



Novartis India Limited Annual Report 2009-2010

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Board of Directors

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

Company Secretary &
Head Investor Relations

H. K. Maniar

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Registrar and Transfer Agents

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sharepro@shareproservices.com

Registered Office

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Dr Annie Besant Road
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 Transfer Agents, Sharepro Services, at the address above.

Annual General Meeting

11:00 am, July 30, 2010

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





“If I have seen further than others, it is by standing on the shoulders of giants.”

Sir Isaac Newton

Dear Shareholder

Medical science has made significant strides in the last century with most of the newer, more radical, therapies being invented in the last two decades. This pace of development has somewhat slowed in the last few years as diseases have got more complex and the time taken to bring a new drug to market has taken longer. Targeted therapies and customized medicines are the future of medicine. Scientists the world over are working to overcome some of the biggest threats to healthy living.

The greatest wealth is good health. While India is on the way to becoming a developed nation, there are several hurdles to overcome, notwithstanding the improving infrastructure, slowing down of population growth and decline in poverty. The sheer numbers and scale of the burden of disease means we are still some distance away from being called a developed nation.

India faces the dichotomy of a growing economy. We live 18th and 21st centuries back to back. At one end we have diseases associated with poverty and malnutrition and, at the other, diseases that are a result of changing lifestyles. The Indian pharmaceutical industry is among the most recognized in the world and has contributed significantly to improving the health of the nation. Equally important is the role played by research-driven pharmaceutical companies like Novartis that have been present in India and contributed to the economy and the health of the people since Independence and before.

For several decades, India disallowed product patents, in the mistaken belief that these would lead to higher costs of medicines. The linkage between product patents and pricing is fallacious given that we have over 30,000 brands competing in the market. The Indian Patent Act of 2005, which allowed product patents, was a step in the right direction. It provided encouragement to the Indian pharmaceutical industry to invest in research. It provided hope to the many Indian scientists who had made their home abroad to return to research opportunities here. It instilled confidence in budding scientists that they could be at the forefront of cutting-edge research through local and global collaboration and contribute to a healthier India.

It will be a proud moment when a drug for diseases inherent to the developing world comes out of a home-grown laboratory. In our desire to make this a reality we need to create an environment and a complete ecosystem that encourages innovation. Incremental research or innovation is the very life blood of scientific progress, as so eloquently yet pithily summarized above, by one of history's greatest scientists – Sir Isaac Newton. Incremental innovation is of particular significance in pharmaceutical research where discovery of compounds requires hundreds of step-by-step changes before they become usable drugs. Over 70% of medicines today were developed through incremental improvements on a base compound or existing medicine. In today's world of global pandemics, drug-resistant microbes and even biological weapons, what is needed is to shorten the time it takes to bring a medicine to the market.

Our annual report this year highlights how incremental innovation makes drugs safer, faster acting, easier to administer, allows multi-drug therapy, addresses specific needs of segments of population, is effective against new indications or just increases productivity and frees healthcare resources. Medicine prices and intellectual property are only two small pieces of a complex jigsaw that is India's healthcare puzzle. Other elements include issues related to inadequate health infrastructure, inefficient healthcare delivery systems, underfunding and poverty. We need multiple stakeholders to come together to solve this Sisyphean task. The pharmaceutical industry is but one of them. Let us work together to put in place this ecosystem that fosters innovation and encourages the magic of innovation to work. I count on each of you, our shareholders, to be ambassadors in spreading the message of innovation.

Best regards

Ranjit Shahani



The Magic of Innovation

"To raise new questions, new possibilities...to regard old problems from a new angle, requires creative imagination and marks real advance in science."

- Albert Einstein

The invention of the wheel was a breakthrough innovation in transportation. It freed humans from the constraints of distance, allowing them to travel hundreds of kilometers at higher speeds, in relative comfort and safety, while carrying greater loads. It may not be an exaggeration to say that the invention of the wheel was one of the key steps to the building of modern civilization.

The inventor of the bicycle simply combined two wheels with pedals and gears and revolutionized land travel by eliminating the need for a horse. Steam engines were added to the wheels and gears after their invention, offering an alternative power source for transportation.

Once a suitable gas-powered engine was perfected, this innovation replaced the earlier steam engine, creating the first automobile and revolutionizing personal transportation.

At no time in this process of invention did an innovator return to the drawing board to reinvent the wheel. Each used prior research and experimentation as a foundation, building on existing knowledge with additional creative thinking, research and trials. One base technology – the wheel – has been continuously modified to allow transportation to become what it is today.

