# 3.C Reasons for the offer and use of proceeds

Not applicable.

#### 3.D Risk Factors

Our business faces significant risks and uncertainties. You should carefully consider all of the information set forth in this annual report on Form 20-F and in our other filings with the SEC before deciding to invest in any Novartis securities, including the following risk factors. Our business, financial condition or results of operations could be materially adversely affected by any of these risks as well as other risks and uncertainties not currently known to us or which we currently deem immaterial.

#### Risks Facing Our Business

Our Pharmaceuticals Division is confronted by a record level of industry patent expirations and increasingly aggressive generic competition.

Our Pharmaceuticals Division's products are generally protected by patent rights which are intended to provide us with exclusive marketing rights in various countries. However, those patent rights are of varying strengths and durations. Loss of market exclusivity for one or more important products—either due to patent expiration, generic challenges or other reasons—could have a material adverse effect on our results of operations. This is because the introduction of a generic version of the same or a similar medicine typically results in a significant and sharp reduction in net sales for the relevant product, given that generic manufacturers typically offer their versions of the same medicine at sharply lower prices. The pharmaceuticals industry is confronted by a continuing high level of patent expirations, with products representing approximately \$20 billion in combined annual sales facing patent expiry in 2008, similar to levels seen in 2006 and 2007, according to IMS Health. In addition, some generic manufacturers are increasingly conducting so-called "launches at risk" of products that are still under legal challenge for patent infringement and before final resolution of legal proceedings.

In 2007, sales of four Novartis pharmaceutical products—Lotrel (high blood pressure), Lamisil (fungal infections), Trileptal (epilepsy) and Famvir (viral infections)—were negatively affected by the start of generic competition in the US, which in some cases was unexpected. These four products had combined 2006 annual net sales of approximately \$2.6 billion in the US. As a result of generic competition, combined net sales for these products declined 38% to \$1.6 billion in 2007, and are expected to decline significantly further in 2008. The sharp and significant reduction in net sales of these products had an adverse effect on the results of operations of our Pharmaceuticals Division in 2007. Generic versions for Lamisil and Trileptal were launched following the expiry of patents, while US generic competition for Lotrel and Famvir was the result of "launches at risk" by other generics manufacturers.

Other products of our Pharmaceuticals Division that are the subject of ongoing US patent litigation include Femara (breast cancer), Lescol (high cholesterol), Focalin/Ritalin LA (ADHD) and Comtan/Stalevo (Parkinson's disease). The loss of exclusivity of some of these products could have a significant adverse effect on the results of operations of our Pharmaceuticals Division. In addition, Neoral (transplantation) and Voltaren (pain), which are still among our top ten-selling products and had combined net sales of \$1.7 billion in 2007, have already encountered generic competition in many markets, which may cause sales from these products to decline significantly in the future. A number of other top-selling products, including Diovan (high blood pressure) as well as the Gleevec/Glivec and Zometa (both for cancers), could also potentially face generic competition in the coming four to seven years in various markets, particularly the US and Europe, either due to potential patent challenges or the regular expiration of patents. Diovan, Gleevec/Glivec and Zometa had combined net sales of \$9.4 billion in 2007, and the loss of exclusivity of any one of these three products could have a material adverse effect on our business, financial condition and results of operations.

# Our business is increasingly affected by pressures on drug pricing.

The growing burden of healthcare costs as a percentage of gross domestic product in many countries means that governments and payors are under intense pressure to control costs even more tightly. As a result, our businesses and the healthcare industry in general are operating in an ever more challenging environment and are significantly affected by ongoing pricing pressures. These pricing pressures include government-imposed industry-wide price reductions, mandatory reference prices, an increase in parallel imports, the shifting of the payment burden to patients through higher co-payments, limiting access to formularies, mandatory substitution of generic drugs and growing pressure on physicians to reduce the prescribing of patented prescription medicines. We expect these efforts to continue as healthcare payors around the globe—in particular government-controlled health authorities, insurance companies and managed care organizations—step up initiatives to reduce the overall cost of healthcare to patients, restrict access to higher priced new medicines, increase the use of generics and impose overall price cuts. These initiatives do not only affect the results of our Pharmaceuticals Division, but also have an increasing impact on the prices which we are able to charge for the generic drugs marketed by our Sandoz Division. This is particularly true in Europe and especially Germany, our second largest market for generic products, where various measures have been introduced to require generic manufacturers to lower their prices. A combination of aggressive efforts by our distributors to increase their profit margins on generics products that are considered commodities and expected new government regulations, however, have also placed increasing downward pressure on our prices in the US. We expect that these and other challenges will continue to put pressure on our revenues, and therefore could have a material adverse effect on our business, financial condition and results of operations.

