

Novartis India Limited Annual Report 2011-2012

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Board of Directors

C. Snook	Chairman
R. Shahani	Vice Chairman and Managing Director
J. Hiremath	Director
Dr R. Mehrotra	Director

Company Secretary and
Compliance Officer

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Annual General Meeting

11.30 am July 25, 2012

Hall of Culture
Nehru Centre
Worli
Mumbai 400 018

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 Share Transfer Agents, Sharepro Services (India) Private Limited, at the address above.



The Board of Directors (from left): C. Snook, Chairman; J. Hiremath, Director; R. Shahani, Vice Chairman and Managing Director; Dr R. Mehrotra, Director

Dear Shareholder

The uncertainty surrounding the new pharmaceutical policy and the regulatory environment continues to dampen the potential for the pharmaceutical industry at a very crucial juncture when India's health parameters do not compare favourably with other countries of the developing world. Targeting just drug prices and leaving other serious health issues is not the solution to affordable and accessible healthcare.

According to a 2011 report by Confederation of Indian Industry (CII) and Pricewaterhouse Coopers (PwC), the Indian pharma industry is today the third largest market globally in terms of volume and 14th largest by value. PwC states that the domestic pharma market is expected to grow at a CAGR of 15 to 20% annually to be a US \$49 billion to 74 billion market by 2020. In a scenario where the pharmaceutical industry the world over is seeing much volatility and slowing down of growth, Indian companies are being perceived as offering a ray of hope. "India's large domestic market, product development skills and scientific talent are being increasingly sought by pharma MNCs to tackle the challenges of growth and innovation," the report says. It also speaks of the importance of developing strategies for inclusive and sustainable growth.



For Novartis, innovation and inclusiveness have always been priorities. Initiatives like Arogya Parivar, the Glivec International Patient Assistance Program (GIPAP) and now Novartis Oncology Access (NOA) have done much to bring healthcare and hope to thousands of Indians. Since 2002 when we introduced GIPAP, for instance, Novartis has distributed Glivec valued at \$1.7 billion (> ₹9,500 crore) completely free to patients in India alone.

Novartis firmly believes that patents have helped to advance scientific innovation, which in turn has led to new medicines for people suffering from diseases without effective or in many cases, any treatment option. For example, Glivec, a breakthrough drug, has forever changed the way cancer is treated, replacing painful chemotherapy with an easy-to-swallow pill, significantly improving patients' quality of life in the process. It is therefore an irony that while the drug has received patents in 40 countries, it has been denied one in India. We are now before the Supreme Court in appeal. Novartis is seeking clarity on India's patent law to know what is patentable and what is not, and, further, to know whether India will follow a predictable norm for patentability. We believe that working through the judicial system is the appropriate approach to gaining clarity on the unique aspects of India's patent law and have complete confidence in the Indian legal system. Meanwhile, patients who have benefited from Glivec continue to espouse the efficacy of the drug that has made the key difference to their lives.

Imatinib, the first of a new class of drugs that act by specifically inhibiting a certain enzyme, was patented in 1993 in several countries - though not in India since we did not have a product patent law at that time. It was never a drug that was meant to be consumed. Novartis developed the beta crystal form of Imatinib mesylate to make it suitable for patients to be taken in pill form that would deliver consistent, safe and effective levels of the medicine. By no stretch of imagination can Glivec be considered merely as an attempt at 'evergreening', as some critics have tried to insist.

Some people believe that Glivec is unaffordable and its price must be reduced. However, I would like to stress that the cost of this drug is completely irrelevant because more than 95 per cent of those who are prescribed the medicine receive it absolutely free, while the others are on a very generous co-pay program. With forty per cent of India's population living on less than \$2 a day, medicines are unaffordable to them at any price, yet Novartis has endeavoured to ensure that treatment is available to them regardless.

India is home to one of the most vibrant generic industries in the world, but 65 per cent of its population has no access to modern healthcare. What is crucial is for all stakeholders to come together to address this larger goal of healthcare for all. Government needs to play a role here in addressing a host of issues including lack of diagnosis, healthcare infrastructure and distribution. If healthcare is to be easily available, much depends on the 'last mile' - trained healthcare staff and infrastructure, and accessibility of healthcare facilities.