Yet no one would argue that since the base technology is the same – the wheel – an oxcart is the same as a modern car in terms of speed, comfort, safety or carrying capacity.

It is then strange that this kind of an argument is not only accepted but is in fact the underlying basis for the Indian Patents (Amendment) Act 2005, when it comes to incremental innovation in pharmaceutical research.

Consider an example. Thalassemia is a genetic blood disorder particularly prevalent in the South Asia subcontinent. It causes the body to make fewer healthy red blood cells and less hemoglobin than normal. Hemoglobin is an iron-rich protein in red blood cells. It carries oxygen to all parts of the

body. It also carries carbon dioxide (a waste gas) from the body to the lungs, where it's exhaled. It is often diagnosed in childhood and children with thalassemia need several blood transfusions.

Frequent transfusions result in iron accumulation in the body, which could eventually cause serious liver problems or lead to heart conditions. Novartis has a drug that is able to take the iron

a result of incremental innovation, someone were to develop a version of the same drug that could be taken as a pill, it would obviate the need of the pump and significantly enhance the quality of life of children with this unfortunate condition.

But if this innovator tried to patent this new pill in India, the Indian Patents (Amendment) Act of 2005 would in all likelihood not allow it unlike in other countries. This is because this Act discriminates against certain types of inventions and thus would force patent examiners to regard this pill as the same basic chemical that is presently being given intravenously – the major enhancement of the patient's quality of life notwithstanding.

THE IMPORTANCE OF INCREMENTAL INNOVATION

Incremental innovation is the lifeblood of any research-based industry. In the pharmaceutical industry, discovery of compounds requires hundreds of step-by-step changes before they become usable drugs – modifications that make a medicine administrable to patients, and then improve how it is administered, how it is processed by the body, and how effective it is. Incremental changes can also improve product stability, eliminating the need for temperature regulation, or they can increase manufacturing efficiency, lowering production cost.

In the pharmaceutical industry, discovery of compounds requires hundreds of step-by-step changes before they become usable drugs

back out of the blood, but it has to be given in continuous intravenous infusion. That means these children had to have a pump bigger than a cellular phone on them all day and a needle going into one of their veins every few hours. Now if as





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The introduction of a new medicine is the result of intensive research and development activity taking anywhere between 10 to 15 years. Several years are gone by the time the compound passes pre-clinical testing – including toxicology studies – before the compound would be ready to test on humans.

It would take another couple of years before the drug could pass its Phase I clinical trials, comprising testing on healthy volunteers for safety and dosage. These volunteers are often researchers who have been involved in its development. Assuming the compound passes this phase, it would then need to pass the Phase II and Phase III clinical trials on progressively larger groups of volunteers. These volunteers are fully informed patients who are actually suffering from the disease in question. Hospitals and physicians all over the world cooperate to ensure that the widest possible variety of cases and outcomes are studied. This is so that adverse reactions, if any, as a result of long term use of the drug are monitored and studied. Even so there is no guarantee of success at the end.

If it survives the clinical testing phase, the drug would be ready to be submitted to the regulatory authorities for approval. Even after it receives such an approval and is introduced in the market, additional post-marketing testing continues for a couple of years.

At any point in time during this long process, the test results could be negative and researchers would be forced to abandon the compound altogether and return to the drawing board. It is worth remembering that for every new drug that makes it to the market, over 10,000 compounds are tested and abandoned for one reason or another. Pharmaceutical companies spend between USD 2-3 billion on research, development and testing, to create a single drug.

The pharmaceutical industry invests more than USD 65 billion per year in research and development, offering the single most important source of investment in health research. There would also be almost no incentive for risking this investment in research if scientists were forced back to square one for every new drug. More importantly, if drug discovery was forced back to the beginning each time a new medicine was needed, time and monetary investments would increase exponentially and significantly delay the delivery of medicines to patients.

By adding value to an existing compound or drug, pharmaceutical companies contribute to patients' quality of life without starting from scratch.

As global pandemics becomes a reality, biological weapons become a threat, and preventable diseases continue to take lives, the need of the hour is to shorten the time it takes to bring a product to market, not to lengthen it.

From improving a medicine's safety and side effect profile to increasing a country's productivity, incremental innovation provides exceptional value for patients and society. Over 70% of medicines on the market today were developed through incremental improvements on a base compound or existing medicine.

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INCREMENTAL INNOVATION AND PUBLIC HEALTH

The challenges of public health are complex and multi-faceted. But the biggest global healthcare challenge is economic in origin. Today about three billion people in the world subsist on less than two US dollars a day. About a billion barely manage to survive on less than one US dollar a day. According to estimates about three-quarters of a billion people receive inadequate nourishment and about 10 million children die from malnutrition each year.

