%	20%
JANUVIA / JANUMET	1,261	1,344	-6%	-10%
GARDASIL / GARDASIL 9	1,234	656	88%	78%
PROQUAD, M-M-R II and VARIVAX	516	378	36%	35%
BRIDION	387	224	72%	67%
Lynparza*	248	178	39%	34%
ROTATEQ	208	168	23%	19%
SIMPONI	202	191	5%	-3%
ISENTRESS / ISENTRESS HD	192	196	-2%	-5%
Lenvima*	181	151	19%	15%
Animal Health	1,472	1,101	34%	27%
Livestock	820	647	27%	20%
Companion Animals	651	453	44%	38%
Other Revenues**	(50)	74	-167%	-1%

*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. The revenue-hedging activities resulted in negative revenue in the second quarter of 2021.

Pharmaceutical Revenue

Second-quarter pharmaceutical sales increased 22% to \$10.0 billion. Excluding the favorable effect of foreign exchange, sales grew by 18%, reflecting ongoing recovery from the COVID-19 pandemic and strong underlying demand. The COVID-19 pandemic unfavorably affected sales in the second quarter of 2021 but to a lesser extent than in the second quarter of 2020. The estimated net favorable benefit of the ongoing COVID-19 pandemic recovery to year-over-year sales growth was approximately \$900 million.

Growth in oncology was largely driven by higher sales of KEYTRUDA, which rose 23% to \$4.2 billion in the quarter. Global sales growth of KEYTRUDA reflects continued strong momentum from the non-small-cell lung cancer indications as well as continued uptake in other indications, including adjuvant melanoma, RCC, bladder, head and neck squamous cell carcinoma and MSI-H cancers. Also contributing to higher sales in oncology was a 39% rise in Lynparza alliance revenue, reflecting continued uptake in approved indications in the United States, Europe and China, as well as a 19% increase in Lenvima alliance revenue, driven primarily by higher demand in China.

Growth in vaccines for the second quarter was primarily driven by higher combined sales of GARDASIL [Human Papillomavirus Quadrivalent (Types 6, 11, 16 and 18) Vaccine, Recombinant] and GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant). Second-quarter 2021 GARDASIL/GARDASIL 9 sales rebounded to

\$1.2 billion, growing 88%, primarily due to the ongoing COVID-19 pandemic recovery and strong underlying demand in the United States, as well as continued market uptake in certain ex-U.S. markets, including China, which also benefitted from increased supply.

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, for second-quarter 2021 rose 36% to \$516 million driven primarily by the ongoing market recovery from the COVID-19 pandemic in the United States.

Growth in hospital acute care reflects higher demand globally for BRIDION (sugammadex) 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 rose 72% to \$387 million attributable in part to the ongoing COVID-19 pandemic recovery; and the continued uptake of PREVYMIS (letermovir), a medicine for prophylaxis (prevention) of cytomegalovirus (CMV) infection and disease in adult CMV-seropositive recipients of an allogeneic hematopoietic stem cell transplant. Growth in hospital acute care was partially offset by the suspension of sales of ZERBAXA (ceftolozane and tazobactam) 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.

Sales of JANUVIA (sitagliptin) and JANUMET (sitagliptin and metformin HCl) decreased 6% in the quarter to \$1.3 billion reflecting continued pricing pressure in the United States, partially offset by higher demand in certain international markets.

Animal Health Revenue

Animal Health sales totaled \$1.5 billion for the second quarter of 2021, an increase of 34% compared with the second quarter of 2020. Excluding the favorable effect from foreign exchange, Animal Health sales grew 27%. Sales growth reflects higher demand globally for companion animal products, driven by companion animal vaccines, as well as growth in parasiticide lines of products, including BRAVECTO (fluralaner). Sales growth in livestock products reflects higher demand for ruminant, swine and poultry products, as well as higher demand globally for Animal Health Intelligence products. The COVID-19 pandemic unfavorably affected Animal Health sales by approximately \$100 million in the second quarter of 2020 but had no impact in the second quarter of 2021.

