

NOVARTIS AG
Form 6-K
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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 or 15d-16 OF THE SECURITIES EXCHANGE ACT OF 1934

Report on Form 6-K dated February 7, 2003
(Commission File No. 1-15024)

Novartis AG

(Name of Registrant)

Lichtstrasse 35
4056 Basel
Switzerland

(Address of Principal Executive Offices)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

Form 20-F: Form 40-F:

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Indicate by check mark whether the registrant by furnishing the information contained in this form is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes: No:

Enclosures: **Novartis AG Annual Report 2002 to Shareholders**

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Financial Highlights

- (1) Excluding discontinued Novartis Agribusiness
- (2) Before acquisition of product and marketing rights and Roche Holding AG voting shares

Key ratios

	2002	2001
Return on sales (%)	24.3	23.0
Return on average equity (%)	17.9	17.8
Group research and development as % of sales	13.4	13.2
Debt/equity ratio	0.20:1	0.21:1
Current ratio	2.5:1	2.4:1

Share information

	2002	2001
Average number of shares outstanding	2 515 311 685	2 571 673 365
Earnings per share (CHF)	2.91	2.73
Operating cash flow per share (CHF)	3.24	2.85
Dividend per share(3) (CHF)	0.95	0.90
Pay-out ratio based on outstanding shares (%)	33	33
Share price at end of year (CHF)	50.45	60.00

- (3) 2002: Proposal to the shareholders' meeting

News in 2002

Strong volume growth in Pharmaceuticals and Generics: Group sales up 11% in local currencies (+2% in CHF)

Pharmaceuticals steadily gaining market share in all major markets, with sales growth of 13% in local currencies (+4% in CHF), driven by the Cardiovascular and Oncology franchises

Registration dossiers for 18 new drugs, indications and formulations were submitted

Group operating income climbs 8%, spurred by strong top line growth and enhanced productivity

Net income up 4%, due to strong operating performance and an attractive level of financial income amid adverse market conditions

Earnings per share rise 7%, supported by share buy-back program

Based on solid performance, a dividend increase of 6% to CHF 0.95 per share will be proposed to shareholders

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Letter from Daniel Vasella

Dear Shareowner

In these times of economic uncertainty and volatility, it gives me pleasure to present another year of record results and consistent growth the sixth year since Novartis was formed from the merger of Ciba and Sandoz in 1996.

Let me summarize the key achievements which contributed to our success in 2002:

Double-digit growth was achieved in group sales, which totaled CHF 32.4 billion (+11% in local currencies).

Operating income was up 8% to CHF 7.9 billion, net income rose 4% to CHF 7.3 billion, and earnings per share increased by 7% to CHF 2.91.

Gains in market share were achieved by virtually all of our business franchises.

11 approvals were obtained for new pharmaceutical products, indications and formulations in major markets around the world, marking another industry-leading achievement.

18 registration dossiers for new drugs and indications were submitted for regulatory approval.

In the US, pharmaceutical sales grew by 12%, making Novartis one of the fastest-growing major pharmaceutical companies. Altogether, the US market accounted for 42% of our global pharmaceutical business sales.

Our oncology (+28%) and cardiovascular (+40%) businesses were successfully expanded, with significant rejuvenation of our product portfolio.

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The Consumer Health Division was refocused, with the establishment of global business units and the sale of Ovaltine/Ovomaltine, Caotina and Lacovo to Associated British Foods.

Our Generics business was strengthened by the acquisition of the Slovenian generics company Lek.

Net financial income reached CHF 949 million despite the difficult stock market conditions.

Our financial investment in Roche was increased to 32.7% of the voting shares.

We expanded our programs designed to facilitate the supply of drugs to indigent patients suffering from leprosy, malaria, tuberculosis and chronic myeloid leukemia (CML).

These good results are the fruits of a shared focus on clear, unchanged strategic goals and of the positive attitude and high level of commitment of our associates. I would like to take this opportunity to express my sincere thanks to all those who contributed to this year's success.