Given this scenario it is then vital that all stakeholders – governments, non-governmental organizations, multi-lateral aid agencies as well as the pharmaceutical industry – ensure that they spend each dollar of investment in the most effective manner. Incremental innovation allows the pharmaceutical industry to do that in the area of research.

Improved safety, side effects, tolerability: Many medicines for ovarian cancer used to cause heart

damage. A new cancer medicine, Doxorubicin, uses the same active ingredient as these previous medicines but encapsulates it in fat molecules in order to limit cardiac tissue damage. This important change dramatically improves the safety of this type of chemotherapy. An improved safety profile benefits patients already using a drug, and can also extend the possibility of treatment to others who, because of pre-existing conditions, were previously unable to use the drug.

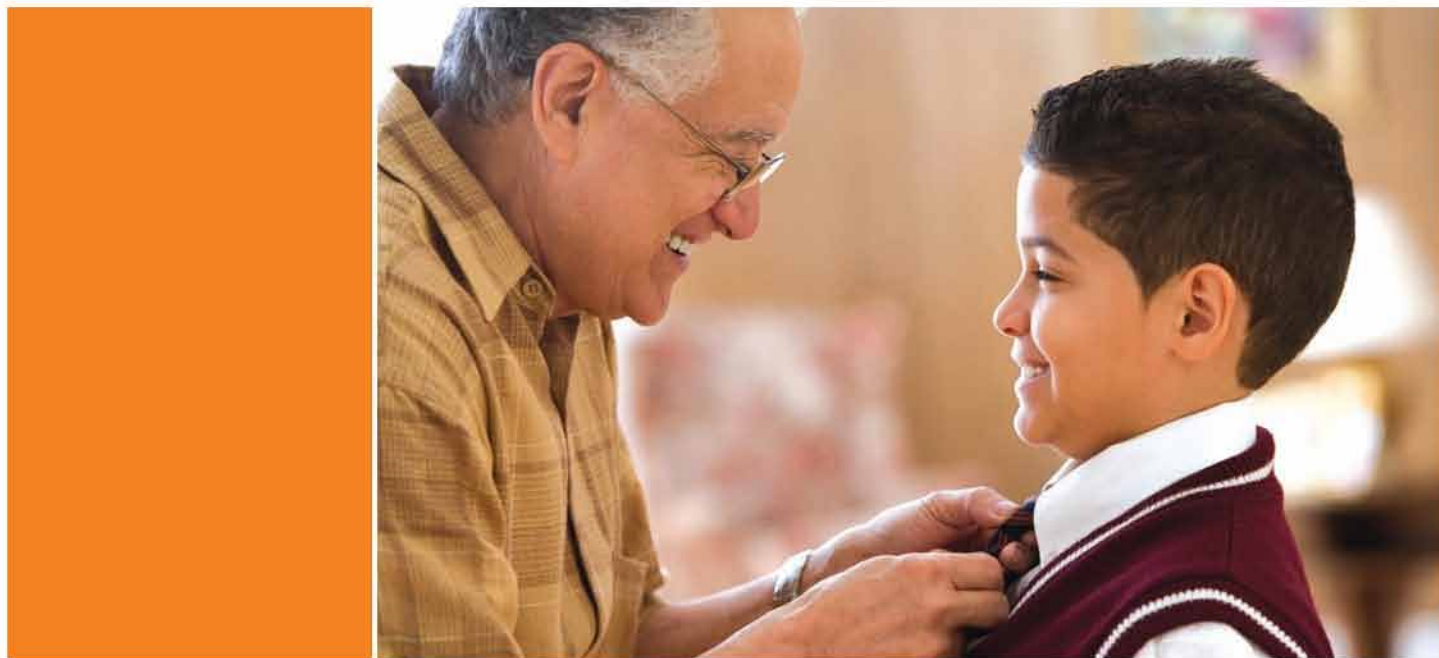
Faster treatment: Insulin injections do not always work quickly enough for diabetes patients. Fast-acting insulins, like Insulin Aspart and Insulin Lispro, are similar to conventional diabetes medicines, but drastically improve speed of treatment. They build on proven safe and effective treatment options, but offer patients a faster reaction. Having a drug that acts as soon as patients need it can help avoid more radical treatment options, allowing patients to avoid unnecessary hospital visits and additional recovery.

