



NOVARTIS INDIA LIMITED
annual report 2007-2008

 **NOVARTIS**
caring and curing.

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Board of Directors

Dr E. Schillinger Chairman
[up to 23rd October 2007]

Dr P. Jager Chairman
[w.e.f. 23rd October 2007]

R. Shahani Vice-Chairman &
Managing Director

A. Mirchandani Executive Finance
Director

Dr J. Acebillo

J. Hiremath

Dr R. Mehrotra

Company Secretary,
Head Investor Relations &
General Counsel

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Executive Committee

R. Shahani Vice-Chairman &
Managing Director

K. N. Chandrasekaran Generics

A. Matai Pharmaceuticals

A. Mirchandani Finance

Dr P. R. Rao Animal Health

V. Singhal OTC

Members are requested to bring their copy of the Annual Report to the meeting. Members are also requested to direct all correspondence relating to shares to the Company's Registrar and Transfer Agents, Sharepro Services, at the address above.

Annual General Meeting

11:00 am 16th July 2008

Y.B. Chavan Auditorium
Yashwantrao Chavan Pratishthan
Gen. Jagannath Bhosale Marg
Next to Sachivalaya Gymkhana
Mumbai 400 021



Dear Shareholder

It is indeed ironic that most public health activists tend to portray protection of intellectual property through patents and access to medicines particularly for the poorest sections of the society as two diametrically opposite issues. Their central belief is that patents raise the cost of medication, hindering patient access to medicine.

At Novartis we believe that protection of intellectual property is the fundamental premise that determines patient access to medicine. Patent protection alone offers innovative pharmaceutical companies impetus to invest in research and develop newer, more effective therapies for unmet medical needs.

With effective patent laws, companies continue to bring improvements and innovations to patients and societies. For a research-based company such as Novartis, patents are non-negotiable. On the other hand, we do not challenge provisions that provide for access under international trade agreements, specifically the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Doha Declaration. Novartis has always supported, and continues to support, TRIPS conditions that promote access for developing countries.

Markets like India continue to present Novartis with a globalization dilemma that characterizes many emerging economic powers today: two markets within one country. India has a booming middle class on one hand and a vast number of extremely poor people on the other. We are aware of the many obstacles that poor patients face regarding access to medical care.

In this annual report we highlight the work being done by Novartis worldwide in both these critical areas – developing drugs for neglected diseases and improving access. We look at some length at the work being done by the Novartis Institute of Tropical Diseases, one of the few instances of institutionalised R&D investments by big pharma in tackling diseases of the developing world. We give an overview of the Novartis Vaccines Institute for Global Health – a unique not-for-profit initiative aimed at closing the "10/90 Gap", where less than ten per cent of research funds are allocated to diseases that affect 90 per cent of humanity.

We also focus on the landmark work being done by Novartis in combating three scourges of humanity – Leprosy, Malaria and Tuberculosis. It is estimated that Novartis drug donation programmes related to these three diseases alone have benefited over five million patients worldwide.

I believe that this work was possible only because Novartis was able to protect its intellectual property. If these five million patients are alive today and enjoy a better quality of life it was because patents ensured that they had access to life-saving drugs.

Of course, initiatives of the kind being followed by Novartis can only contribute towards solving the problems of poverty and related health issues. A range of underlying and related issues with respect to health infrastructure, inequitable or otherwise, are inefficient health systems, underfunding on health care and poverty, to name a few. Tiered pricing, donation programmes and corporate social responsibility activities can alleviate the problem to some extent, but they are not sustainable solutions.

Providing complete access is fraught with challenges. Novartis continues to play a critical role in improving access through its various initiatives. But the key role will have to be played by governments, if necessary, aided by multi-lateral agencies, and ideally in partnership with the private sector. And in doing this, what needs to be understood is that protecting intellectual property and access to medicines are two sides of the same coin. One cannot be achieved without the other.

In India, as elsewhere, Novartis is committed to provide better access to medicines through our corporate social responsibility initiatives. We recently received recognition from the highly regarded *Reader's Digest* for the work done by the Novartis Comprehensive Leprosy Care Association. External recognition serves as great encouragement to work harder and aim higher – and this is a commitment we would like to renew as we move into another exciting and challenging year.