In these difficult times, as the global pharmaceutical industry turns towards India for the next stage of growth, I believe our country can stake its claim to meeting not just our own healthcare needs but also becoming a leader in drug discovery and truly becoming the pharmacy of the world. With the right policies in place and a vibrant ecosystem which encourages innovation, this is certainly possible.

To you, our shareholders, my very sincere thanks for supporting us in all that we do.

With best wishes

Ranjit Shahani

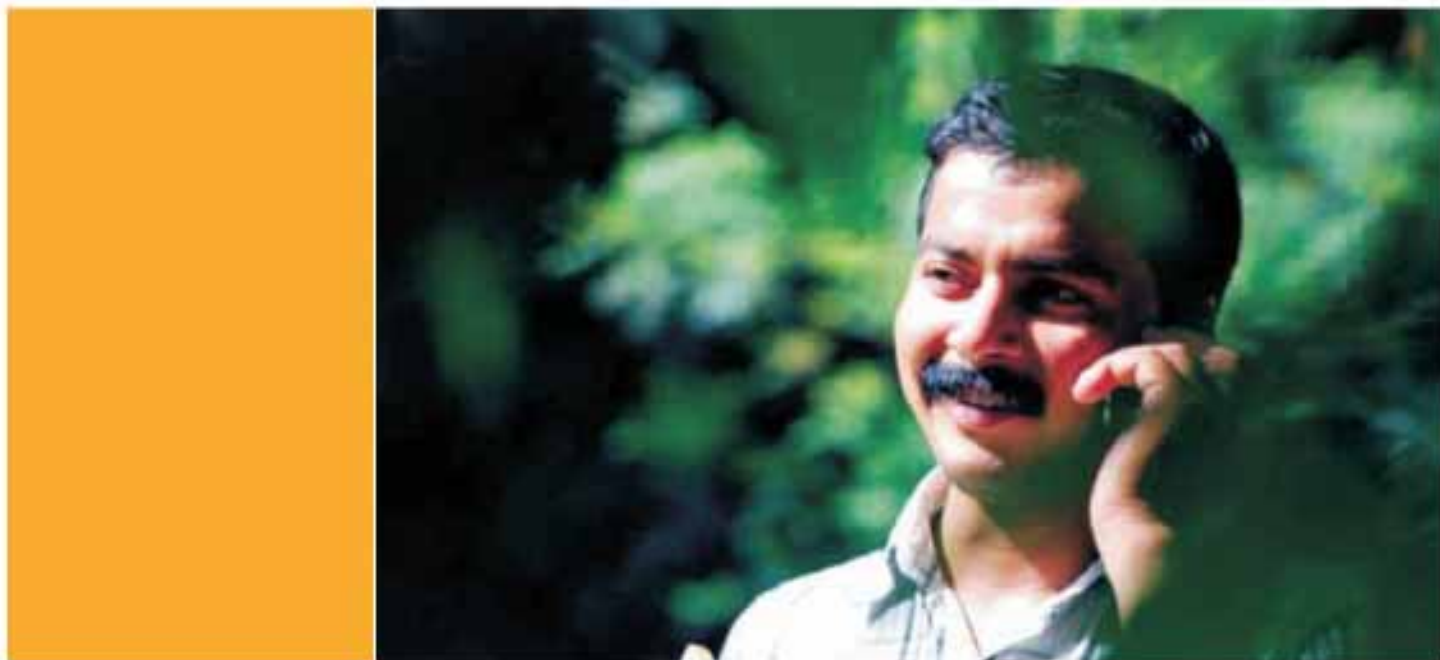
Celebrate Life!