Enhanced multi-drug therapy: Multi-drug therapy is really a combination of two or more drugs given together in one convenient dose. Combinations, such as those used for patients with HIV, are carefully researched and designed to avoid unsafe or efficacy-decreasing drug interaction. When compared to mono-therapy, or treatment with only one medication, combination therapy is proven to

be more effective, to save additional lives and to decrease chances of resistance in infectious diseases. In addition, combinations are convenient, allowing patients to receive all of their medications in one dose. Added convenience nearly always leads to improved patient compliance. In addition, any improvements that lead to higher patient compliance in infectious diseases help limit drug resistance which in turn creates a constant need for new treatments.

Convenience for patients: Patients hope that treatment will improve a medical condition to the point that they can return to normal life; unfortunately medications requiring multiple doses each day or frequent, painful injections can be disruptive and reduce their quality of life. Medicines with reduced dosage, like the osteoporosis treatment Aclasta® that is administered only once per year, help patients to lead normal day-to-day lives, even as they undergo treatment to manage a disease.

Individualized treatment for special populations: Certain groups, including children or the elderly, need special formulations of medicines to meet their needs. Infants and children need smaller doses than adults, and new formulations allow them to be effectively treated with the correct fixed dosage. Because patients have varied responses to different drugs, it is essential to have options for patients in any therapeutic class. Drug allergies





It is commonly believed that according patent protection to incremental innovation would increase healthcare costs, but this is a fallacy

are prevalent, and in the absence of options certain populations would not be treatable. Often there is no explanation as to why drugs work differently for different patients, so options are extremely valuable, even if the variance between these options are not completely evident to all. More options allow drugs to be tailored to patients, instead of the other way around.

New indications: A medicine originally formulated for one use, like Infliximab for arthritis, has been applied to another disease with some reformulation and further testing. Creative application of one innovation can make a difference for thousands of patients with several seemingly unrelated diseases, as is the case with Infliximab. Patients with diseases including paediatric and adult Crohn's disease had few or no treatment options available before these indications were added to the profile of an existing medication.

Better quality of life, higher productivity, releasing other healthcare resources: By treating diseases with medicines, patients, doctors and payors can avoid more debilitating, invasive and costly in-hospital treatment. Reducing hospitalizations due to preventable and treatable conditions drives healthcare costs down and worker productivity up – benefiting both patients and the national economy. Over the past 40 years, the trend toward effectively controlling disease with medicines has resulted in a 50% reduction of hospital admissions for 12 major diseases. Without anti-hypertensive medicines, for example, more than 800,000 additional people would have been hospitalized in the US alone in 2002. Another study estimated that the US loses USD 2.4 billion to USD 4.6 billion per year due to decreased worker productivity caused by hay fever. Between 1965 and 1990, Gross Domestic Product (GDP) per capita of malaria-free countries was 38% higher than that of similar-sized countries where malaria was prevalent, lending credibility to the idea that healthy citizens help create a healthy economy. That medicines maintain health is clear, as is the fact that the vast majority of medicines that have changed the lives of patients globally were developed through incremental innovation.

While many diseases can be treated with medicines, medical researchers are still working toward curing more diseases with medicines. Problems with drug resistance are constantly increasing, particularly in the areas of tuberculosis, malaria and respiratory infections. Disease prevention is another area for expansion, contributing to global health by stopping disease

before it starts. Of the 47 priority infectious diseases defined by World Health Organization (WHO) and the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), only nine have sufficient treatment or prevention options available. This lack of options represents unmet medical needs that must be addressed quickly. Thousands of public health needs go unmet each day, and industry and patients cannot depend on breakthrough innovations to address these needs at a quick enough pace.

Given the central role of incremental innovation in medical progress, the value that these types of advancement bring is exceptional. Without these building-block improvements, healthcare would not have progressed to where it is today.

Given the central role of incremental innovation in medical progress, the value that such advancements bring is exceptional

INCREMENTAL INNOVATION AND HEALTHCARE COSTS

One common belief is that according incremental innovation patent protection would increase healthcare costs. This is a fallacy.

For the 585 million people in India living on less than USD 1 per day, the price of a medicine is basically irrelevant. Nearly all medicines are out of reach, regardless of patents and regardless of price. On the other hand, India also has a booming middle-class which all estimates indicate is only going to explode further. India then, presents a typical globalization dilemma – two markets in one country.

For the poor, the central issue is access to healthcare and healthcare financing. Diluting patent laws will not help in addressing this key concern, since disallowing patent protection would only mean that global pharmaceutical companies would refrain from introducing innovative medicines in India,