Similarly, in the year ahead we will continue pursuing a strategy oriented towards sustainable growth. Strategic focus, the capacity for innovation, successful marketing and enhanced productivity remain key success factors. In addition to the quality of our staff and products, the size and strength of our pharmaceutical business, particularly in the US market, is of crucial importance. The focus on these priorities led, among other criteria, to the decision last year to divest our Health & Functional Food operations. Part of this business, as mentioned above, has been sold to Associated British Foods, and the remainder will be disposed of once an attractive bid is received. At the same time, we have further strengthened our Generics business, which also achieved dynamic organic growth, by acquiring the Slovenian company Lek. The latter's strong position in Central and Eastern Europe and its attractive product portfolio will enable the Generics Business Unit to be rebranded under the established Sandoz name to become a global market leader. Given the growing numbers of elderly patients requiring healthcare services and drugs, the role of low-cost generics will become even more important

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in future. The savings achieved as a result can then be used to finance innovative new drugs with improved efficacy and safety profiles benefitting the patient.

Innovation and new products will thus remain our company's lifeblood. For this reason, we have decided to set up a new research headquarters in Cambridge, Massachusetts, under the direction of our new Global Head of Research, Professor Mark Fishman. As President of the new institute, Professor Fishman plans to incorporate new insights from the fields of genetics and molecular biology into our research in a systematic manner and to draw on the rich pool of young scientists from the local network of universities and hospitals in and around Boston. This research initiative will involve substantial levels of investment, which will have an appreciable impact in the coming year. However, in view of our strategy of innovation and our long-term growth aspirations, we believe that these investments are justified and that they will result in important new medicines for patients in the years ahead.

In 2002, we further expanded our share in various segments of the US market and successfully launched two new drugs. After a regulatory setback in 2001, *Zelnorm/Zelmac* was approved earlier than expected by the FDA for patients with constipation-related irritable bowel syndrome and is now available in many countries. *Elidel*, a non-steroid cream for the treatment of atopic dermatitis, became the leading product in its segment only a few months after its introduction. The antihypertensives *Diovan* and *Lotrel* and the anticancer agents *Zometa* and *Gleevec/Glivec* continue to grow dynamically. *Gleevec/Glivec*, our breakthrough drug, received approval as first-line therapy for chronic myeloid leukemia (CML) in several markets, enabling patients to receive treatment immediately upon the diagnosis of their disease, improving their chances of survival and providing new hope for patients and families.

However, as expenditures on sales and marketing remain at a high level, it is not surprising that cost pressures will persist into the future. As far as possible, these will be counteracted through productivity programs, since it is rarely possible to increase prices. On the contrary, governments and insurers are constantly calling for price reductions and discounts. At the same time, certain developing countries and groups of activists are seeking to systematically undermine intellectual property rights. If the World Trade Organization were to yield rashly to this pressure, the long-term result would be a continuous decline in investments in R&D, as there would be little prospect of achieving a reasonable return for our shareholders. Our position is one of unequivocal support for patents that are strong but apply only for a limited period. At the same time, we advocate that these patents should not be applicable for the 49 poorest countries with regard to life-saving drugs used to treat diseases such as

AIDS, malaria and tuberculosis. We also continue to support the World Health Organization (WHO) by donating drugs for leprosy and tuberculosis and by supplying our innovative antimalarial agent *Coartem* at cost. It should be mentioned, too, that our new institute, The Novartis Institute for Tropical Diseases, dedicated to research on tropical diseases, will be opening in Singapore early in 2003. While we are aware that a lack of medicines is only one of the problems afflicting many developing countries, we trust that our efforts can make a substantial contribution to improving healthcare in these regions. In industrialized nations, we have also launched a number of programs for the benefit of uninsured and needy patients (for a summary, see p. 37).

Unfortunately, the past year will also be remembered as one of corporate scandals, challenging the credibility and integrity of many executives. Novartis did constantly strengthen its Corporate Governance in the past and will comply with new Swiss and foreign legislation and regulations but more importantly aspire to match the absolute highest standards. This commitment to progressive corporate governance structure and processes will lead to an increase in the responsibilities and tasks of the Board of Directors and its committees especially in the case of the Audit and Compliance Committee.

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This Annual Report fully responds to the widespread calls for greater transparency. It should enable you to form a realistic assessment of your company's current financial position and future growth prospects. This is the last Annual Report in which our results will be reported in Swiss francs. Because an ever-increasing proportion of our revenues are generated in the dollar zone, we have decided to present our future financial reporting in the US currency. This will also facilitate fairer comparisons with our predominantly American competitors, and I trust that these comparisons will further our recognition as a leading global pharmaceutical company dedicated to the discovery of innovative medicines for patients.

To you, our shareowners, I wish to express my gratitude for your loyalty and confidence.