Second-Quarter Expense, EPS and Related Information

The tables below present selected expense information.

\$ in millions	GAAP	Acquisition- and Divestiture- Related Costs 3	Restructuring Costs	(Income) Loss from Investments in Equity Securities	Certain Other Items	Non- GAAP 2
Second-Quarter 2021	\$3,104	\$345	\$38	\$-	\$37	\$2,684
Cost of sales						
Selling, general and administrative	2,281	25	2	-	-	2,254
Research and development	4,321	16	6	-	1,765	2,534
Restructuring costs	82	-	82	-	-	-
Other (income) expense, net	(103)	117	-	(258)	-	38
Second-Quarter 2020	\$2,747	\$580	\$25	\$-	\$-	\$2,142
Cost of sales						
Selling, general and administrative	2,085	44	11	-	-	2,030
Research and development	2,085	(63)	31	-	-	2,117
Restructuring costs	82	-	82	-	-	-
Other (income) expense, net	(387)	63	-	(511)	(16)	77

GAAP Expense, EPS and Related Information

Gross margin was 72.8% for the second quarter of 2021 compared to 70.6% for the second quarter of 2020. The increase reflects lower acquisition- and divestiture-related costs and favorable product mix, partially offset by the unfavorable effects of foreign exchange, pricing pressure and higher manufacturing costs.

Selling, general and administrative expenses were \$2.3 billion in the second quarter of 2021, an increase of 9% compared to the second quarter of 2020. The increase primarily reflects higher promotion and administrative costs, as well as the unfavorable effects of foreign exchange.

Research and development expenses were \$4.3 billion in the second quarter of 2021 compared with \$2.1 billion in the second quarter of 2020. The increase was primarily driven by a \$1.7 billion charge for the acquisition of Pandion, as well as higher expenses related to clinical development, and increased investment in discovery research and early drug development.

Other (income) expense, net, was \$103 million of income in the second quarter of 2021 compared to \$387 million of income in the second quarter of 2020, primarily reflecting lower income from investments in equity securities in 2021 compared with 2020.

The effective income tax rate of 29.3% for the second quarter of 2021 reflects no tax benefit recognized on the Pandion acquisition charge.

GAAP EPS was \$0.48 for the second quarter of 2021 compared with \$0.92 for the second quarter of 2020.

Non-GAAP Expense, EPS and Related Information

Non-GAAP gross margin was 76.5% for the second quarter of 2021 compared to 77.1% for the second quarter of 2020. The decrease in non-GAAP gross margin reflects the unfavorable effects of foreign exchange, pricing pressure and higher manufacturing costs, partially offset by favorable product mix.

Non-GAAP selling, general and administrative expenses were \$2.3 billion in the second quarter of 2021, an increase of 11% compared to the second quarter of 2020. The increase primarily reflects higher promotion and administrative costs, as well as the unfavorable effects of foreign exchange.

Non-GAAP R&D expenses were \$2.5 billion in the second quarter of 2021, a 20% increase compared to the second quarter of 2020. The increase primarily reflects higher expenses related to clinical development, as well as increased investment in discovery research and early drug development.

Non-GAAP other (income) expense, net, was \$38 million of expense in the second quarter of 2021 compared to \$77 million of expense in the second quarter of 2020.

The non-GAAP effective income tax rate was 14.6% for the second quarter of 2021.