To you, our shareholders, many thanks for the trust you continue to repose in Novartis.

Ranjit Shahani

The burden of disease as a result of poverty remains a key developmental challenge...



POVERTY AND ACCESS TO MEDICINES

The biggest healthcare crisis in the world today has nothing to do with any particular kind of virus or its geographical spread. The biggest healthcare crisis is economic in its origin.

Out of a global population of 6.5 billion, close to three billion people in developing countries live on less than two US dollars a day. More than a billion subsist on less than one US dollar a day. As a consequence, more than three quarters of a billion people receive inadequate nourishment and each

poverty – diarrhoea, pneumonia and other lower respiratory tract conditions and malaria. HIV/AIDS is now the world's leading cause of death in adults aged 15-59 and is killing almost 5,000 men and women of this age, and almost 1,000 children, every 24 hours in sub-Saharan Africa.

With the global population expected to hit the 9.2 billion mark by 2050, the number living below the poverty line is only expected to increase and the consequent health crisis will only exacerbate.

Poverty and the health crisis that it spawns represent a vicious cycle for human kind. Poor people affected by a variety of diseases are incapable of contributing fully to societies and economies. Their diseases are a huge drain on productivity as these people, while incapable of contributing their full share, also require chronic care. The costs of this care and at times the stigma associated with the diseases can wreak havoc with families, compounding the misery.

But this dark cloud does have a silver lining. It is not as if poverty-related health issues are insurmountable. Today there exist enough financial, technological and managerial resources to tackle these problems. What is needed is for all stakeholders, including governments, multi-lateral agencies, philanthropic organisations and the pharmaceutical industry to work together.

Over half a million women – about 1,400 per day – die during pregnancy or childbirth each year from lack of medical facilities and malnourishment

year about 10 million children die from malnutrition – about 28,000 a day. Over half a million women – about 1,400 per day – die during pregnancy or childbirth each year from lack of medical facilities and malnourishment.

The health disparities between the developed and developing societies are stark. A baby girl born in an industrialised nation can expect to live for about 80-85 years, while a baby girl born at the same moment in some of the developing countries has a life expectancy of only about 35 years. In several parts of the world, the disparities have only increased in the last two decades. In Africa, for instance, over 35 per cent of children are at a higher risk of death than they were a couple of decades ago. Every hour, more than 500 African mothers lose a small child. Those who do make it past childhood are confronted with adult death rates that exceed those of 30 years ago.

The main causes of death among children are peri-natal conditions closely associated with

R&D FOR THE DEVELOPING WORLD

As one of the world's leading pharmaceutical companies, Novartis has always played a critical role in discovering, developing, producing, and marketing innovative products to prevent and cure diseases, to ease suffering, and to enhance the quality of life. While doing so it has endeavoured to strike a balance between protecting its intellectual property through patents while at the same time increasing access to medicines.

As the world leader in innovation the company invests more than 15% of its net sales every year in research and development of new therapies. A significant proportion of it is invested in tackling diseases of the developing world. Two of its significant initiatives are:

NOVARTIS INSTITUTE FOR TROPICAL DISEASES (NITD)

Novartis established the Novartis Institute for Tropical Diseases, Singapore, in 2002. Novartis' investment in the field of tropical disease research is an exception in an industry that has

Poverty and the health crisis that ensues represent a vicious cycle for humankind



traditionally neglected illnesses that are seen as endemic within the developing world. The NITD aims to discover novel treatments and prevention methods of major tropical diseases. In those countries where such diseases are prevalent, the Novartis Group intends to make treatments readily available at no profit. The NITD's long-term aim is to help reduce the global disease burden of tropical diseases and improve the prosperity and health of the populations of all developing countries.

NITD is broadly focusing on three of the deadliest tropical diseases – Tuberculosis, Dengue and Malaria.

○ **Tuberculosis:** It was estimated by the World Health Organisation that about two billion people – one in every three humans – are infected by *Mycobacterium tuberculosis*, the bacteria causing tuberculosis. According to WHO estimates, eight million people become infected and two million people die every year from TB.