Sincerely,

Daniel Vasella, MD
Chairman and CEO

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Amazing Patient Stories

by Lisa Melton, PhD

Patients' Perspectives: Barbara Howell

Barbara should have died a long time ago. In 1998, the 53-year-old businesswoman from San Diego was lying immobile in a hospital bed, her bones packed with tumors too many to even count. She was suffering from breast cancer that had spread to the bones. Her arms, legs, spine and skull were obliterated by cancer cells and the bone was crumbling. "I had tumors everywhere," she recalls. "My condition was so serious that my husband contacted our son asking him to come home because he may not have another chance." But drugs saved Barbara's life. "Something incredible happened, I started getting better. I wouldn't believe this story if somebody told me, except that I lived through it," she says.

Barbara's first brush with cancer came as a young woman. At 36, she had a breast tumor removed and for more than a decade she was healthy, until new problems erupted. "It started with an ache, and from one moment to the next I could not pick up my arm, it just hung there," says Barbara. Within two days, she could no longer eat, walk or even sit up in bed. The cancer had spread to her bones and the pain was excruciating. "I only had a wafer-thin strip of bone left in my arm, my legs were also a mess and a tumor on my skull grew so fast you could actually watch it getting bigger." Barbara had emergency surgery to place rods in both her legs. Another grueling operation was planned to strengthen her spine with "chicken wire" because doctors feared it would buckle under the weight of her head.

Fortunately, Barbara never had to face such an ordeal. The drugs alone did the trick. In a double-pronged strategy, Barbara took *Aredia* (pamidronate sodium), a Novartis drug, to prevent her bones from breaking, and tamoxifen (from another company) to stop the cancer cells from growing. Within three months Barbara's recovery was spectacular. "To everyone's amazement, the bone grew back. The doctor had tears in his eyes. He admitted he had never seen anything like it before," she says. Today, she is back at work, walks three miles a day, enjoys hiking on weekends with her husband and tackles comfortably two flights of steps at home. "I'm doing much better than they ever imagined I would," she exults. "My life expectancy at the time was six months, and here I am, five years later."

Yet nobody can predict how long Barbara's health will hold out. To improve her chances of a sustained recovery, she recently changed her bone medication to Novartis' newly released *Zometa*. The prospects are good. *Zometa* belongs to a family of drugs, the biphosphonates, that have long been used to prevent bone complications in cancer patients. But *Zometa* (zoledronic acid) is much more potent than any compound that has gone before. By developing a different molecule, Novartis' team of chemists produced a medication that offers a 6% lower risk of developing bone complications in some cancers than *Aredia*.

Even in healthy people, bone is constantly breaking down and being rebuilt. *Zometa* interferes with this natural cycle by stopping osteoclasts, the cells engaged in demolishing bone, allowing bone density to increase. Bone complications in cancer patients are very common. In fact, bone metastases occur in 65 to 75% of all advanced breast and prostate cancer patients and in up to 40% of all lung cancer patients. Since each year, worldwide, 1.2 million women are diagnosed with breast cancer alone, this new treatment has the potential to help millions of cancer patients suffering from debilitating and painful bone complications.

Patients' Perspectives: Gerd Goldhammer

Three years ago, Gerd, a fleet manager from Eisleben, Germany, was shocked to discover that his constant abdominal cramps were caused by a large tumor. "I had never been ill in my entire life," says the 60-year-old man, who found the diagnosis hard to believe. But the tumor was as big as a fist and surgeons removed it, together with 35 cm of intestine. Unfortunately, 18 months later, the tumors returned, this time in the membrane that envelops the abdomen, the peritoneum. His prospects were bleak. Gerd was suffering from a lethal form of gastrointestinal cancer called gastrointestinal stromal

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tumor (GIST) that resists every form of therapy. Further surgery was planned to eradicate the new tumor, and Gerd had no option but to brave it.

Just then his luck changed. One of his doctors heard of *Gleevec/Glivec* (imatinib mesylate), a new cancer treatment by Novartis which was achieving some spectacular successes. The drug was being tested in a clinical trial in Berlin, and without hesitation Gerd packed his bags and drove 300 km to the hospital. Once there, instead of surgery, he was asked to take four capsules of *Gleevec/Glivec* a day. To his delight the tumor began to shrink, and he now hopes that his next scan will show it has become even smaller.

Gerd's recovery is nothing short of miraculous. Today he works full-time, feels fit, and the pains that once plagued him never returned. "I am so happy about the tablets that helped me avoid further surgery. Now my wife, daughter and I, are a happy family again," he enthuses.