Non-GAAP EPS was \$1.31 for the second quarter of 2021 compared with \$1.02 for the second 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	Second Quarter	
	2021	2020
EPS		
GAAP EPS	\$0.48	\$0.92
Difference	0.83	0.10
Non-GAAP EPS that excludes items listed below ²	\$1.31	\$1.02
Net Income		
GAAP net income ¹	\$1,213	\$2,341
Difference	2,108	245
Non-GAAP net income that excludes items listed below ^{1,2}	\$3,321	\$2,586
Decrease (Increase) in Net Income Due to Excluded Items:		
Acquisition- and divestiture-related costs ³	\$503	\$624
Restructuring costs	128	149
(Income) loss from investments in equity securities	(258)	(511)
Charge for the acquisition of Pandion	1,704	-
Charge for the discontinuation of COVID-19 development programs	37	-
Other	61	(16)
Net decrease (increase) in income before taxes	2,175	246
Income tax (benefit) expense ⁴	(67)	(1)
Decrease (increase) in net income	\$2,108	\$245

Financial Outlook

Merck continues to experience strong global underlying demand across its business. Consequently, at mid-July 2021 exchange rates, Merck now expects sales growth of 12% to 14% in 2021 with full-year 2021 revenue estimated

to be between \$46.4 billion and \$47.4 billion, including a positive impact from foreign exchange of less than 2%.

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

Merck expects full-year 2021 GAAP EPS to be between \$4.24 and \$4.34.

Merck expects full-year 2021 non-GAAP EPS to be between \$5.47 and \$5.57, 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.

For full-year 2021, Merck continues to expect the pandemic will have a negligible impact on operating expenses, as spending on the development of its COVID-19 antiviral program is expected to offset the favorable impact of lower spending in other areas due to the COVID-19 pandemic.

Neither the sales nor the EPS guidance 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	\$46.4 to \$47.4 billion	\$46.4 to \$47.4 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 15.5%	14.5% to 15.5%
EPS**	\$4.24 to \$4.34	\$5.47 to \$5.57

*The company does not have any non-GAAP adjustments to revenue.
 **EPS guidance for 2021 assumes a share count (assuming dilution) of approximately 2.53 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.

	Full-Year 2021
\$ in millions, except EPS amounts	
GAAP EPS	\$4.24 to \$4.34
Difference	\$1.23
Non-GAAP EPS that excludes items listed below ²	\$5.47 to \$5.57
Acquisition- and divestiture-related costs	\$2.100

Restructuring costs	700
(Income) loss from investments in equity securities	(1,200)
Charge for the discontinuation of COVID-19 development programs	225
Charge for the acquisition of Pandion	1,704
Other	61
Net decrease (increase) in income before taxes	3,590
Income tax (benefit) expense ⁴	(475)
Decrease (increase) in net income	\$3,115

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-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 5951886. Members of the media are invited to monitor the call by dialing (833) 353-0277 or (469) 886-1947 and using ID code number 5951886. 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 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 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; 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).

1 Net income 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.

3 Includes expenses for the amortization of intangible assets and purchase accounting adjustments to inventories recognized as a result of acquisitions, 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.

4 Includes the estimated tax impact on the reconciling items. In addition, the amount for full-year 2021 includes a \$207 million net tax benefit related to the settlement of certain federal income tax matters.

MERCK & CO., INC.
CONSOLIDATED STATEMENT OF INCOME - GAAP
(AMOUNTS IN MILLIONS, EXCEPT PER SHARE FIGURES)
(UNAUDITED)
Table 1

On June 2, 2021, Merck completed the spinoff of products from its women's health, biosimilars and established brands businesses into a new, independent, publicly traded company named Organon & Co. (Organon) through a distribution of Organon's publicly traded stock to company shareholders. The historical results of the women's health, biosimilars and established brands businesses that were contributed to Organon in the spin-off are excluded from sales and expenses below and reflected as discontinued operations in the company's Consolidated Statements of Income provided below.