For more information on the pricing controls and on our challenging business environment see "Item 4.B Business Overview—Pharmaceuticals—Price Controls" and "Item 5.A Operating Results—Factors affecting results of operations—Increasing pressure on drug pricing and access to medicines".

## Increasing regulatory scrutiny of drug safety and efficacy may have a negative effect on our results of operations.

We must comply with a broad range of regulatory requirements for the development, manufacture, marketing, labeling, distribution and pricing of our products. These requirements do not only affect our development costs, but also the time required to reach the market and the uncertainty of successfully doing so. Stricter regulatory requirements also heighten the risk of withdrawal of existing products by regulators on the basis of post-approval concerns over product safety, which would reduce revenues and can result in product recalls and product liability lawsuits. In addition, we may voluntarily cease marketing a product or face declining sales based on concerns about efficacy or safety, whether or not scientifically justified, even in the absence of regulatory action. The development of the post-approval adverse event profile for a product or the relevant product class may have a material adverse effect on the marketing and sale of the relevant product. For more detail on the governmental regulations that affect our business see the sections headed "Regulation" included in the descriptions of our four operating divisions under "Item 4.B Business Overview".

Following widely publicized product recalls such as Merck & Co., Inc.'s recall of its pain medicine Vioxx® in 2004, health regulators are increasingly focusing on product safety and efficacy as well as on the risk/benefit profile of developmental drugs. This has led to requests for more clinical trial data with a significantly higher number of patients and for more detailed analysis. As a result, obtaining regulatory approvals has become more challenging for pharmaceutical companies. In addition, maintaining regulatory approvals has become increasingly expensive since companies are being required to gather far more detailed safety and other clinical data on products after approval.

We have suffered setbacks in gaining regulatory approvals for new products as well as being able to keep products on the market, primarily in the Pharmaceuticals Division. For example, in March 2007, *Galvus* (diabetes) received a so-called "approvable" letter from the FDA requiring Novartis to conduct major additional clinical trials before US regulatory approval. However, we subsequently received

approval in the EU in September 2007. In March 2007, we also suspended the marketing and sales of *Zelnorm* (irritable bowel syndrome) in the US and several other countries in response to a request from the FDA to do so pending further discussions of the product's risks and benefits. As a result of these suspensions, net sales of *Zelnorm* fell 84% in 2007 as compared to 2006, and are expected to fall significantly further in 2008. Separately, in the second half of 2007, *Prexige* (osteoarthritic pain) was withdrawn from the market in Australia as well as in some countries of the EU based on postmarketing reports of serious liver side-effects allegedly associated with long-term uses of higher doses, including the deaths of two patients in Australia.

Any additional delays in the regulatory approval process for new products or adverse regulatory developments with regard to significant existing products could have a material adverse effect on our business, financial condition and results of operations.

## Legal proceedings may have a significant impact on our results of operations.

In recent years, the industries that make up our business have become important targets of litigation around the world, especially in the US. A number of our subsidiaries are, and will likely continue to be, subject to various legal proceedings that arise from time to time, including product liability, commercial, employment and wrongful discharge, securities, environmental and tax litigations and claims, government investigations and intellectual property disputes. As a result, we may become subject to substantial liabilities that may not be covered by insurance. Litigation is inherently unpredictable and excessive verdicts occur. As a consequence, we may in the future incur judgments or enter into settlements of claims that could have a material adverse effect on our results of operations or cash flows.

In addition, our Pharmaceuticals Division frequently defends its patents against challenges by our competitors. Should we fail to successfully defend our patents, we will be faced with generic competition for the relevant products, and the resulting loss of revenue.

At the same time, our Sandoz Division may, from time to time, seek approval to market a generic version of a product before the expiration of patents claimed by one of our competitors for the relevant product. We do this in cases where we believe that the relevant patents are invalid, unenforceable, or would not be infringed by our generic product. As a result, we frequently face patent litigation and in certain circumstances, we may elect to market a generic product even though patent infringement actions are still pending. Should we elect to proceed in this manner and conduct a "launch at risk", we could face substantial damages if the final court decision is adverse to us.

The CIBA Vision Business Unit of our Consumer Health Division also has been required to defend its patents against frequent challenges by its competitors. Adverse judgments or settlements in any of these cases could have a material adverse effect on our business, financial condition and results of operations.

Governments and regulatory authorities have in recent years been stepping up their compliance with law enforcement activities in key areas, including corruption, marketing practices, antitrust and trade restrictions. Our businesses have from time to time been subject to such governmental investigations and information requests by regulatory authorities like the recent unannounced inspection of the Sandoz companies in Holzkirchen, Germany, by European Commission officials. While the outcome of government and regulatory authorities investigations are unpredictable they are costly, divert management from our business and may affect our reputation.

For more detail regarding specific legal matters currently pending against us, see "Item 18. Financial Statements—note 19" and "Item 4. Information on the Company—4.B Business Overview—Pharmaceuticals—Intellectual Property."