And Gerd is not alone. *Gleevec/Glivec* has brought thousands of people back from the brink of death. "*Gleevec/Glivec* is a groundbreaking drug," enthuses Peter Reichardt, MD, the oncologist at the Virchow Clinics, Berlin, who conducted the trial and witnessed Gerd's response. "GIST patients went from having nothing to having an extremely active treatment. We see tumors melt away in only two or three months." In 70% of GIST patients the tumors shrivel, eventually to nothing. And although GIST is considered a rare form of cancer, with approximately 12 000 new cases worldwide each year, the impact is enormous. "Before, when we had a sarcoma patient, we always hoped it would not be GIST," Peter Reichardt, MD, admits. "Now we carefully re-examine the histology just to check whether it might be GIST because we can now offer an extremely active treatment. Things have changed a lot."

Novartis' breakthrough drug is at the cutting-edge of cancer treatment. *Gleevec/Glivec* is one of the first drugs to inhibit the growth of malignant cells while having a limited effect on healthy tissue, usually without the distressing hair loss, sickness and weakened immune system that accompany conventional cancer therapies.

Gleevec/Glivec was originally developed to treat a rare type of blood cancer called chronic myeloid leukemia (CML). Although the treatment was designed to be specific for CML, researchers soon realized that *Gleevec/Glivec* could also target tumor cells in GIST patients, and they are studying it as a potential treatment for other forms of cancer. In all, hundreds of thousands of lives could be transformed by this revolutionary drug.

Patients' Perspectives: Laura Brizar

Laura was only a baby when she joined the clinical trial for *Elidel* (pimecrolimus). "I could see how much she was suffering. She looked exhausted, she barely slept," recalls Diamant Thaci, MD. The seven-month-old child from a small town in central Germany was ill, not with a life-threatening disease, but with eczema. Yet her young life was in shambles. "The skin on her face, neck and behind her knees was red, dry and itchy. Despite putting gloves on her little hands, Laura could not stop scratching so her skin was broken and weepy. It looked awful. On the street, strangers would ask me what was wrong with her." Laura's mother rejected reverting to corticosteroids, the only previously effective treatment, because they can cause skin thinning, especially of the face, with prolonged use. None of the other treatments helped and Laura's mother was in despair.

Their visit to Dr. Thaci changed all that. The senior dermatologist at the Dermatological University Clinic in Frankfurt am Main, Germany, enrolled Laura in a clinical trial for the Novartis drug *Elidel*. "We used this wonder cream," says Laura's mother, "and after two weeks her condition had noticeably improved. After a month her skin had made a remarkable recovery. By her first birthday you could hardly see any marks at all." Dr. Thaci who has followed Laura's progress, is equally elated. "We were the last resort for the mother and the child. Every time the child came through the door, I was curious: had the situation improved? It was a joy to witness what happened," he says.

Elidel is derived from a natural substance produced by a fungus, *Streptomyces hygroscopicus*. It was discovered by scientists at the Novartis Research Institute in Vienna who were looking for a medicine that would prevent T-cells from churning out chemicals known as cytokines that trigger skin inflammation. *Elidel* reduces the severity of eczema by an average of 64% compared to a 12% reduction in patients using a control cream. More than 4 000 patients have now been treated with

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Elidel in clinical trials and the most frequently observed side effect is a mild feeling of warmth when the cream is applied. As eczema typically begins in childhood and commonly occurs on the face, no doubt physicians will welcome a non-steroid cream that can be used on any skin.

Making a Real Difference

New medicines such as *Gleevec/Glivec*, *Elidel* and *Zometa*, are making a real difference in the lives of millions of families living with disease. These outstanding medicines have provided the impetus for Novartis to make a huge and exciting investment into research and development. In 2003, a new institute for research, based in Cambridge, Massachusetts, will open under the name of the Novartis Institutes for Biomedical Research, Inc. (NIBRI). The aim is to strengthen Novartis' position as a leader in pharmaceutical innovation.

Researchers in laboratories across Europe, the US and Japan will be looking towards Cambridge to follow the leadership of top scientist Professor Mark Fishman who will be heading the global research effort of Novartis, at the new Cambridge site.

Professor Fishman is a physician, a Harvard medical school professor, and was chief of cardiology at Massachusetts General Hospital. He was responsible for transforming research in his field by introducing the zebra fish as a model organism for understanding new genes and pathways in cardiovascular disease. He has every intention of applying the same up-beat, revolutionary strategies to drug discovery (see interview, page 10).

