



News Release

FOR IMMEDIATE RELEASE

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Merck Announces Fourth-Quarter and Full-Year 2016 Financial Results

- Fourth-Quarter 2016 Worldwide Sales Were \$10.1 Billion, a Decrease of 1 Percent, Including a 1 Percent Negative Impact from Foreign Exchange; Full-Year 2016 Worldwide Sales Were \$39.8 Billion, an Increase of 1 Percent, Including a 2 Percent Negative Impact from Foreign Exchange
- Fourth-Quarter 2016 GAAP EPS Was \$0.42; Fourth-Quarter Non-GAAP EPS Was \$0.89; Full-Year 2016 GAAP EPS Was \$2.04; Full-Year Non-GAAP EPS Was \$3.78
- 2017 Financial Outlook
 - Expects Full-Year 2017 GAAP EPS to be Between \$2.47 and \$2.62; Expects Non-GAAP EPS to be Between \$3.72 and \$3.87, Including an Approximately 2 Percent Negative Impact from Foreign Exchange
 - Anticipates Full-Year 2017 Worldwide Sales to be Between \$38.6 Billion and \$40.1 Billion, Including an Approximately 2 Percent Negative Impact from Foreign Exchange
- Advanced KEYTRUDA Development Program
 - U.S. Food and Drug Administration (FDA) Approved KEYTRUDA for Previously Untreated Patients with Metastatic Non-Small Cell Lung Cancer (NSCLC) Whose Tumors Have High PD-L1 Expression (Tumor Proportion Score of 50 Percent or More) Without EGFR or ALK Genomic Tumor Aberrations
 - FDA Granted Priority Review for Three Supplemental Biologics License Applications for KEYTRUDA

KENILWORTH, N.J., Feb. 2, 2017 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced financial results for the fourth quarter and full year of 2016.

“The performance of Merck’s broad and balanced portfolio allows us to remain committed to biomedical innovation that saves and improves lives and delivers long-term value to shareholders,” said Kenneth C. Frazier, chairman and chief executive officer, Merck. “The momentum behind our pipeline and key product launches, including the continued growth and expansion of KEYTRUDA into new indications and markets around the world, further reinforces our company’s strategic direction.”

Financial Summary

\$ in millions, except EPS amounts	Fourth Quarter		Year Ended	
	2016	2015	Dec. 31, 2016	Dec. 31, 2015
Sales	\$10,115	\$10,215	\$39,807	\$39,498
GAAP EPS	0.42	0.35	2.04	1.56
Non-GAAP EPS that excludes certain items ^{1*}	0.89	0.93	3.78	3.59
GAAP net income ²	1,177	976	5,691	4,442
Non-GAAP net income that excludes certain items ^{1,2*}	2,470	2,608	10,538	10,195

*Refer to table on page 8.

Worldwide sales were \$10.1 billion for the fourth quarter of 2016, a decrease of 1 percent compared with the fourth quarter of 2015, including a 1 percent negative impact from foreign exchange. Sales in the fourth quarter of 2016 reflect the unfavorable impact of approximately \$150 million of sales in Japan, which occurred in the third quarter of 2016 rather than in the fourth quarter due to the implementation of a resource planning system. Full-year 2016 worldwide sales were \$39.8 billion, an increase of 1 percent compared with the full year of 2015, including a 2 percent negative impact from foreign exchange.

GAAP (generally accepted accounting principles) earnings per share assuming dilution (EPS) were \$0.42 for the fourth quarter and \$2.04 for the full year of 2016. Non-GAAP EPS of \$0.89 for the fourth quarter and \$3.78 for the full year of 2016 excludes acquisition- and divestiture-related costs, restructuring costs and certain other items, which include a charge to settle the worldwide KEYTRUDA patent litigation.

Pipeline Highlights

Merck significantly advanced the clinical development program for KEYTRUDA (pembrolizumab), an anti-PD-1 therapy.

- The FDA [approved](#) a supplemental Biologics License Application (sBLA) for KEYTRUDA for the first-line treatment of patients with metastatic NSCLC whose tumors have high PD-L1 expression (Tumor Proportion Score [TPS] of 50 Percent or More) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations.
- The FDA granted Priority Review for three additional sBLAs for KEYTRUDA, including:
 - Use in combination with chemotherapy as a first-line [treatment](#) for patients with metastatic or advanced NSCLC regardless of PD-L1 expression and with no EGFR or ALK genomic tumor aberrations. The PDUFA action date is May 10, 2017.

