



News Release

FOR IMMEDIATE RELEASE

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Merck Announces First-Quarter 2015 Financial Results

- First-Quarter 2015 Non-GAAP EPS of \$0.85, Excluding Certain Items; GAAP EPS of \$0.33
- Company Narrows and Raises 2015 Full-Year Non-GAAP EPS Target to \$3.35 to \$3.48, Excluding Certain Items; Lowers 2015 Full-Year GAAP EPS Target to \$1.58 to \$1.85
- First-Quarter 2015 Worldwide Sales Were \$9.4 Billion, a Decrease of 8 Percent, Reflecting Net Unfavorable Impact of Acquisitions and Divestitures and a 5 Percent Negative Impact from Foreign Exchange
- First-Quarter Results Reflect Sales Growth in Diabetes, Vaccines, Hospital Acute Care, Oncology and Animal Health and Sales Decline in Hepatitis C
- Company Submitted sBLA for KEYTRUDA for Advanced Non-Small Cell Lung Cancer and Expects to Submit sBLA for First-Line Indication in Advanced Melanoma in Mid-2015
- Multiple Data Sets Evaluating Chronic Hepatitis C Combination Regimen Grazoprevir/Elbasvir Were Presented at EASL; Company Reiterated Plans for NDA Submission in the First Half of 2015

KENILWORTH, N.J., April 28, 2015 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced financial results for the first quarter of 2015.

\$ in millions, except EPS amounts	First Quarter	
	2015	2014
Sales	\$9,425	\$10,264
GAAP EPS	0.33	0.57
Non-GAAP EPS that excludes items listed below ¹	0.85	0.88
GAAP Net Income ²	953	1,705
Non-GAAP Net Income that excludes items listed below ^{1,2}	2,426	2,601

¹ Merck is providing certain 2015 and 2014 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 performance. This information should be considered in addition to, but not in lieu of, information prepared in accordance with GAAP. For description of the items, see Table 2a, including the related footnotes, attached to this release.

² Net income attributable to Merck & Co., Inc.

Non-GAAP (generally accepted accounting principles) earnings per share (EPS) of \$0.85 for the first quarter exclude acquisition- and divestiture-related costs and restructuring costs.

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

\$ in millions, except EPS amounts

	First Quarter	
	2015	2014
EPS		
GAAP EPS	\$0.33	\$0.57
Difference ³	0.52	0.31
Non-GAAP EPS that excludes items listed below ¹	\$0.85	\$0.88

Net Income

GAAP net income ²	\$953	\$1,705
Difference	1,473	896
Non-GAAP net income that excludes items listed below ^{1,2}	\$2,426	\$2,601

Decrease (Increase) in Net Income Due to Excluded Items:

Acquisition- and divestiture-related costs ⁴	\$1,526	\$1,137
Restructuring costs	225	326
Net decrease (increase) in income before taxes	1,751	1,463
Income tax (benefit) expense ⁵	(278)	(567)
Decrease (increase) in net income	\$1,473	\$896

Commentary from Chairman and Chief Executive Officer Kenneth C. Frazier

“Our strong performance this quarter demonstrates that our scientific and business strategies, together with our focused investments, are paying off.”

“We remain focused on bringing forward the best scientific and medical innovations.”

“By capitalizing on the exciting scientific and clinical opportunities that lie ahead, Merck is poised to play a major role in transforming health care for patients, as well as payers and shareholders.”

Select Business Highlights

Worldwide sales were \$9.4 billion for the first quarter of 2015, a decrease of 8 percent compared with the first quarter of 2014, including a 5 percent negative impact from foreign

³ Represents the difference between calculated GAAP EPS and calculated non-GAAP EPS, which may be different than the amount calculated by dividing the impact of the excluded items by the weighted-average shares for the period.

⁴ 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 fair value measurement of contingent consideration. Also includes integration, transaction and certain other costs related to business acquisitions and divestitures.

⁵ Includes the estimated tax impact on the reconciling items. In addition, amount for the first quarter of 2014 includes a benefit of approximately \$300 million associated with a capital loss generated in the quarter.

exchange and a 9 percent net unfavorable impact resulting from the divestiture of the Consumer Care business and select products, partially offset by the acquisition of Cubist Pharmaceuticals, Inc. (Cubist).