"Our establishment, NIBRI in Cambridge, in the midst of one of the world's most impressive pools of scientific talent, outstanding academic institutions, and large patient populations, will help us to attract the best researchers," says Daniel Vasella, MD, Chairman and CEO of Novartis AG. The new research facility will open in March 2003 with an initial 28 000 m² of lab space which will accommodate 400 scientists. In April 2004, Novartis will take over an additional 56 000 m² of laboratories in a renovated building which abuts the MIT campus. When the institute is fully staffed, it is expected that almost 1 000 Novartis scientists will be working in Cambridge, complementing the 1 500 scientists who are now located in Basel. With an initial investment of USD 250 million, the focus will be on the discovery of new drugs for oncology, diabetes, cardiovascular and infectious diseases, as well as for fundamental molecular and genetic studies that bring about a quantum leap in the pace and predictability of drug discovery.

To Professor Fishman, a key to success is to forge close partnerships between the institute, academia and the biotech community. For this, Cambridge provides the perfect environment. "The institute had to be strategically situated in an area where the best academic institutions and hospitals with large patient networks are located," he says.

Inspired by Success

While NIBRI gears up to open its doors, Barbara plans to attend her son's wedding and PhD graduation in a year's time, and Gerd's life is back to normal. Laura's mother is grateful that her toddler can finally sleep comfortably.

For a pharmaceutical company, it is being able to have an impact on people's lives through its discoveries that provides the impetus to produce more and better medicines. "One of the most motivating things that happens to us as scientists is to hear people's amazing stories," enthuses Alex Matter, MD, Global Head of Translational Research at Novartis. "People whose lives have improved are our best advocates."

Interview with Prof. Mark Fishman, MD

Is drug discovery in need of a radical shake up?

There remain many illnesses without effective therapy. As we unravel the genome and learn how to put function to the genes, we will generate a foundation for mechanistic explanation of disease and acquire many new potential targets for medicines. To give you an idea of how early we are in the process, all medicines from all companies today hit only about 120 targets. Since there are in the order of 30 000 genes and 200 000 proteins, many of which could be involved in illness, clearly we are missing great opportunities for discovery. The trick will be to decipher which genes are critical. This will be a long-term project, in part because different patients with the same illness may actually have different underlying causes because of genetic predisposition. In the future, medicines may well be directed by the patient's genetic make-up and more attuned to patient-specific mechanisms of disease. For this reason Novartis has elected to ensure that we engage in activities at the frontier, in order to be prepared for this sea-change.

Will the newly sequenced human genome feature heavily in the new institute's agenda?

Currently the genome is pretty much a list of genes by sequence. To increase the pace and predictability of discovery of new drugs we need to unravel the function of these genes. Of course, this is a mammoth task, with implications for all of science and medicine, and we cannot, and should not, go it alone. To do so, we need to form ventures and partnerships with our colleagues in academia and in biotech.

Will the marriage of pharma and academia pan out, or is it just pie in the sky?

The two already are engaged. Over the last years it has become clear that many academics would dearly like to make medicines, in some cases as a vindication for their fundamental work. The support from academia for the opening of NIBRI in Cambridge has been uniformly positive and strong precisely because many desire such involvement. There are real issues, of course, around intellectual property, for example, but in many cases we can break through these barriers by common sense and asking where lies the real value. It will benefit no one if the walls get higher and barriers more impregnable, least of all our patients who have the right to full benefit of the fundamental discoveries now coming forth at an ever-increasing pace.

What is your biggest challenge?

To assemble a system that delivers medicines continuously, keeping an eye on the horizon for the sweeping changes while, in a practical way, using each day's knowledge to generate drugs. Science is a moving target, and no assumptions today can be confidently predicted to hold in 5 years – except that most of today's predictions will be wrong.

Are some traditional research methods flawed?

One major assumption that clearly needs to be challenged is that two patients with apparently the same disease, by today's definition – be it diabetes, heart failure, or leukemia – have the same cause for that disease, and therefore will benefit equally from the same drugs. We therefore will need better to attune drugs to individuals, in order to increase efficacy and decrease toxicity. In addition, we can utilize new model organisms in the discovery process. Much is shared, in terms of essential molecular pathways, the biological building blocks. For example, one pathway essential to making the fruitfly wing, when perturbed in humans, causes cancer. On the flip side, we need to recognize that in many ways man is different, and so need to examine how to change these model systems to make them better predictors of the human response to drugs.