	GAAP		% Change	GAAP		% Change
	2Q21	2Q20		June YTD 2021	June YTD 2020	
Sales	\$ 11,402	\$ 9,353	22%	\$ 22,029	\$ 19,641	12%
Costs, Expenses and Other						
Cost of sales	3,104	2,747	13%	6,303	5,576	13%
Selling, general and administrative	2,281	2,085	9%	4,468	4,276	4%
Research and development	4,321	2,085	*	6,732	4,260	58%
Restructuring costs (1)	82	82	0%	380	152	*
Other (income) expense, net	(103)	(387)	-73%	(558)	(325)	72%

Income from Continuing Operations Before Taxes	1,717	2,741	-37%	4,704	5,702	-18%
Income Tax Provision	503	396		741	891	
Net Income from Continuing Operations	1,214	2,345	-48%	3,963	4,811	-18%
Less: Net Income (Loss) Attributable to Noncontrolling Interests	1	4		5	(1)	
Net Income from Continuing Operations Attributable to Merck & Co., Inc.	\$ 1,213	\$ 2,341	-48%	\$ 3,958	\$ 4,812	-18%
Income from Discontinued Operations, Net of Taxes and Amounts Attributable to Noncontrolling Interests	\$ 332	\$ 661	-50%	\$ 766	\$ 1,409	-46%
Net Income Attributable to Merck & Co., Inc.	\$ 1,545	\$ 3,002	-49%	\$ 4,724	\$ 6,221	-24%
Basic Earnings per Common Share Attributable to Merck & Co., Inc. Common Shareholders:						
Income from Continuing Operations	\$ 0.48	\$ 0.93	-48%	\$ 1.56	\$ 1.90	-18%
Income from Discontinued Operations	\$ 0.13	\$ 0.26	-50%	\$ 0.30	\$ 0.56	-46%
Net Income	\$ 0.61	\$ 1.19	-49%	\$ 1.87	\$ 2.46	-24%
Earnings per Common Share Assuming Dilution Attributable to Merck & Co., Inc. Common Shareholders:						
Income from Continuing Operations	\$ 0.48	\$ 0.92	-48%	\$ 1.56	\$ 1.89	-17%
Income from Discontinued Operations	\$ 0.13	\$ 0.26	-50%	\$ 0.30	\$ 0.55	-45%
Net Income	\$ 0.61	\$ 1.18	-48%	\$ 1.86	\$ 2.45	-24%
Average Shares Outstanding	2,533	2,527		2,532	2,531	
Average Shares Outstanding Assuming Dilution	2,540	2,536		2,540	2,542	
Tax Rate from Continuing Operations (2)	29.3%	14.4%		15.8%	15.6%	

* 100% or greater

(1) Represents separation and other related costs associated with restructuring activities under the company's formal restructuring programs.

(2) The effective income tax rates for the second quarter and first six months of 2021 reflect the unfavorable impact of a charge for the acquisition of Pandion Therapeutics, Inc. for which no tax benefit was recognized. Additionally, the effective income tax rate for the first six months of 2021 reflects a net tax benefit of \$207 million related to the settlement of certain federal income tax matters.

MERCK & CO., INC.
SECOND QUARTER AND SIX MONTHS ENDED JUNE 30, 2021 GAAP TO NON-GAAP RECONCILIATION - CONTINUING OPERATIONS
(AMOUNTS IN MILLIONS, EXCEPT PER SHARE FIGURES)
(UNAUDITED)
Table 2a

The table below reflects a reconciliation of GAAP to non-GAAP financial information on a continuing operations basis. As Organon results are reflected within discontinued operations, they are excluded from the financial information provided below.

	GAAP	Acquisition and Divestiture-Related Costs (1)	Restructuring Costs (2)	(Income) Loss from Investments in Equity Securities	Certain Other Items	Adjustment Subtotal	Non-GAAP
Second Quarter							
Cost of sales	\$ 3,104	345	38		37(3)	420	\$ 2,684
Selling, general and administrative	2,281	25	2			27	2,254