# Our research and development efforts may not succeed.

Our ability to continue to grow our business and to replace any lost sales due to the loss of exclusivity for our products—either due to patent expiration, generic challenges, competition from new branded products or changes in regulatory status—depends upon the ability of our research and development activities to identify and develop high-potential breakthrough products that address unmet needs, are accepted by patients and physicians, and are reimbursed by payors. To accomplish this, we commit substantial effort, funds and other resources to research and development, both through our own dedicated resources, and through various collaborations with third parties. Developing new pharmaceutical products and bringing them to market, however, is a costly, lengthy and uncertain process and there can be no guarantee that our research and development activities will produce a sufficient number of commercially viable new products, in spite of these significant investments.

The pharmaceuticals industry has been suffering a dearth of new drugs gaining regulatory approvals in recent years. For example, the FDA approved only 18 entirely new drugs (new molecular entities) in 2007, the lowest single-year total since 1983, when there were 14 new approvals. This decline in research productivity comes at a time when the world-wide pharmaceuticals industry is estimated to be spending more than \$40 billion each year on research and development activities.

The research and development process for a new pharmaceutical product can take up to 15 years, or even longer, from discovery to commercial product launch. New products do not only need to undergo intensive pre-clinical and clinical testing, but also to pass a highly complex, lengthy and expensive approval process. During each stage of the process, there is a substantial risk that we will encounter serious obstacles or will not achieve our goals and accordingly we may abandon a product in which we have invested substantial amounts of time and money. We are therefore taking steps to accelerate research and development activities throughout the Group and to find ways to lower attrition rates among pipeline products in the final states before approval. For example, a reorganization of the Pharmaceuticals Development organization began in 2007 with the aim of strengthening project focus, integrating decision making at the therapeutic franchise level and simplifying development decision-making structures. Should these efforts fail to achieve the desired results or should we be unable to maintain a continuous flow of successful new products and successful new indications or brand extensions for existing products sufficient to cover our substantial research and development costs and to replace sales that are lost as older products approach the end of their commercial life cycles or are displaced by competing products or therapies, this could have a material adverse effect on our business, financial condition or results of operations.

In addition, we invest a significant amount of effort and financial resources into research and development collaborations with third parties which we do not control. Many of these third parties may be small companies which may not have the same organizational resources and development expertise as Novartis. Should these third parties fail to meet our expectations, we may lose our investment in these collaborations or fail to receive the expected benefits, which could have a material adverse effect on our business, financial condition or results of operations.

# Reduced availability of exclusivity periods may have an adverse effect on the success of our Sandoz Division.

A significant source of revenue for our Sandoz Division are exclusivity periods granted in certain markets—particularly the 180-day exclusivity period granted in the US by the Hatch-Waxman Act. However, a number of factors have had the effect of limiting the availability of those exclusivity periods or of decreasing their value, including a variety of aggressive steps taken by branded pharmaceuticals companies to counter the growth of generics, increased competition among generics companies to achieve these periods of exclusivity as well as regulatory changes that create the risk of potential forfeiture of exclusivity periods in the US.

We may not be able to realize the expected benefits from our ongoing productivity initiatives.

In December 2007, we launched a new strategic initiative called "Forward" to enhance productivity by simplifying organizational structures, accelerating and decentralizing decision-making and redesigning the way we operate. Through this initiative, we aim to reduce our cost-base by approximately \$1.6 billion by 2010 compared to 2007 levels. Our ability to achieve these expected cost-savings, however, depends on a number of factors beyond our control and our inability to successfully complete "Forward" and other ongoing productivity initiatives could have a material adverse effect on our business, financial condition and results of operations.

## We may not be able to realize the expected benefits from our significant investments in biologics.

We believe that recent advances in technologies, particularly those within the last decade that have advanced the analysis of human genome data, could have a fundamental effect on product development, and in turn on our results of operations. We are therefore making major investments in those technologies and are devoting significant resources to building our position in biologic therapies, which now represent approximately 25% of our pre-clinical research portfolio. For our efforts in this area to be successful, we need to ensure a speedy expansion of our capabilities, expertise and skills in the development, manufacturing and marketing of biological therapies. This, however, poses a number of significant challenges, including intense competition for qualified individuals. See also "—An inability to attract and retain qualified personnel could adversely affect our business" below.

In the second half of 2007, we formed our new Novartis Biologics Unit. To complement these internal research and development activities, we have also made significant investments in licensing agreements with specialized biotechnology companies. At the same time, our Sandoz Division is taking steps to expand its expertise in the area of biosimilars (generic versions of biological therapies) and is actively working with regulators to establish appropriate rules for the approval of these types of generic products.

There can be no guarantee that our efforts in the biologics area will be successful or that we will be able to realize the expected benefits from our significant investment in this area. A failure to build and expand our position in biologics or to achieve the expected benefits from our significant investments in this area could have a material adverse effect on our business, financial condition and results of operations.