¹ Merck is providing certain 2016 and 2015 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. Senior management's annual compensation is derived in part using non-GAAP income and non-GAAP EPS. 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 items, see Tables 2a and 2b attached to this release.

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

- The [treatment](#) of previously treated patients with advanced microsatellite instability-high cancer. The PDUFA action date is March 8, 2017.
- The [treatment](#) of patients with refractory classical Hodgkin lymphoma (cHL) or for patients with cHL who have relapsed after three or more prior lines of therapy. The PDUFA action date is March 15, 2017.
- KEYTRUDA received Breakthrough Therapy Designations from the FDA for the second-line treatment of patients with urothelial carcinoma with disease progression on or after platinum-containing chemotherapy and for the treatment of patients with primary mediastinal B-cell lymphoma that is refractory to or has relapsed after two prior lines of therapy.
- The European Commission [approved](#) KEYTRUDA for the first-line treatment of metastatic NSCLC in adults whose tumors have high PD-L1 expression (TPS of 50 percent or more) with no EGFR or ALK positive tumor mutations.
- KEYTRUDA [was approved](#) in Japan as a first- and second-line treatment of certain patients with PD-L1-positive unresectable advanced/recurrent NSCLC.
- Merck and Incyte Corporation recently [announced](#) the expansion of the clinical development program investigating KEYTRUDA in combination with epacadostat, Incyte's investigational oral selective IDO1 inhibitor, to include pivotal studies for NSCLC, renal cell carcinoma, bladder cancer and squamous cell carcinoma of the head and neck.

The company recently completed enrollment in its Phase 3 APECS study ([NCT01953601](#)) evaluating the safety and efficacy of verubecestat (MK-8931) in people with prodromal, or mild, Alzheimer's disease. Estimated primary completion date for the trial is February 2019.

Fourth-Quarter and Full-Year Revenue Performance

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

\$ in millions	Fourth Quarter				Year Ended			
	2016	2015	Change	Change Ex-Exchange	Dec. 31, 2016	Dec. 31, 2015	Change	Change Ex-Exchange
Total Sales	\$10,115	\$10,215	-1%	0%	\$39,807	\$39,498	1%	3%
Pharmaceutical	8,904	9,027	-1%	-1%	35,151	34,782	1%	2%
JANUVIA/JANUMET	1,509	1,447	4%	4%	6,109	6,014	2%	2%
ZETIA/VYTORIN	873	999	-13%	-13%	3,701	3,777	-2%	-1%
GARDASIL/GARDASIL 9	542	497	9%	9%	2,173	1,908	14%	14%
PROQUAD, M-M-R II and VARIVAX	405	409	-1%	-1%	1,640	1,505	9%	10%
KEYTRUDA	483	214	125%	128%	1,402	566	148%	151%
ISENTRESS	337	374	-10%	-9%	1,387	1,511	-8%	-6%
REMICADE	269	396	-32%	-31%	1,268	1,794	-29%	-28%
CUBICIN	119	322	-63%	-63%	1,087	1,127	-4%	-4%
SINGULAIR	210	273	-23%	-26%	915	931	-2%	-4%
PNEUMOVAX 23	238	188	27%	25%	641	542	18%	17%
Animal Health	884	832	6%	7%	3,478	3,331	4%	8%
Other Revenues	327	356	-8%	30%	1,178	1,385	-15%	15%

Pharmaceutical Revenue

Fourth-quarter pharmaceutical sales decreased 1 percent to \$8.9 billion. The decline was driven primarily by the loss of U.S. market exclusivity in 2016 for CUBICIN (daptomycin for injection), an I.V. antibiotic; NASONEX (mometasone furoate monohydrate), an inhaled nasal corticosteroid for the treatment of nasal allergy symptoms; and ZETIA (ezetimibe), a medicine for lowering LDL cholesterol; as well as by the ongoing impact of biosimilar competition in the company's marketing territories in Europe for REMICADE (infliximab), a treatment for inflammatory diseases. In the aggregate, sales of these products declined \$564 million during the fourth quarter of 2016 compared to the fourth quarter of 2015.

These declines were largely offset by growth in oncology, hepatitis C, diabetes and vaccines, which include the ongoing launches of KEYTRUDA and ZEPATIER (elbasvir and grazoprevir), a medicine for the treatment of chronic hepatitis C virus genotypes 1 or 4 infection. Additionally, the ongoing launch of BRIDION (sugammadex) Injection 100 mg/mL, a medicine for the reversal of neuromuscular blockade induced by rocuronium bromide or vecuronium bromide in adults undergoing surgery, generated sales of \$139 million during the fourth quarter of 2016.