○ **Dengue:** Dengue and Dengue Haemorrhagic Fever (DHF) are caused by four closely related viral strains. The virus is transmitted to humans through the bites of infected mosquitoes (*Aedes aegypti* and *Aedes albopictus*). The global prevalence of Dengue has risen dramatically, and

the disease is now endemic in more than 100 countries in Africa, the Americas, the Eastern Mediterranean, and the most serious outbreaks are found in Southeast Asia and the Western Pacific region. WHO estimates that 50 million cases occur each year, requiring 500,000 hospitalizations.

○ **Malaria:** Caused mainly by two protozoan parasites, *Plasmodium falciparum* and *Plasmodium vivax*, the mortality due to malaria, has risen over the last few decades. It is estimated that about 1-3 million people die every year from malaria – mostly children under the age of five. This increase in malaria mortality is due in part to the fact that *Plasmodium falciparum*, the deadliest malaria parasite, has acquired resistance against nearly all available anti-malarial drugs – the only exception being the artemisinin derivatives. Artemisinin-containing combination therapies (ACT) such as Novartis' Coartem® are the only effective treatments against drug-resistant malaria.

NOVARTIS VACCINES INSTITUTE FOR GLOBAL HEALTH (NVGH)

In 2007, Novartis launched the Novartis Vaccines Institute for Global Health, its not-for-profit mission to develop effective and affordable vaccines for neglected infectious diseases of developing countries.



NVGH, located in Siena, Italy, aims to build on the research and development expertise and assets within Novartis. Its goal is to help address the vast unmet medical need that exists for vaccines to prevent some of the developing world's most prevalent diseases.

The NVGH initiative is in recognition of the fact that vaccines have saved billions of lives in the past century and are still the most cost-effective way of controlling the spread of infectious diseases. Without a comprehensive approach to address the gaps in funding, research and global immunisation

Vaccines have saved billions of lives and are still the most cost-effective mode of controlling the spread of infectious diseases

coverage, developing countries will continue to be plagued by some of the most devastating diseases, face the reintroduction of old diseases and the emergence of new infections.

NVGH aims to address two well-known issues afflicting investments in health research. The first, known as the "10/90 Gap", was identified by the Commission on Health Research for Development. The Commission pointed out that less than 10% of the investment in health research was devoted to diseases that affect 90% of the world.

The second issue is known as the "translational gap". This stems from the fact that Academia has traditionally focused on basic research and subsequent technical product development of a vaccine product has been conducted by vaccine manufacturers. For diseases that afflict underdeveloped countries, the potential for reasonable commercial returns is usually risky and therefore few companies are willing to invest in these vaccine projects. This unfortunately leads to a

situation where promising leads or antigens may remain in the laboratory, without being realised into potential vaccines. This is known as the "translational gap", which NVGH aims to bridge.

As its first project, NVGH has decided to try and develop a broad-range enteric vaccine for Salmonella infections, responsible for over 4.5 billion cases of diarrhoea per year. In areas where water and sanitation are compromised, dehydration caused by diarrhoea can be particularly devastating. Of the estimated 1.8 million deaths due to diarrhoeal diseases, a vast majority occur in developing countries.

COMBATING THREE OF THE DEVELOPING WORLD'S SCOURGES

Apart from investing in R&D to tackle diseases affecting the poorest sections of the world's population, Novartis has also been in the forefront of combating several diseases in a more hands-on manner. Here is a look at three such initiatives.

LEPROSY

An ancient scourge, leprosy has, at some stage, afflicted every country in the world. Before the development of an effective cure, society dealt with the disease by isolating sufferers. In virtually every society, people suffering from leprosy were cast out of their families and communities to be isolated in leprosaria or segregated villages for fear of their spreading the disease.

Leprosy was more than just an infectious disease. It was considered a shameful affliction, brought about by wrongdoing in a previous life, through a curse of God or witchcraft – in other words, a punishment of sorts. Sufferers were ashamed of their condition and tried to hide the disease for fear of social repercussions. Yet lack of treatment, or even delayed treatment, merely served to increase the risk of disabilities which, in turn, strengthened and perpetuated the stigma of the disease – a vicious circle.

