

Generic competition, charges cut Merck Q4 profit (Update)

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Merck & Co.'s fourth-quarter profit fell 7 percent because of hits from generic competition and one-time charges, and the company pushed back plans to seek approval of a key experimental osteoporosis drug.

The quarterly results beat Wall Street expectations, but Merck shares fell in premarket trading Friday as investors learned Merck is reviewing safety and efficacy data from a crucial late-stage patient test of odanacatib.

During a morning conference call with analysts, Merck said that instead of applying for approval of odanacatib in the first half of this year, it won't do so until 2014. That will allow Merck time to finish an extension of an odanacatib study that includes about 8,200 women, so that Merck can also submit those longer-term results to regulators—apparently a strategy to improve chances the drug will be approved.

In early trading, Merck shares fell \$1.42, or 3.3 percent, to \$41.83.

The world's third-biggest drugmaker by revenue said net income was \$1.4 billion, or 46 cents per share, down from \$1.51 billion, or 49 cents per share, a year earlier.

Excluding one-time restructuring and acquisition charges totaling \$1.14 billion, net income was \$2.54 billion, or 83 cents per share, 2 cents more than analysts polled by research provider FactSet were expecting.

The maker of Januvia and other diabetes pills says revenue totaled \$11.74 billion, down 5 percent from 2011's fourth quarter. Analysts expected \$11.47 billion.

The sales drop was due to generic competition for asthma and allergy drug Singulair, which had brought Merck about \$5.5 billion in annual sales until its U.S. patent expired in August, as well as for blood pressure medicines Cozaar and Hyzaar.

"Merck did have a very strong fourth quarter and a good year overall," CEO Kenneth Frazier told the analysts.

He said that despite the generic competition, the company expected to keep revenue this year at about the same level as last year's \$47.27 billion.

Analysts on the conference call repeatedly asked exactly why Merck was changing its plans for odanacatib, and whether the data showed a serious risk that could block approval of the drug, which is viewed as a potential blockbuster. Company executives declined to give details.

"We continue to believe in the potential of this drug to meet the unmet needs of people with osteoporosis," CEO Kenneth Frazier told the analysts.

He noted that most women with osteoporosis aren't being treated with medication, and about a quarter of patients find they can't tolerate side effects of osteoporosis drugs in an older class called bisphosphonates, including heartburn, nausea, diarrhea and joint pain and swelling. Merck's Fosamax, which has had generic competition for four years, was the first drug in that class and had been the top seller.

Along with the weak global economy and government health programs in

many countries trying to rein in spending, Merck has been hurt by generic rivals to what had been its top seller. Singulair, which treats asthma and allergies, lost patent protection in the U.S. in early August. In the last quarter, its global sales nosedived 67 percent to \$480 million.

That pulled down total prescription drug sales by 6 percent, to \$10.09 billion. Most of Merck's other big drugs produced higher sales, led by the Januvia Type 2 diabetes drug, up 18 percent to \$1.13 billion, and Janumet, a diabetes combo pill, up 17 percent to \$452 million.

Cholesterol-lowering drug Zetia posted a 6 percent increase in sales to \$676 million, and sales jumped 61 percent to \$442 million for Gardasil a vaccine against sexually transmitted cancers.

Merck's smaller divisions saw increased sales, however. Veterinary medicine sales edged up 3 percent to \$898 billion. Sales of consumer health products such as Dr. Scholl's foot care products climbed 9 percent to \$395 million.

Merck, based in New Jersey, forecast 2013 earnings per share of \$3.60 to \$3.70, excluding charges. Analysts were expecting \$3.68 per share.

For the full year, Merck reported net income of \$6.66 billion, or \$2.16 per share, up from \$6.27 billion, or \$2.02 per share. But sales in 2012 dipped nearly 2 percent, to \$47.27 billion.

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