Growth of KEYTRUDA reflects the company's continued efforts to launch the product with new indications, particularly as a first-line treatment for NSCLC and for previously treated recurrent or metastatic head and neck cancer in the United States, and as a second-line treatment for NSCLC globally.

ZEPATIER sales growth was primarily driven by the ongoing launch in the United States, as well as ongoing launches in emerging markets and the launches in Europe and Japan. In the fourth quarter of 2016, sales of ZEPATIER were \$229 million.

Pharmaceutical sales also reflect an increase in the diabetes franchise of JANUVIA (sitagliptin) and JANUMET (sitagliptin and metformin HCl), medicines that help lower blood sugar in adults with type 2 diabetes, driven by sales growth in the United States, partially offset by lower sales in Japan due to the timing of shipments.

Growth in vaccines resulted from higher sales of PNEUMOVAX 23 (pneumococcal vaccine polyvalent) in the United States due to the adoption of recently issued vaccination guidelines from the Centers for Disease Control and Prevention; and GARDASIL 9 (Human Papillomavirus 9-valent Vaccine, Recombinant) and GARDASIL [Human Papillomavirus Quadrivalent (Types 6, 11, 16, and 18) Vaccine, Recombinant], vaccines to prevent certain cancers and other diseases caused by HPV, due to increased pricing and demand in the United States. On Dec. 31, 2016, Merck and Sanofi Pasteur ended the Sanofi Pasteur MSD vaccines joint venture. As a result, beginning in 2017, Merck will operate its vaccines business in Europe and will record vaccine sales in the 19 European countries previously part of the joint venture.

In April 2017 the company will lose market exclusivity in the United States for VYTORIN (ezetimibe/simvastatin), a medicine for lowering LDL cholesterol, and anticipates a significant decline in U.S. VYTORIN sales thereafter. Full-year 2016 U.S. sales of VYTORIN were \$473 million.

Full-year 2016 pharmaceutical sales increased 1 percent to \$35.2 billion, including a 1 percent negative impact from foreign exchange. Growth was driven by sales in oncology, vaccines and hepatitis C products, partially offset by sales declines of \$887 million due to the loss of U.S. market exclusivity for NASONEX and CUBICIN, and the impact of biosimilar competition for REMICADE in the company's marketing territories in Europe.

Animal Health Revenue

Animal Health sales totaled \$884 million for the fourth quarter of 2016, an increase of 6 percent compared with the fourth quarter of 2015, including a 1 percent negative impact from foreign exchange. Worldwide sales for the full year of 2016 were \$3.5 billion, an increase of 4 percent, including a 4 percent negative impact from foreign exchange. Sales growth in both periods was primarily driven by an increase in sales of companion animal products, particularly the BRAVECTO (fluralaner) line of products that kill fleas and ticks in dogs and cats for up to 12 weeks.

Fourth-Quarter and Full-Year Expense, EPS and Related Information

The tables below present selected expense information.

\$ in millions		Acquisition- and Divestiture- Related Costs ³	Restructuring Costs	Certain Other Items	Non-GAAP ¹
Fourth-Quarter 2016					
	GAAP				
Materials and production	\$3,332	\$756	\$32	\$—	\$2,544
Marketing and administrative	2,593	22	4	—	2,567
Research and development	1,720	(33)	9	—	1,744
Restructuring costs	265	—	265	—	—
Other (income) expense, net	721	35	—	654	32
Fourth-Quarter 2015					
Materials and production	\$3,850	\$1,194	\$81	\$—	\$2,575
Marketing and administrative	2,615	47	8	—	2,560
Research and development	1,797	(24)	18	—	1,803
Restructuring costs	233	—	233	—	—
Other (income) expense, net	905	47	—	707	151

\$ in millions		Acquisition- and Divestiture- Related Costs ³	Restructuring Costs	Certain Other Items	Non-GAAP ¹
Year Ended Dec. 31, 2016					
	GAAP				
Materials and production	\$13,891	\$4,035	\$181	\$—	\$9,675
Marketing and administrative	9,762	78	95	—	9,589
Research and development	7,194	222	142	—	6,830
Restructuring costs	651	—	651	—	—
Other (income) expense, net	810	47	—	648	115
Year Ended Dec. 31, 2015					
Materials and production	\$14,934	\$4,869	\$361	\$—	\$9,704
Marketing and administrative	10,313	436	78	—	9,799
Research and development	6,704	39	52	—	6,613
Restructuring costs	619	—	619	—	—
Other (income) expense, net	1,527	54	—	1,125	348