What does the new Novartis Institutes for Biomedical Research Inc. (NIBRI) offer ordinary citizens?

The mission is to discover medicines at an increasing pace and with even greater specificity, to better treat those now suffering disease, and to improve the process so effectively over the coming years that our children look back with disbelief, surprised that such diseases ever were

untreatable.

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Pharmaceuticals

The Novartis Pharmaceuticals Division is a world leader in the discovery, development, manufacture and marketing of prescription medicines. Our goal is to provide a broad portfolio of innovative, effective and safe products and services to patients through healthcare professionals around the world. This goal is supported by a dedicated organization operating in more than 140 countries through approximately 80 affiliates.

	2002 CHF millions	2001 CHF millions	Change in CHF %
Sales	21 002	20 181	4
Operating income	6 022	5 677	6
Research and development	3 580	3 447	4
Research and development as % of sales	17	17	
Free cash flow(1)	6 919	6 663	4
Net operating assets	11 287	13 144	-14
Investments in tangible fixed assets	785	617	27

(1) Before acquisition of product and marketing rights

	2002	2001	% change
Number of employees	44 110	41 256	7

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Top ten products	2002 sales in CHF millions	Change in local currencies %
<i>Diovan/Co-Diovan</i>	2 580	49
<i>Neoral/Sandimmun</i>	1 607	-5
<i>Lamisil (group)</i>	1 355	4
<i>Lotrel</i>	1 011	35
<i>Gleevec/Glivec</i>	953	303
<i>Sandostatin (group)</i>	943	23
<i>Voltaren (group)</i>	925	-3
<i>Lescol</i>	896	18
<i>Zometa</i>	758	NA
<i>Cibacen/Lotensin/Cibadrex</i>	714	9

NA Not applicable as insignificant prior year sales

Key Marketed Products

Therapeutic area	Compound	Generic name	Indication	Formulation
Cardiovascular, metabolism and endocrinology	<i>Cibacen/Lotensin</i> <i>Co-Diovan(1)</i>	benazepril valsartan + HCT	Hypertension, heart failure Hypertension, congestive heart failure	Coated tablet Film-coated tablet
	<i>Diovan</i>	valsartan	Hypertension, heart failure	Capsule
	<i>Lescol</i>	fluvastatin	Cholesterol-lowering agent	Capsule
	<i>Lotrel</i>	benazepril & amlodipine	Hypertension	Capsule
	<i>Starlix</i>	nateglinide	Type-2 diabetes	Tablet
	<i>Zelnorm/Zelmac</i>	tegaserod/tegaserod maleate	Symptomatic treatment of irritable bowel syndrome	Tablet
Oncology and hematology	<i>Aredia</i>	pamidronate	Bone complications associated with cancer	Intravenous infusion
	<i>Femara</i>	letrozole	Advanced breast cancer	Coated tablet
	<i>Gleevec/Glivec</i> <i>Sandostatin LAR</i>	imatinib mesylate octreotide	Chronic myeloid leukemia Acromegaly, carcinoid syndrome	Tablet Ampoule i.m.
	<i>Zometa</i>	zoledronic acid	Hypercalcemia of malignancy	Infusion
Central nervous system	<i>Comtan</i>	entacapone	Parkinson's disease	Film-coated tablet
	<i>Exelon</i>	rivastigmine	Alzheimer's disease	Capsule
	<i>Leponex/Clozaril</i>	clozapine	Antipsychotic agent for treatment-resistant schizophrenia(4)	Tablet, ampoule i.m.
	<i>Tegretol</i>	carbamazepine	Epilepsy, acute and bipolar affective disorders	Tablet, chewable tablets, syrup, suppository
	<i>Trileptal</i>	oxcarbazepine	Epilepsy, seizures	Tablet, oral suspension
Transplantation	<i>Neoral/Sandimmun</i>	cyclosporine	Prophylaxis of organ rejection following kidney, liver and heart allogenic organ	Soft gelatin capsule, oral solution, intravenous infusion