Leprosy is an infectious disease caused by a bacillus, *Mycobacterium leprae*. *M. leprae* multiplies very slowly, and the incubation period of the disease is about five years. Symptoms can take as long as 20 years to appear. Leprosy is not highly infectious. It is transmitted via droplets from the nose and mouth during close and frequent contact with untreated multi-bacillary cases. Leprosy mainly affects the skin and nerves. If untreated, there may be progressive and permanent damage to the skin, nerves, limbs and eyes.

As the world leader in innovation Novartis Group invests more than 15% of its net sales every year in research and development of new therapies



The first breakthrough in the treatment of leprosy occurred in the 1940s with the use of the drug dapsone, which arrested the disease. Dapsone was synthesized at the University of Freiburg (Germany) in 1908 for treating patients with tuberculosis (TB). It was used for the first time in leprosy treatment only in 1946. Dapsone needed to be taken for many years, possibly for life, making patient compliance an issue. Then, in the 1960s, *M. leprae* started to develop resistance to dapsone, the world's only known anti-leprosy drug at the time. With growing rates of primary and secondary resistance to dapsone, the search for alternative treatment regimens was accelerated.

The two other key drugs in the treatment of leprosy – Lamprene® (clofazimine) and Rimactane® (rifampicin) – were also originally targeted at TB. Developed in the research laboratories of Novartis in the 1960s, Rimactane remains a key drug in the treatment of TB, whereas dapsone and Lamprene proved ineffective for TB. The recommendation by the WHO study group to use Lamprene, Rimactane and dapsone together as a multi-drug therapy for the treatment of leprosy was made in 1981.

In fact, it was an Indian scientist – Shantaram Yawalkar – working for Novartis in Switzerland who thought of the multi-drug therapy aimed at combating leprosy and planned the international, multi-centre, controlled single blind trial that proved the efficacy of the treatment.

MDT revolutionised the prospects for leprosy elimination because, for the first time, it became feasible to move beyond passive acceptance of living with leprosy forever to eliminating the disease as a public health problem. Elimination was defined as reducing the disease burden or prevalence rate to less than one case per 10,000 inhabitants.

The WHO prepared a strategic plan in 2000 to eliminate leprosy by 2010. The same year Novartis, in a landmark decision, decided to provide high-quality MDT, free of charge, to all leprosy patients in the world through the WHO. Additionally, Novartis provides the funds for managing the donation, transport, insurance and independent quality control of MDT. This decision was a practical expression of Novartis corporate values and the belief that special efforts need to be made in tackling the diseases of poverty.

The drugs are manufactured at the Kolshet plant of Sandoz, the generics arm of Novartis. The plant has received Good Manufacturing Practice (GMP)

certification from the European Health Authorities. As a result of this initiative leprosy is a public health success story. The WHO estimates that 4.3 million people have been cured as a result of the Novartis MDT donation. Disease prevalence has dropped by 90%. The availability, free of charge, of a global supply of high-quality MDT has helped to bring leprosy services closer to affected communities, through general health services rather than specialized clinics. This is particularly important for poor communities, most at risk of leprosy, who cannot afford to travel far for treatment.

Leprosy is a leading cause of permanent physical disability. MDT has dramatically reduced the risk of

Novartis, in a landmark decision, decided to provide high-quality multi-drug therapy (MDT), free of charge, to all leprosy patients in the world through the WHO



Novartis has been in the forefront of combating several diseases including leprosy, malaria and tuberculosis

disability, thereby relieving the social and economic burden of the disease and protecting people from the downward spiral of social exclusion and destitution.

MALARIA

Malaria is a disease which can be transmitted to people of all ages. It is caused by parasites of the species *Plasmodium* that are spread from person to person through the bites of infected mosquitoes. If not treated promptly with effective medicines, malaria can cause severe illness that is often fatal.

There are four types of human malaria – *Plasmodium falciparum*, *P. vivax*, *P. malariae*, and *P. ovale* with *P. falciparum* and *P. vivax* being the most common. *P. falciparum* is by far the most deadly type of malaria infection.

Approximately, 40% of the world's population, mostly those living in the world's poorest countries, is at risk of malaria. Every year, more than 500 million people become severely ill with malaria. A child dies of malaria every thirty