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

\$ in millions	First Quarter		Change	Change Ex-Exchange
	2015	2014		
Total Sales	\$9,425	\$10,264	-8%	-3%
Pharmaceutical	8,266	8,451	-2%	5%
JANUVIA / JANUMET	1,393	1,334	4%	10%
ZETIA / VYTORIN	887	972	-9%	-2%
REMICADE	501	604	-17%	-3%
ISENTRESS	385	390	-1%	6%
GARDASIL / GARDASIL 9	359	383	-6%	-5%
PROQUAD, M-M-R II and VARIVAX	348	280	24%	25%
NASONEX	289	312	-7%	0%
Animal Health	829	813	2%	13%
Consumer Care*	2	546	**	**
Other Revenues	328	454	-28%	-65%

*divested on Oct. 1, 2014

**≥100%

Commercial and Pipeline Highlights

The company focused on important launches in the first quarter of 2015, including KEYTRUDA (pembrolizumab) for the treatment of advanced melanoma in patients whose disease has progressed after other therapies, BELSOMRA (suvorexant) for the treatment of insomnia and ZERBAXA (ceftolozane/tazobactam), a combination product for the treatment of certain serious bacterial infections in adults. ZERBAXA was acquired through the acquisition of Cubist, which was completed in late January.

- Merck continued to accelerate its KEYTRUDA clinical development program.
 - The company has submitted a [supplemental Biologics License Application \(sBLA\)](#) to the U.S. Food and Drug Administration (FDA) for KEYTRUDA for the treatment of patients with advanced non-small cell lung cancer (NSCLC) whose disease has progressed on or after platinum-containing chemotherapy and an FDA-approved therapy for EGFR or ALK genomic tumor aberrations, if present. Under PDUFA, the FDA has 60 days from submission of the sBLA to determine if the application will be accepted for review. [Data](#) used to form the basis for the sBLA submission, presented last week at the American Association for Cancer Research (AACR) Annual Meeting

- and simultaneously published in the *New England Journal of Medicine*, demonstrated robust response rates and durable clinical benefit in naïve and previously treated patients with NSCLC.
- Additionally, the company expects to file a sBLA in mid-2015 for KEYTRUDA for the first-line treatment of advanced melanoma based on data from the Phase 3 [KEYNOTE-006 study](#), presented last week at AACR and simultaneously published in the *New England Journal of Medicine*. These data demonstrated KEYTRUDA was statistically superior to ipilimumab, the current standard of care, for overall survival, progression-free survival and overall response rate in patients with advanced melanoma. In March, the company [announced](#) the study would be stopped early based on the recommendation of the study's independent Data Monitoring Committee.
 - The company also recently submitted data from the KEYNOTE-002 study in ipilimumab-refractory melanoma as part of a supplemental application to the FDA.
 - Early findings with KEYTRUDA in patients with [malignant pleural mesothelioma](#) presented last week at AACR demonstrated encouraging overall response and disease control rates in the difficult-to-treat cancer of the lining of the lungs, abdomen and other organs.
 - Merck announced collaborations with [Eli Lilly and Company](#), [Eisai Co., Ltd.](#), [Syndax Pharmaceuticals, Inc.](#) and [TetraLogic Pharmaceuticals Corporation](#) to evaluate KEYTRUDA in combination settings. Merck is advancing a broad and fast-growing clinical development program for KEYTRUDA with more than 85 clinical trials – across more than 30 tumor types and more than 14,000 patients – both as a monotherapy and in combination with other therapies.
 - In March, KEYTRUDA became the first treatment to be [accepted under the U.K.'s new Early Access to Medicines Scheme](#) for the treatment of advanced melanoma.
 - The company also advanced its clinical development program for the treatment of chronic hepatitis C virus (HCV) infection.
 - The first data presentations of the pivotal [Phase 3 C-EDGE program evaluating grazoprevir/elbasvir](#), an investigational oral once-daily regimen for the treatment of chronic HCV infection, presented last week at The International Liver Congress 2015 – the 50th annual congress of the European Association for the Study of the Liver (EASL), showed high rates of sustained virologic response 12 weeks after completion of treatment (SVR12) across a broad range of patients with genotypes 1, 4 and 6 infection in a number of trials.

