

## DRUG DEVELOPMENT

**Novartis' role in 21st century drug development***Daniel Vasella*

As the newest—and largest—pharmaceutical company, we have often been asked about our strategy and long-term vision with respect to drug and new technology development in the coming century. Questions such as, “Can a company this size be innovative?” or “Will we cut back our spending in research?” seem to be on everyone’s mind in this era of pharmaceutical consolidation and restructuring.

Although we have been in operation less than one year as Novartis, I would like to review our objectives in joining two innovative and powerful companies—Sandoz and Ciba-Geigy—into one. I would also hope to shed light on what this union will mean for the development of new drugs and technologies.

Novartis is now far better positioned than either Sandoz or Ciba alone could have been to invest in R&D and the development of new technologies for the long term. But taken together, as Novartis, the combined investment in R&D is the largest in the health-care industry—totaling 2.2 billion CHF (US\$3.1 billion), or 19% of sales. The size of our research budget for the past year reveals that we have increased—not cut—our R&D by 6% during the merger process.

How was this possible? The structure of the Novartis merger protected our balance sheet. This was a merger of equals, based on a tax-free exchange of shares according to current market valuations, rather than an acquisition. Further, the pooling of financial interests meant that there was no goodwill depreciation. We created a lean organization, reducing our administration and overhead costs by 4% in 1996, further freeing up resources for investing in strategic areas. Overall, in the merger we committed to achieving cost synergies of 2 billion CHF (US\$2.8 billion).

The end result is that we have very strong financial resources, in contrast to the financial burdens that would have accompanied a typical acquisition. The company now has a formidable cash position that enables substantial investment in value-creating activities, in line with our long-term perspective.

**Our strategic outlook**

In a business rooted in uncertainty, such as the health-care industry, our financial strength enables us to take risks that others cannot sustain. Thus, once we recognize that

a new technology is likely to become a key technology, we will not hesitate to become involved.

For anyone who has been faced with the problem of buying a new computer, the issues in choosing new technologies are clear: You can either be caught in the trap of waiting for the “next generation” of computers—in which case you risk never owning one—or you participate in the growth of the industry by buying what you believe to be the best value for the money at the time.

During the past few months, we have put the latter strategy to work by focusing our business portfolio in the life sciences, where we are already the world leader. For example, we acquired Imutran (Cambridge, UK), our xenotransplantation center of excellence. We also acquired the shares that we did not already own of SyStemix (Palo Alto, CA)—a leader in hematopoietic stem cell therapy. Conversely, we divested our Ciba Specialty Chemicals Business (Basel), Mettler Toledo (Greifensee, Switzerland), and the Gerber children’s wear business (Greenville, SC), which no longer fit in our portfolio. As a result, all of our businesses—health care, agribusiness, and nutrition—now have biology as their underlying R&D orientation.

**How do we choose new technologies?**

Novartis is interested in exploring projects at every stage of the R&D cycle, as long as they meet several general criteria: They must provide an exponential increase in biomedical knowledge, immediate access to and accelerated implementation of new technologies, rapid testing of additional hypotheses, or start of a new field or activity. And for a new therapy, which can be at any stage of development, it must address an unsatisfied medical need.

Do these opportunities all have to be blockbusters in order to gain our attention? As part of our strategy to lead the field in enabling technologies, we are committed to undertaking projects that we realize do not have the immediate potential to produce a blockbuster drug. We will undertake this type of research because it will contribute to our knowledge and provide us with opportunities to advance our expertise in critical areas. We will fund initiatives that strengthen our ability to tackle the technical hurdles we face in our work.

External alliances accelerate the pace of drug discovery far more rapidly than a company establishing research capabilities solely in house. They give a company the flexibility to abandon a hypothesis as soon as it is

determined that it is not viable. To this end, Novartis will dedicate up to one-third of its resources to external alliances and partnerships. When a project or technology becomes standard or enabling, and also fits with our long-term interests, we will bring that expertise in-house. These activities must also be fundamental for branching out, pursuing new initiatives, commercially attractive, and with an acceptable risk.

**An example: Gene therapy**

One area in which we have put these principles to practice is that of gene therapy. Genetic Therapy (Gaithersburg, MD) is a wholly owned subsidiary of Novartis that now serves as the hub of our gene therapy work. The pioneering efforts of the company have produced the most advanced findings in gene therapy, based on French Anderson’s initial research, as well as on cutting-edge work in the use of thymidine kinase genes. The growth of this technology has been so significant that we have expanded our in-house effort to several therapeutic areas, as well as continuing to work with French Anderson’s lab (University of Southern California) in their efforts to develop a simplified delivery system for gene therapy. We cross-fertilize this research area whenever we identify new innovative methods to overcome technical hurdles. Thus, we have also invested \$10 million in Alexion Pharmaceuticals (New Haven, CT) to develop less immunogenic vectors.

**Challenges ahead**

At present, Novartis is the leading pharmaceutical company with 4.4% market share. To maintain our position in the context of global movements by governments to exert more control on pricing, coupled with tougher regulations for the approval of new drugs, we must produce truly innovative drugs in a shorter time frame.

The winning strategy for Novartis in this environment is to seize opportunities and take risks where others cannot. Taking a compound to market in 1996, including all R&D expenditures, cost about US\$600 million based on our internal estimates. We anticipate that these costs will continue to increase. Through its merger, Novartis has achieved the critical mass and the financial resources to withstand these spiraling costs. Novartis is committed to leveraging its financial strength and the broad spectrum of its activities into therapeutic breakthroughs for the next century. *///*

*Daniel Vasella is president of Novartis AG, Basel, Switzerland.*