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Therapeutic area	Compound	Generic name	Indication	Formulation
	<i>Simulect</i>	basiliximab	transplantation(2) Prophylaxis of acute organ rejection in de novo renal transplantation	Intravenous infusion or injection
Dermatology	<i>Elidel</i>	pimecrolimus cream	Atopic dermatitis	1% cream
	<i>Famvir</i>	famciclovir	Acute herpes zoster	Tablet
	<i>Lamisil</i>	terbinafine	Fungal infections	Tablet, cream, DermGel solution, spray
Respiratory	<i>Foradil</i>	formoterol	Asthma, COPD	Inhalation capsule (aerosol)
Rheuma, bone and hormone replacement therapy	<i>Estalis(3)</i>	estradiol norethisterone	Estrogen deficiency due to menopause and preventing osteoporosis	Patch
	<i>Estraderm TTS/MX</i>	estradiol	Estrogen deficiency due to menopause	Patch
	<i>Miacalcic</i>	salmon calcitonin	Osteoporosis, regulator of mineral homeostasis and skeletal metabolism, Paget's disease of bone, neurodystrophic disorders	Nasal spray, ampoules
	<i>Voltaren</i>	diclofenac	Inflammatory forms of rheumatism, pain management	Enteric coated tablet, drop, ampoule, suppositories, gel
Ophthalmics	<i>Rescula</i>	unoprostone	Glaucoma	Eye drop
	<i>Visudyne</i>	verteporfin	Wet form of age-related macular degeneration	Intravenous infusion

- (1) *Co-Diovan/Diovan HCT* in the USA
- (2) In the US, *Neoral* approved for severe psoriasis and rheumatoid arthritis
- (3) *Vivelle, Vivelledot*
- (4) Also approved for suicide prevention in the US

Compounds in development

The Novartis pipeline holds a broad stream of promising future products, with 52 projects in Phase II and beyond as of December 2002, including both new molecular entities and additional indications or formulations for marketed products.

Compound

Molecular chemical entity.

Generic name

Designation assigned to compound.

Indication

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A disease or condition for which a particular drug is believed to be an appropriate therapy.

Phase II

Clinical trials in patients to determine dose ranging, safety and efficacy.

Phase III

Large clinical trials to determine definitive safety and efficacy in patients.

Filed

In registration.

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Therapeutic area	Project/compound	Generic name	Indication
Cardiovascular and metabolism	SPP100	aliskiren	Hypertension
	LAF237		Type-II diabetes
	<i>Diovan</i>	valsartan	Congestive heart failure
		valsartan	Post- and pre-myocardial infarction
	<i>Navigator*</i>		Progression to type-II diabetes
	<i>Sandostatin LAR</i>	octreotide acetate	Diabetic retinopathy, other indications
	<i>Lotrel 10-20</i>		Hypertension
	<i>Lotrel 10-40</i>		Hypertension
	NKS104	pitavastatin	Dyslipidemia
<i>Lescol (LIPS)</i>	fluvastatin sodium	Secondary prevention of cardiac events	
Oncology	<i>Femara</i>	letrozole	Breast cancer (adjuvant therapy)
	ICL670		Chronic iron overload
	<i>Gleevec/Glivec</i>	imatinib mesylate	Solid tumors
	<i>OctreoTher</i>	edotreotide	Somatostatin receptor positive tumors
	EPO906		Solid tumors
	PTK787	vatalanib	Solid tumors
	PKC412	midostaurin	Acute myeloid leukemia
SOM230		Acromegaly, GEP neuroendocrine tumors	
Central nervous system	<i>Ritalin LA</i>	methylphenidate	Attention deficit disorders
	<i>Clozaril</i>	clozapine	Suicide prevention
	(InterSePT)		
	ELC200	entacapone/levodopa/carbidopa	Parkinson's disease
	ILO522	iloperidone	Schizophrenia
	<i>Exelon</i>	rivastigmine	Non-Alzheimer's dementia
	<i>Exelon TDS</i>	rivastigmine	Alzheimer's disease
	<i>Trileptal</i>	oxcarbazepine	Neuropathic pain
TCH346		Parkinson's disease, ALS(1)	
AMP397		Epilepsy	
Transplantation, immunology	FTY720		Transplantation
	<i>Certican</i>	everolimus	Transplantation
	<i>Myfortic (ERL080)</i>	mycophenolate sodium	Transplantation