- Additional [Phase 2/3 data for grazoprevir/elbasvir presented last week at EASL](#) showed a high rate of SVR12 in treatment-naïve and treatment-experienced patients with advanced chronic kidney disease infected with chronic HCV genotype 1.
- The company reiterated its plans to submit a New Drug Application (NDA) to the FDA for grazoprevir/elbasvir in the first half of 2015.
- The company [received two Breakthrough Therapy Designations](#) from the FDA for grazoprevir/elbasvir for the treatment of patients with chronic HCV genotype 4 infection, and for the treatment of chronic HCV genotype 1 infection in patients with end stage renal disease on hemodialysis.
- At this week's [European Congress of Clinical Microbiology and Infectious Diseases](#), more than 30 abstracts are being presented on the company's portfolio of marketed and investigational anti-infective medicines.
- The company announced the [Trial Evaluating Cardiovascular Outcomes with Sitagliptin \(TECOS\)](#) of JANUVIA (sitagliptin), a medicine that helps lower blood sugar levels in adults with type 2 diabetes, achieved its primary endpoint of non-inferiority for the composite cardiovascular endpoint. Among secondary endpoints, there was no increase in hospitalization for heart failure in the sitagliptin group versus placebo.
- The company received a Complete Response Letter (CRL) from the FDA for sugammadex injection, an investigational medicine for the reversal of neuromuscular blockade induced by rocuronium or vecuronium. Merck is evaluating the information provided in the CRL. Sugammadex injection is marketed as BRIDION in more than 60 countries.
- The company submitted data from the IMPROVE-IT study to the FDA to support a new indication for reduction of cardiovascular events for ZETIA (ezetimibe) and VYTORIN (ezetimibe/simvastatin), medicines for lowering LDL cholesterol.

Pharmaceutical Revenue Performance

First-quarter pharmaceutical sales declined 2 percent to \$8.3 billion, including a 7 percent negative impact from foreign exchange. Excluding the impact of exchange, growth was driven by the four core therapeutic areas – diabetes, vaccines, hospital acute care and oncology. The increase in hospital acute care was driven by strong sales growth of inline brands, as well as the addition of \$208 million of Cubist product sales following Merck's acquisition of Cubist in late January, including \$182 million in sales of CUBICIN (daptomycin for injection), an I.V. antibiotic. Sales of CUBICIN in 2015 prior to Merck's acquisition of Cubist were \$74 million. Oncology growth was due to \$83 million in sales from the continued launch of KEYTRUDA. Pharmaceutical sales also reflect the continued decline in the HCV portfolio of VICTRELIS (boceprevir) and PEGINTRON (peginterferon alfa-2b).

Animal Health Revenue Performance

Animal Health sales totaled \$829 million for the first quarter of 2015, an increase of 2 percent compared with the first quarter of 2014, including an 11 percent negative impact from foreign exchange. Growth was primarily driven by an increase in sales of companion animal products mainly from the continued launch of BRAVECTO (fluralaner), a chewable tablet that kills fleas and ticks in dogs for up to 12 weeks.

Other Revenue Performance

Other revenues – primarily comprising alliance revenue, miscellaneous corporate revenues and third-party manufacturing sales – decreased 28 percent to \$328 million compared to the first quarter of 2014. The decrease was driven primarily by \$232 million in proceeds from the sale of marketing rights for SAPHRIS (asenapine) in the United States recognized in the first quarter of 2014, as well as the loss of revenue from AstraZeneca recorded by Merck, which was \$147 million in the first quarter of 2014.

First-Quarter 2015 Expense and Other Information

The costs detailed below totaled \$8.0 billion on a GAAP basis during the first quarter of 2015 and include \$1.8 billion of acquisition- and divestiture-related costs and restructuring costs.

\$ in millions	Included in expenses for the period			
	GAAP	Acquisition- and Divestiture- Related Costs ⁴	Restructuring Costs	Non-GAAP ¹
First Quarter 2015				
Materials and production	\$3,569	\$1,250	\$105	\$2,214
Marketing and administrative	2,601	227	36	2,338
Research and development	1,737	63	2	1,672
Restructuring costs	82	—	82	—
First Quarter 2014				
Materials and production	\$3,903	\$1,126	\$119	\$2,658
Marketing and administrative	2,734	11	31	2,692
Research and development	1,574	—	51	1,523
Restructuring costs	125	—	125	—

The gross margin was 62.1 percent for the first quarter of 2015 compared to 62.0 percent for the first quarter of 2014, reflecting 14.4 and 12.1 unfavorable percentage point impacts, respectively, from the acquisition- and divestiture-related costs and restructuring costs noted above. The increase in non-GAAP gross margin was driven by product mix, including the impact of acquisitions and divestitures, and foreign exchange.

