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Severin Schwan: A healthy forecast for pharma

BASEL -- Severin Schwan thinks the skeptics are wrong. Those who shun the pharmaceutical sector for its lack of prospects don't understand the potential created by a rapidly growing understanding of genetics and molecular biology, and the new drugs that will follow.

"There are people who would argue that all the low-hanging fruits have been harvested and that the pharmaceutical industry is at an end," Mr. Schwan says.

But the chief executive of Roche Holding AG, the world's seventh-largest drug firm by sales, is an informed optimist. "I believe there are enormous opportunities in this industry as we are only now beginning to understand how diseases are working," he says during an interview at the company's headquarters in the Swiss city of Basel.

Eight months ago, such confidence from the 43-year-old Austrian, who took over Roche's top job in 2008, would have met with disbelief from investors. The Swiss company had just embarked on a 2.7-billion-Swiss-franc (\$3.4 billion) restructuring that is set to last two years. The revamp was needed in the wake of the failure of more than half a dozen drugs in development, including the shelving of diabetes compound taspoglutide, which had promised to become a blockbuster with more than \$1 billion in annual peak sales.

The series of setbacks saw Roche's share price fall 20% in 2010. Investors feared that, coupled with the U.S. health-care reform, drug-price cuts in Europe and increased regulatory scrutiny of its cancer drug Avastin as a breast-cancer treatment and its eye medicine Lucentis, the Swiss giant's potential for growth had evaporated. Even the restructuring plan, announced in November, which involves shedding 4,800 jobs and aims to save around 2.4 billion Swiss francs in costs from 2012 onward, left many investors unimpressed as growth concerns remained acute because of the growing insecurity about new drugs in its pipeline.

Indeed, in the first half of 2011, Roche's sales dropped 12% to 21.67 billion francs from 24.63 billion francs as it suffered from the soaring Swiss currency and weakness in sales of its cancer treatments, which generate more than half the company's revenue. Had currencies remained unchanged, sales would have been flat. Roche's problems were typical of the sector as a whole, hampered as it is by competition from generics and price cuts, which have seen the industry's growth rate fall to around 4% in 2010, from annual growth rates of around 7% to 9% over the previous seven years, according to data from consultancy IMS Health.

But Mr. Schwan is adamant about the sector's prospects. The father of three, who has spent his entire career at Roche since starting out as a trainee in 1993, is full of confidence when he talks about his belief in scientific progress. And perhaps recent developments justify his optimism. This year, all of Roche's seven drug approval applications have been accepted by health authorities, including this month's U.S. approval of skin-cancer treatment Zelboraf, which analysts estimate could help Roche generate more than \$1 billion in annual peak sales if it is also accepted to treat other cancer forms.

The nod from the U.S. Food and Drug Administration, which came two months earlier than expected as regulators were impressed with the medicine's effectiveness, is a major milestone for Roche as the drug belongs to the company's growing class of targeted therapies.

These treatments come together with diagnostic tests that can identify whether a patient can benefit from a drug that targets a specific, genetically mutated protein that is believed to be the root cause of a disease.

Mr. Schwan has been in the pharmaceutical industry long enough to know that the recent string of good trial results and approval news is unlikely to last and that setbacks are part of the industry's development process risk. But his confidence in Roche's strategy and drug pipeline remains unshaken.

"We have a huge potential with our targeted therapies and believe that this strategy is working," he says. "And more is expected to come when we consider that all of today's existing medicines address only some 150 different targets, whereas there are more than two million proteins in the human body, of which many potentially can cause diseases. We are only scratching the surface."

Among Roche's most promising experimental compounds, Mr. Schwan says, are lung-cancer treatment Metmab, asthma compound lebrikizumab and breast-cancer treatment pertuzumab. "If approved, the drugs could be used to treat hundreds of thousands of patients and could have blockbuster potential," Mr. Schwan says. "But of course, these experimental compounds need to prove themselves first."

Roche plans to file pertuzumab in Europe and in the U.S. later this year and is in the process of entering late stage trials for Metmab and lebrikizumab.

But Mr. Schwan has yet to infect investors with his optimism. Part of the problem faced by high-end pharma products is governments' increasing reluctance to pay for expensive medicines in a regulatory environment that prioritizes cost-cutting.

The expected loss of Avastin's use as a treatment for metastatic breast cancer in the U.S., which forced Roche to lower its sales forecast of its best-selling medicine 22% to seven billion francs, has kept investors cautious. Roche's shares, despite outperforming the Swiss blue-chip index, have lost almost 11% this year. The stock closed Friday at 128 Swiss francs. This is close to the five-year low of 122.8 francs reached in June 2009 during the global financial crisis.

"Pricing pressure, which is expected to cut our sales by 1% this year, is expected to continue," says Mr. Schwan. "But we are confident that our strategic response with a clear focus on innovation will help us, going forward. At the same time we are constantly working on productivity improvements across the entire organization."

Such efforts, Mr. Schwan says, have helped put the company slightly ahead of schedule on its restructuring, even as it temporarily shelved plans to sell its U.S. pharmaceutical plant in Florence, S.C., because of a lack of attractive bids. Roche is also open to compromise with regulators to limit prices and make medicines available to more patients, but as its recent dispute with the U.K. price regulator -- which vetoed reimbursement for Avastin on cost grounds -- showed, Roche won't bend too much, Mr. Schwan says.

As for competition from generic-drug manufacturers -- which analysts from brokerage Bernstein expect to lead to an annual sales loss of around 2% from 2014 to 2020 for Roche -- Mr. Schwan thinks the likely impact has been exaggerated. "First, one has to be aware that in the medium term we will only lose the patents on two drugs in Europe, which are cancer drug Herceptin and rheumatoid arthritis and cancer medicine Rituxan," he says. "Both are biological medicines where identical copies are not possible and therefore regulatory hurdles will be much higher. While it is true that generic competition on simple small molecules can lead to price cuts of 80%, no one yet knows how this will work out for complex biologics," he says. After all, he points out, despite generic competition to its biological blood medicine NeoRecormon, which is used to treat anemia in patients with chronic kidney failure, NeoRecormon is still the leading medicine in a competitive market like Germany. Analysts say that due to the complexity of these drugs, price reductions for Roche may be limited but could reach more than 30%.

But even those who don't share Mr. Schwan's confidence in the sector have to admit the strength of Roche's performance. Even as the company struggled in a difficult market environment in the first half of this year, its fast revamp allowed it to increase its profit target. And Mr. Schwan says the company is on track to reach its financial guidance for the full year. Roche also said at half-year that it aims to raise its dividend payment in line with earnings per share. And if the franc continues to soar and depress earnings, Roche says it will at least maintain last year's dividend in Swiss francs. If the franc retains its current strength, this will mean a double-digit dividend increase for foreign investors, as the franc has strengthened by some 20% against both the dollar and the euro this year.

Goran Mijuk

Severin Schwan

Age: 43

Nationality: Austrian

Position: CEO

Based: Basel

Time in job: Since 2008

Previous positions: 2006 - 2008 Chief Executive of Roche Diagnostics; 2004 - 2006 Head Region Asia Pacific, Roche Diagnostics Singapore; 2000 - 2004: Head Global Finance & Services at Roche Diagnostics, Basel; 1995 - 2000 Head Finance at several units; 1993 - 1995 Trainee at Corporate Finance, Roche Basel