GAAP Expense, EPS and Related Information

On a GAAP basis, the gross margin was 67.1 percent for the fourth quarter of 2016 compared to 62.3 percent for the fourth quarter of 2015. The increase in gross margin for the fourth quarter of 2016 was primarily driven by lower acquisition- and divestiture-related costs and restructuring costs noted above, which negatively affected gross margin by 7.7 percentage points in the fourth quarter of 2016 compared with 12.5 percentage points for the fourth quarter of 2015. The gross margin was 65.1 percent for the full year of 2016 compared to 62.2 percent for the full year of 2015. The increase in gross margin for the full year of 2016 was primarily driven by lower acquisition- and divestiture-related costs and restructuring costs, which

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 contingent consideration. Also includes integration, transaction and certain other costs related to business acquisitions and divestitures.

negatively affected gross margin by 10.6 percentage points in the full year of 2016 compared with 13.2 percentage points for the full year of 2015.

Marketing and administrative expenses were \$2.6 billion in the fourth quarter of 2016, a 1 percent decrease compared to the fourth quarter of 2015. The decline primarily reflects lower acquisition- and divestiture-related costs. Full-year 2016 marketing and administrative expenses were \$9.8 billion, a 5 percent decrease compared to the full year of 2015. The decline reflects lower acquisition- and divestiture-related costs, the favorable impact of foreign exchange and lower direct selling costs.

Research and development (R&D) expenses were \$1.7 billion in the fourth quarter of 2016, a 4 percent decrease compared to the fourth quarter of 2015. The decline reflects a reduction in expenses resulting from a decrease in the estimated fair value of liabilities for contingent consideration, partially offset by higher in-process research and development (IPR&D) impairment charges. R&D expenses were \$7.2 billion for the full year of 2016, a 7 percent increase compared to the full year of 2015. The increase primarily reflects higher IPR&D impairment charges, clinical development spending and restructuring costs, partially offset by a reduction in expenses resulting from a decrease in the estimated fair value of liabilities for contingent consideration.

Other (income) expense, net, was \$721 million of expense in the fourth quarter of 2016 compared to \$905 million of expense in the fourth quarter of 2015 and was \$810 million of expense for the full year of 2016 compared to \$1.5 billion of expense for the full year of 2015. Other (income) expense, net for the fourth quarter and full year of 2016 includes a \$625 million charge to settle the worldwide KEYTRUDA patent litigation. Other (income) expense, net for the fourth quarter and full year of 2015 includes \$161 million and \$876 million, respectively, of foreign exchange losses related to the devaluation of the company's net monetary assets in Venezuela and a \$680 million net charge to settle the Vioxx shareholder class action litigation.

GAAP EPS was \$0.42 for the fourth quarter of 2016 compared with \$0.35 for the fourth quarter of 2015. GAAP EPS was \$2.04 for the full year of 2016 compared with \$1.56 for the full year of 2015.

Non-GAAP Expense, EPS and Related Information

The non-GAAP gross margin was 74.8 percent for the fourth quarter of 2016, the same as the fourth quarter of 2015. The non-GAAP gross margin was 75.7 percent for the full year of 2016 compared to 75.4 percent for the full year of 2015. The increase in GAAP gross margin for the full year of 2016 reflects lower inventory write-offs.

Non-GAAP marketing and administrative expenses were \$2.6 billion in the fourth quarter of 2016, comparable to the fourth quarter of 2015. Non-GAAP marketing and administrative

expenses were \$9.6 billion for the full year of 2016, a 2 percent decrease compared to the full year of 2015. The decline reflects the favorable impact of foreign exchange and lower direct selling costs.

Non-GAAP R&D expenses were \$1.7 billion in the fourth quarter of 2016, a 3 percent decline compared to the fourth quarter of 2015. The decline reflects lower licensing costs. Non-GAAP R&D expenses were \$6.8 billion for the full year of 2016, a 3 percent increase compared to the full year of 2015 reflecting increased clinical development spending.

Non-GAAP EPS was \$0.89 for the fourth quarter of 2016 compared with \$0.93 for the fourth quarter of 2015. Non-GAAP EPS was \$3.78 for the full year of 2016 compared with \$3.59 for the full year of 2015.