Research and development	4,321	16	6		1,765(4)	1,787	2,534
Restructuring costs	82		82			82	-
Other (income) expense, net	(103)	117		(258)		(141)	38
Income From Continuing Operations Before Taxes	1,717	(503)	(128)	258	(1,802)	(2,175)	3,892
Income Tax Provision (Benefit)	503	(98)(5)	(15)(5)	57(5)	(11)(5)	(67)	570
Net Income from Continuing Operations	1,214	(405)	(113)	201	(1,791)	(2,108)	3,322
Net Income from Continuing Operations Attributable to Merck & Co., Inc.	1,213	(405)	(113)	201	(1,791)	(2,108)	3,321
Earnings per Common Share Assuming Dilution from Continuing Operations	\$ 0.48	(0.16)	(0.04)	0.08	(0.71)	(0.83)	\$ 1.31
Tax Rate	29.3%						14.6%

June YTD

Cost of sales	\$ 6,303	842	65		225(3)	1,132	\$ 5,171
Selling, general and administrative	4,468	35	4			39	4,429
Research and development	6,732	34	13		1,765(4)	1,812	4,920
Restructuring costs	380		380			380	-
Other (income) expense, net	(558)	89		(819)		(730)	172
Income From Continuing Operations Before Taxes	4,704	(1,000)	(462)	819	(1,990)	(2,633)	7,337
Income Tax Provision (Benefit)	741	(187)(5)	(56)(5)	180(5)	(260)(5)	(323)	1,064
Net Income from Continuing Operations	3,963	(813)	(406)	639	(1,730)	(2,310)	6,273
Net Income from Continuing Operations Attributable to Merck & Co., Inc.	3,958	(813)	(406)	639	(1,730)	(2,310)	6,268
Earnings per Common Share Assuming Dilution from Continuing Operations	\$ 1.56	(0.32)	(0.16)	0.25	(0.68)	(0.91)	\$ 2.47
Tax Rate	15.8%						14.5%

Only the line items that are affected by non-GAAP adjustments are shown.

Merck is providing certain 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 as it 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.

(1) Amounts included in cost of sales primarily reflect expenses for the amortization of intangible assets. Amounts included in selling, general and administrative expenses reflect acquisition and divestiture-related costs. Amounts included in research and development expenses primarily reflect expenses for the amortization of intangible assets. Amounts included in other (income) expense, net, for the second quarter and six months period primarily reflect an increase in the estimated fair value measurement of liabilities for contingent consideration related to the termination of the Sanofi-Pasteur MSD joint venture and a loss on a forward exchange contract entered into in conjunction with the Organon spinoff. Amount included in other (income) expense, net, for the six month period is partially offset by royalty income related to the termination of the Sanofi-Pasteur MSD joint venture.

(2) Amounts primarily include employee separation costs and accelerated depreciation associated with facilities to be closed or divested related to activities under the company's formal restructuring programs.

(3) Represents charges for the discontinuation of COVID-19 development programs.

(4) Includes a \$1.7 billion charge for the acquisition of Pandion Therapeutics, Inc.

(5) Represent the estimated tax impacts on the reconciling items based on applying the statutory rate of the originating territory of the non-GAAP adjustments. Certain other items for the six month period also includes a \$207 million net tax benefit related to the settlement of certain federal income tax matters.