Marketing and administrative expenses, on a non-GAAP basis, were \$2.3 billion in the first quarter of 2015, a decrease from \$2.7 billion in the same period of 2014, which was primarily driven by the sale of the Consumer Care business and declines in direct selling costs.

R&D expenses, on a non-GAAP basis, were \$1.7 billion in the first quarter of 2015, a 10 percent increase compared to the first quarter of 2014, largely driven by an increase in licensing expenses.

Other (income) expense, net, was \$55 million of expense in the first quarter of 2015 compared to \$163 million of income in the first quarter of 2014. The first quarter of 2014 included a \$182 million gain on the divestiture of the company's Sirna Therapeutics, Inc. subsidiary.

The GAAP effective tax rate of 30.6 percent for the first quarter of 2015 reflects the impacts of acquisition- and divestiture-related costs and restructuring costs. The non-GAAP effective tax rate, which excludes these items, was 22.4 percent for the first quarter of 2015.

Financial Outlook

Merck has narrowed and raised its full-year 2015 non-GAAP EPS range to be between \$3.35 and \$3.48, including a \$0.27 negative impact from foreign exchange. The range excludes acquisition- and divestiture-related costs and costs related to restructuring programs. The company has lowered its full-year 2015 GAAP EPS range to be between \$1.58 and \$1.85. The change in the GAAP EPS range primarily reflects the incorporation of updated estimated Cubist intangible amortization expense.

At current exchange rates, the company continues to anticipate full-year 2015 revenues to be between \$38.3 billion and \$39.8 billion, including a \$2.8 billion negative impact from foreign exchange and approximately \$1 billion of net lost sales from acquisitions and divestitures.

In addition, the company continues to expect full-year 2015 non-GAAP marketing and administrative expenses to be below 2014 levels and R&D expenses to be modestly above 2014 levels.

The company continues to anticipate its full-year 2015 non-GAAP tax rate will be in the range of 22 to 23 percent, not including a 2015 R&D tax credit.

A reconciliation of anticipated 2015 EPS, as reported in accordance with GAAP to non-GAAP EPS that excludes certain items, is provided in the table below.

\$ in millions, except EPS amounts	Full-Year 2015
GAAP EPS	\$1.58 to \$1.85
Difference ³	1.77 to 1.63
Non-GAAP EPS that excludes items listed below	\$3.35 to \$3.48

Acquisition- and divestiture-related costs	\$5,400 to \$5,100
Restructuring costs	950 to 750
Net decrease (increase) in income before taxes	6,350 to 5,850
Estimated income tax (benefit) expense	(1,300) to (1,200)
Decrease (increase) in net income	\$5,050 to \$4,650

Total Employees

As of March 31, 2015, Merck had approximately 70,000 employees worldwide.

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 <http://www.merck.com/investors/events-and-presentations/home.html>. Institutional investors and analysts can participate in the call by dialing (706) 758-9927 or (877) 381-5782 and using ID code number 96680253. Members of the media are invited to monitor the call by dialing (706) 758-9928 or (800) 399-7917 and using ID code number 96680253. 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

Today's Merck is a global health care leader working to help the world be well. Merck is known as MSD outside the United States and Canada. Through our prescription medicines, vaccines, biologic therapies and animal health products, we work with customers and operate in more than 140 countries to deliver innovative health solutions. We also demonstrate our commitment to increasing access to health care through far-reaching policies, programs and partnerships. For more information, visit www.merck.com and connect with us on [Twitter](#), [Facebook](#) and [YouTube](#). You can also follow our Twitter conversation at \$MRK.

Forward-Looking Statement

This news release 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 Merck'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 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; Merck'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 Merck's patents and other protections for innovative products; and the exposure to litigation, including patent litigation, and/or regulatory actions.

Merck 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 Merck's 2014 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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