A few steps away from Novartis India's headquarters in Mumbai, in a once non-descript basement of the adjoining building, is an unexpected burst of sunshine. Here, at the home of The Max Foundation, Novartis' partner in a Patient Assistance Program, the walls are alive with pictures of smiling people, and other images of hope, brought to life by cancer patients and their caregivers - a Tree of Life, painted in fresh and delicate shades of green; birds and flowers; rainbows and rivers; the sun peeking out of a mountain. Everywhere the message that comes through is: 'MAXimise Life!' - and there are many who are discovering that this is indeed possible. Several of these artworks celebrate the difference that Glivec has made to these patients' lives - an anti-cancer pill that they receive free of cost, through this unique partnership between Novartis and The Max Foundation, an

organisation that supports cancer patients worldwide.

There was a time when falling critically ill would leave patients with little hope, and cancer was the most dreaded illness of all. It was a death sentence, with a long period of waiting; of life punctuated with painful chemotherapy, with all its unnerving side-effects - falling hair, pain and debilitating fatigue.

In the last fifteen years of Novartis' existence and a history of 150 years of innovation, however, the change has been radical, and remarkable. Healthcare has been transformed dramatically, with new and modern medicines both preventing and curing diseases, while simultaneously improving the quality of life of patients, particularly those with cancer and other devastating illnesses.





Novartis has played an integral role in this transformation, not only by providing access to modern medicines, but also reaching out to these patients through the warmth of personal interaction.

Initiatives like Arogya Parivar have enriched lives in villages across the country, with enhanced access to medicines for over 50 million people across ten states, many of them living in remote rural pockets of India. As a responsible corporate citizen, working towards inspiring hope and restoring dignity, Novartis has also been at the forefront of the fight against other diseases like leprosy, tuberculosis and malaria. In India, thousands of leprosy patients have benefited from reconstructive surgery and rehabilitation programs conducted by Novartis Comprehensive Leprosy Care Association. Treatment of certain forms of cancer are also no longer as traumatic as they used to be, thanks to Novartis' 'magic bullet' - a name given by *Time* magazine - a tiny tablet called

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Glivec® (or Gleevec, as it is known in some parts of the world.) This is distributed free of cost through Novartis Oncology Access (NOA) Glivec previously known as the Glivec International Patient Assistance Program (GIPAP) for patients with Chronic Myeloid Leukemia (CML) and gastrointestinal stromal tumors (GIST).



At the heart of Novartis' access-to-medicines strategy is innovation, particularly in a country like India, where there is limited availability of healthcare

These programs are direct results of the two core beliefs on which Novartis' strong foundations are built; the first involves investing in cutting-edge research for innovative healthcare solutions, and the second is a commitment to increase access to medicines while protecting its intellectual property through patents.

At the heart of Novartis' access-to-medicines strategy is innovation, particularly in a country like India, where there is limited availability of healthcare personnel and facilities, in the face of poverty and a general lack of health awareness in many parts of the country. The Arogya Parivar initiative, for instance, is a novel award-winning business model, boosting Novartis' performance even as it performs a social objective of reaching out to millions of low-income people in rural India, where most people live on less than two dollars a day.

THE MAGIC 'BULLET'

Novartis Oncology Access (NOA) is one of the most comprehensive and far-reaching cancer access programs ever developed on a global scale, helping CML patients in 81 countries worldwide. At last count, 52,395 patients had received free Glivec through a full donation program administered by The Max Foundation.

CML is one of the four most common cancers of the blood cells, accounting for 15-20 per cent of all cases of adult leukemia. It is diagnosed in one or two people per 100,000 every year, the majority between the ages of 30 and 60. Patients may be asymptomatic for years, even as their bone marrow produces increasing numbers of white blood cells (leukocytes), which progressively change the composition of their blood. As the disease progresses, however, it causes fatigue, weight loss, and spleen enlargement, ultimately causing a breakdown in the immune system. Untreated, patients may not survive longer

Sachin Shukla

Bright-eyed, smiling and never at a loss for words, Sachin Shukla is a perky 14-year old from Kurali Anapur village 20 kilometres away from Allahabad. When he was 10, and running a fever, a local doctor examined him, and advised him to go "immediately" to Tata Hospital, a 1400-km journey to Mumbai. He also told the boy's father Rajendra Shukla, that it was quite possible the child would not make it. "You are not God," his father told the doctor. "Just give us the recommendation letter and leave the rest to us".