MERCK & CO., INC.
FRANCHISE / KEY PRODUCT SALES - CONTINUING OPERATIONS
(AMOUNTS IN MILLIONS)
(UNAUDITED)
Table 3

	2021			2020						2Q		June YTD	
	1Q	2Q	June YTD	1Q	2Q	June YTD	3Q	4Q	Full Year	Nom %	Ex-Exch %	Nom %	Ex-Exch %
TOTAL SALES (1)	\$10,627	\$11,402	\$22,029	\$10,288	\$9,353	\$19,641	\$10,929	\$10,948	\$41,518	22	19	12	10
PHARMACEUTICAL	9,238	9,980	19,218	8,905	8,178	17,083	9,714	9,813	36,610	22	18	12	9
Oncology													
Keytruda	3,899	4,176	8,076	3,284	3,388	6,672	3,715	3,993	14,380	23	20	21	18
Alliance Revenue - Lynparza (2)	228	248	475	145	178	323	196	206	725	39	34	47	42
Alliance Revenue - Lenvima (2)	130	181	310	128	151	279	142	158	580	19	15	11	8
Vaccines (3)													
Gardasil / Gardasil 9	917	1,234	2,151	1,097	656	1,753	1,187	998	3,938	88	78	23	17
ProQuad / M-M-R II / Varivax	449	516	965	435	378	813	576	488	1,878	36	35	19	17
Pneumovax 23	171	152	323	256	117	373	375	339	1,087	30	27	-13	-16
RotaTeq	158	208	366	222	168	391	210	196	797	23	19	-6	-8
Vaqta	34	56	90	60	28	88	51	31	170	101	96	2	-
Hospital Acute Care													
Bridion	340	387	727	299	224	524	320	355	1,198	72	67	39	35
Prevymis	82	93	174	60	63	123	77	80	281	47	41	42	36
Noxafil	67	66	133	94	73	168	79	82	329	-10	-14	-21	-24
Primaxin	65	60	125	51	64	115	74	62	251	-6	-14	8	-
Candidas	57	54	111	55	43	98	50	65	213	24	17	13	8
Invanz	57	48	104	64	43	108	51	53	211	10	3	-3	-5
Zerbaxa	(8)	(1)	(9)	37	32	69	43	19	130	-104	-104	-113	-113
Immunology													
Simponi	214	202	416	215	191	406	209	223	838	5	-3	2	-6
Remicade	85	75	160	88	73	160	82	88	330	3	-3	-	-6
Neuroscience													
Belsomra	79	78	157	79	84	163	81	83	327	-7	-6	-4	-5
Virology													
Isentress / Isentress HD	209	192	401	245	196	441	205	211	857	-2	-5	-9	-11
Cardiovascular													
Alliance Revenue - Adempas/Verquvo (4)	74	74	149	53	79	133	83	65	281	-7	13	12	23
Adempas (5)	55	74	129	56	57	113	55	53	220	29	23	15	7
Diabetes (6)													
Januvia	809	784	1,593	774	854	1,628	821	857	3,306	-8	-11	-2	-5
Janumet	486	477	962	503	490	993	506	472	1,971	-3	-8	-3	-7
Other Pharmaceutical (7)													
	581	546	1,130	605	548	1,149	526	636	2,312	-	-5	-2	-6
ANIMAL HEALTH	1,418	1,472	2,890	1,214	1,101	2,314	1,220	1,168	4,703	34	27	25	21
Livestock	819	821	1,640	739	648	1,386	758	794	2,939	27	20	18	15

Companion Animals	599	651	1,250	475	453	928	462	374	1,764	44	38	35	31
Other Revenues (8)	(29)	(50)	(79)	169	74	244	(5)	(33)	205	-167	-1	-132	-15

Sum of quarterly amounts may not equal year-to-date amounts due to rounding.

(1) Only select products are shown.

(2) Alliance Revenue represents Merck's share of profits, which are product sales net of cost of sales and commercialization costs.

(3) Total Vaccines sales were \$1,809 million and \$2,293 million in the first and second quarter of 2021, respectively, and \$2,155 million, \$1,418 million, \$2,521 million and \$2,163 million in the first, second, third and fourth quarters of 2020, respectively.

(4) Alliance Revenue represents Merck's share of profits from sales in Bayer's marketing territories, which are product sales net of cost of sales and commercialization costs.

(5) Net product sales in Merck's marketing territories.

(6) Total Diabetes sales were \$1,363 million and \$1,330 million in the first and second quarter of 2021, respectively, and \$1,353 million, \$1,418 million, \$1,405 million and \$1,412 million in the first, second, third and fourth quarters of 2020, respectively.

(7) Includes Pharmaceutical products not individually shown above.

(8) Other Revenues are comprised primarily of third-party manufacturing sales and miscellaneous corporate revenues, including revenue hedging activities.

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