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Therapeutic area	Project/compound	Generic name	Indication
Dermatology	<i>Elidel (ASM981)</i>	pimecrolimus	Inflammatory skin diseases
		pimecrolimus	Inflammatory skin diseases
	<i>Lamisil</i>	terbinafine	Tinea capitis
Respiratory	<i>Foradil</i>	formoterol	Multi dose dry powder inhaler for asthma
	QAB149		Asthma/COPD(2)
	<i>Xolair</i>	omalizumab	Asthma/prevention of SAR(3)
	<i>Elidel (ASM981)</i>	pimecrolimus	Asthma
Arthritis, bone, anti-infectives, and gastrointestinal diseases	<i>Prexige</i>	lumiracoxib	Rheumatoid arthritis, osteoarthritis, pain
	<i>Zelnorm/Zelmac</i>	tegaserod	Irritable bowel syndrome
		tegaserod	Functional dyspepsia
		tegaserod	Gastroesophagal reflux disease
		tegaserod	Chronic constipation
	ZOL446	zoledronate	Post-menopausal osteoporosis
		zoledronate	Paget's disease
		zoledronate	Rheumatoid arthritis
	RAD001	everolimus	Rheumatoid arthritis
	AAE581		Osteoporosis
SMC021	calcitonin	Osteoporosis	
Ophthalmics	<i>Visudyne</i>	verteporfin	AMD(4) (occult)
		verteporfin	AMD(4) (classic)
		verteporfin	AMD(4) (minimally classic)
	<i>Rescula</i>	unoprostone isopropyl	Glaucoma

*

Navigator trial examining combination therapy of *Starlix* and *Diovan*.

- (1) Amyotrophic lateral sclerosis
- (2) Chronic obstructive pulmonary disease
- (3) Seasonal allergic rhinitis
- (4) Age-related macular degeneration

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Mechanism of action	Formulation	Filing dates	Phase I	Phase II	Phase III	Filed
Renin inhibitor	Oral	2005	██████████			
Dipeptidylpeptidase (DPP-IV) inhibitor	Oral	2005	██████████			
Angiotensin-II receptor blocker	Oral	Filed (UK, France)	██████████			
Angiotensin-II receptor blocker	Oral	2004	██████████			
	Oral	>2005	██████████			
Growth hormone + IGF-1 inhibitor	Intramuscular	2004	██████████			
	Oral	Filed (US)	██████████			
	Oral	Filed (US)	██████████			
HMG CoA reductase inhibitor	Oral	2005 (EU)	██████████			
HMG CoA reductase inhibitor	Oral	Filed	██████████			

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Mechanism of action	Formulation	Filing dates	Phase I	Phase II	Phase III	Filed
Non-steroidal aromatase inhibitor	Oral	2005	██████████			
Iron chelator	Oral	2004	██████████			
Tyrosine kinase inhibitor	Oral	tbd	██████████			
Radiation therapy	Intravenous	2004	██████████			
Microtubule depolymerization inhibitor	Intravenous	2004	██████████			
Tyrosine kinase inhibitor	Oral	2005	██████████			
Protein kinase inhibition	Oral	>2005	██████████			
Binds to somatostatin (sst)1/2/3/5 and inhibitor of hormones	Intravenous	>2005	██████████			
Dopamine transport blocker	Oral	Filed (EU)	██████████			
Dopamine receptor blocker	Oral	Filed (EU)	██████████			
Catechol-O-methyltransferase (COMT) inhibition	Oral	Filed	██████████			
Mixed 5HT2A/D2 antagonist	Oral	tbd	██████████			
Cholinesterase inhibitor	Oral	>2005	██████████			
Cholinesterase inhibitor	Transdermal	>2005	██████████			
Voltage dependant sodium currents blocker	Oral	2004	██████████			
Neuronal GAPDH dependent programmed cell death inhibition	Oral	2005	██████████			
AMPA receptor antagonist	Oral	>2005	██████████			
Immunosuppression	Oral	2005	██████████			
Growth-factor-induced cell proliferation inhibition	Oral	Filed	██████████			
Inhibition of inosine monophosphate dehydrogenase enzyme	Oral	Filed (EU)	██████████			
T-cell and mast cell inhibitor	Oral	2005	██████████			
T-cell and mast cell inhibitor	Ointment	2004	██████████			
Fungal squalene epoxidase inhibitor	Oral	2004	██████████			
Long-acting beta-2 agonist	Dry powder for inhalation	Filed	██████████			
Long-acting beta-2 agonist	Inhalation	>2005	██████████			
Anti-IgE monoclonal antibody	Subcutaneous	Filed (US)	██████████			
T-cell and mast cell inhibitor	Oral	>2005	██████████			
Cyclo-oxygenase-2 inhibitor						