Sachin, who was diagnosed with CML, has now been on Glivec for more than three years, since July 14, 2008; as an eighth-standard student he leads an active life, studying his favourite subjects Hindi and Science with gusto and participating enthusiastically in tennis tournaments. "I was diagnosed with blood cancer, but now all my reports show up as normal," says the boy, who has come out so strong after his illness that he recently underwent stitches on his forehead without anaesthesia for a tennis injury.

For Sachin and his family, Glivec offered so much hope that they were even willing to battle wild animals for it. Returning home with the first ever precious packet of Glivec they had been given, the Shuklas were appalled to see it fall off the moving train. Sachin's uncle immediately pulled the chain, saying that he did not mind paying whatever penalty was involved since it was a question of his nephew's life. "It was 1.30 in the morning, and it was raining; we were in a jungle area, full of bears," Sachin recalls. The tablets were too precious to lose, however, so undeterred, they got off the train to look for them. Luckily, after a frantic search in the dark, they found the medicines!

Today, having watched his son regain his strength and enthusiasm for life, Sachin's father Rajendra says: "Life is so uncertain. But if by having a single tablet of Glivec, one can gain an additional 24 hours, then I am willing to have a thousand tablets!" His 14-year-old son smiles widely and agrees.



than a few months. Often, the disease is discovered accidentally, through medical examinations for job interviews or blood tests for fever and other seemingly minor ailments.

Novartis is working towards the day when cancer patients can lead normal, healthy lives, provided they have access to the right healthcare and medicine. Glivec is one of the first medicines to demonstrate this potential for cancer. The company has developed the beta crystal form of Imatinib mesylate to make it suitable for patients to be taken in pill form - an innovation that helps deliver consistent, safe and effective levels of the medicine in a palatable manner. Glivec (Gleevec) was a scientific breakthrough, making a fundamental difference to the quality of life of patients with CML and GIST around the world. For instance, Kerul Patel, who owns a manufacturing business, says: "Novartis has transformed my life. I am continuing to live life with dignity. There have been no changes in my day-to-day activities.

The company has developed the beta crystal form of Imatinib mesylate to make it suitable for patients to be taken in pill form - an innovation that helps deliver consistent, safe and effective levels of the medicine

I have been able to finally achieve my childhood dream of getting the black belt in karate. I would not have been able to do anything if it hadn't been for Novartis and Glivec." Patel adds: "For other people who are going through similar tough times I believe

you must live your life and dream, nothing is impossible if you put your mind and soul into whatever you truly believe in."

Until Glivec started making a difference to patients the world over, traditional treatments in the 1920s for CML involved radiation therapy, followed by various chemotherapy regimes in the 1950s, which could increase life expectancy by five years, provided it was caught at an early stage. Bone marrow transplantation in the 1970s and interferon alpha therapy in the next decade were among the newer treatments. These therapies had major disadvantages; bone marrow transplantation, for instance, involved finding suitable donors of healthy stem cells, and many patients died after the operation.

Sometime in the 1960s, researchers at the University of Pennsylvania, USA, discovered a genetic mutation among patients suffering from CML. In all cases, chromosome 22 was shortened, with the missing section appearing incorrectly on chromosome 9. Conversely a

smaller part of the latter could be found on chromosome 22. It was the first time in the history of medicine that defective genetic material resulting from translocation of genes had been identified as a trigger for cancer.

Another thirty years of research were required before scientists understood the mechanism by which this 'Philadelphia chromosome', as it became known, caused leukemia. By 1993, Ciba-Geigy, one of Novartis' predecessor companies, developed a substance which blocked the specific protein that triggered CML (a tyrosine kinase named BCR-Abl).

Successor company Novartis then picked up the challenge, with initial clinical trials in 1999, and by 2001, the company had produced several tonnes of Gleevec, which had proved to be a well tolerated drug. In February 2001, barely 32 months after the first clinical trials in humans, Novartis submitted applications to authorities worldwide for approval, completing the development phase in just half the time usually taken in the industry.