Non-GAAP other (income) expense, net, was \$32 million of expense in the fourth quarter of 2016 compared to \$151 million of expense in the fourth quarter of 2015, primarily reflecting the receipt of a milestone payment. Non-GAAP other (income) expense, net, for the full year of 2016 was \$115 million of expense compared to \$348 million of expense for the full year of 2015, reflecting lower foreign exchange losses.

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

\$ in millions, except EPS amounts	Fourth Quarter		Year Ended	
	2016	2015	Dec. 31, 2016	Dec. 31, 2015
EPS				
GAAP EPS	\$0.42	\$0.35	\$2.04	\$1.56
Difference ⁴	0.47	0.58	1.74	2.03
Non-GAAP EPS that excludes items listed below ¹	\$0.89	\$0.93	\$3.78	\$3.59
Net Income				
GAAP net income ²	\$1,177	\$976	\$5,691	\$4,442
Difference	1,293	1,632	4,847	5,753
Non-GAAP net income that excludes items listed below ^{1,2}	\$2,470	\$2,608	\$10,538	\$10,195
Decrease (Increase) in Net Income Due to Excluded Items:				
Acquisition- and divestiture-related costs ³	\$780	\$1,264	\$4,382	\$5,398
Restructuring costs	310	340	1,069	1,110
Charge to settle worldwide KEYTRUDA patent litigation	625	–	625	–
Net charge to settle Vioxx shareholder class action litigation	–	680	–	680
Foreign exchange losses related to Venezuela	–	161	–	876
Gain on divestiture of certain ophthalmic products	–	(147)	–	(147)
Gain on divestiture of certain migraine clinical development programs	–	–	–	(250)
Other	29	13	23	(34)
Net decrease (increase) in income before taxes	1,744	2,311	6,099	7,633
Income tax (benefit) expense ⁵	(451)	(679)	(1,252)	(1,880)
Decrease (increase) in net income	\$1,293	\$1,632	\$4,847	\$5,753

⁴ 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.

⁵ Includes the estimated tax impact on the reconciling items. In addition, amounts for fourth-quarter and full-year 2015 include net benefits of \$40 million and \$410 million, respectively, related to the settlement of certain federal income tax issues.

Financial Outlook

Merck expects its full-year 2017 GAAP EPS to be between \$2.47 and \$2.62. Merck expects its full-year 2017 non-GAAP EPS to be between \$3.72 and \$3.87, including an approximately 2 percent negative impact from foreign exchange. The non-GAAP range excludes acquisition- and divestiture-related costs and costs related to restructuring programs.

At mid-January 2017 exchange rates, Merck anticipates full-year 2017 revenues to be between \$38.6 billion and \$40.1 billion, including an approximately 2 percent negative impact from foreign exchange.

The following table summarizes the company's 2017 financial guidance.

	GAAP	Non-GAAP ¹
Revenue	\$38.6 to \$40.1 billion	\$38.6 to \$40.1 billion**
Operating expenses	Higher than 2016 by a low-single digit rate	Higher than 2016 by a low-single digit rate
Effective tax rate	22.0% to 23.0%	21.0 % to 22.0%
EPS	\$2.47 to \$2.62	\$3.72 to \$3.87

**The company does not have any non-GAAP adjustments to revenue.

A reconciliation of anticipated 2017 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 2017
GAAP EPS	\$2.47 to \$2.62
Difference ⁴	1.25
Non-GAAP EPS that excludes items listed below ¹	\$3.72 to \$3.87
Acquisition- and divestiture-related costs	\$3,600
Restructuring costs	600
Net decrease (increase) in income before taxes	4,200
Estimated income tax (benefit) expense	(750)
Decrease (increase) in net income	\$3,450

The expected full-year 2017 GAAP effective tax rate of 22.0 to 23.0 percent reflects an unfavorable impact of approximately 1 percentage point from the above items.

Total Employees

As of Dec. 31, 2016, Merck had approximately 68,000 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. EST on Merck's website at <http://investors.merck.com/events-and-presentations/default.aspx>. Institutional investors and analysts can participate in the call by dialing (706) 758-9927 or (877) 381-5782 and using ID code number 32136167. Members of the

media are invited to monitor the call by dialing (706) 758-9928 or (800) 399-7917 and using ID code number 32136167. 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 a century, Merck has been 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](#), [YouTube](#) and [LinkedIn](#). You can also follow our Twitter conversation at \$MRK.

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 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 2015 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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