We may not be able to realize the expected benefits from our significant marketing efforts and may fail to develop appropriate marketing models or correctly anticipate changes in our product portfolio.

The time between the launch of innovative "first-in-class" treatments and "me-too" or generic versions has shortened significantly in recent years, which is putting increasing pressure on our Pharmaceuticals Division to maximize revenue from a new product quickly following its launch, in order to be able to recover its significant research and development costs. A strong marketing message and rapid penetration of potential markets in different geographic territories are vital if a product is to attain peak sales as quickly as possible before the loss of patent protection or the entry of significant competitor products. As a consequence, we are required to invest significant resources into our marketing and sales efforts and we also continually evaluate the appropriateness of our marketing models, explore more efficient ways to support new product launches and adjust the composition of our sales force in response to changes in our product portfolio. Should those efforts prove unsuccessful or should we fail to correctly anticipate changes to our product portfolio, for example, as a result of the unexpected loss of exclusivity for existing products or delays in the launch of new products, this could have a material adverse effect on our business, financial condition and results of operations.

A failure to develop differentiated vaccines and to bring key products to market in time for the relevant disease season could have an adverse effect on the success of our Vaccines and Diagnostics Division.

The demand for some types of vaccines marketed by our Vaccines and Diagnostics Division, such as influenza vaccines, is seasonal, while the demand for other vaccines, such as pediatric combination vaccines, depends on birth rates in developed countries. Some vaccines, particularly seasonal influenza vaccines that make an important contribution to the division's net sales and profits, are considered to be commodities, meaning that there are few therapeutic differences among vaccines offered by competitors. The ability to develop differentiated, effective and safe vaccines, to gain approval for inclusion in national immunization recommendation lists, and to consistently produce and deliver high-quality vaccines in time for the relevant disease season are critical to the success of our Vaccines and Diagnostics Division.

## The manufacture of our products is technically highly complex and we may face supply disruptions.

The products we market, distribute and sell are either manufactured at our own dedicated manufacturing facilities or through toll manufacturing or other supply arrangements with third parties. In either case, we need to ensure that the manufacturing process complies with applicable regulations and manufacturing practices as well as our own high quality standards. Many of our products, however, are the result of technically complex manufacturing processes or require a supply of highly specialized raw materials. For some of our products and certain key raw materials, we may also rely on a single source of supply. As a result of these factors, the production of one or more of our products may be disrupted from time to time. Both our Vaccines and Diagnostics Division and our Ciba Vision Business Unit, for example, have experienced significant production shutdowns in the recent past. We may also not be able to rapidly alter production volumes to respond to changes in demand for particular products. A disruption in the supply of certain key products or our failure to accurately predict the demand for those products could have a material adverse effect on our business, financial condition or results of operations. In addition, because our products are intended to promote the health of patients, any supply disruption could lead to allegations that the public health, or the health of individuals, has been endangered and could subject us to lawsuits.

# An increasing amount of intangible assets and goodwill on our books may lead to significant impairment charges in the future.

We regularly review our long-lived assets, including identifiable intangible assets and goodwill, for impairment. Goodwill, acquired research and development and acquired development projects not yet ready for use are subject to impairment review at least annually. Other long-lived assets are reviewed for impairment when there is an indication that an impairment may have occurred. The amount of goodwill and other intangible assets on our consolidated balance sheet has increased significantly in recent years, primarily as a result of our recent acquisitions. Impairment testing under IFRS may lead to further impairment charges in the future. Any significant impairment charges could have a material adverse effect on our results of operations. For a detailed discussion of how we determine whether an impairment has occurred, what factors could result in an impairment and on the increasing impact of impairment charges on our results of operations see "Item 5.A Operating Results—Critical Accounting Policies and Estimates—Impairment of Long-Lived Assets" and "Item 18. Financial Statements—note 9".

# Ongoing consolidation among our distributors may further increase the purchasing leverage of key customers and the concentration of credit risk.

Increasingly, significant portions of our sales, particularly in the US, are made to a relatively small number of US drug wholesalers, retail chains, and other purchasing organizations. For example, our three most important customers, all from the US, accounted for approximately 9%, 8% and 6%, respectively, of Group net sales from continuing operations in 2007 and there has been a trend toward further consolidation among our distributors, especially in the US. As a result, our distributors are gaining additional purchasing leverage over us, which increases the pricing pressures facing our businesses.

Moreover, we are exposed to a concentration of credit risk as a result of this concentration among our customers. Should one or more of our major customers experience financial difficulties, the effect on us would be substantially greater than would have been the case in the past. The increased purchasing power of these customers also increases the risk that we may not be able to effectively enforce the high standards which we expect of our distributors and customers. Each of these factors could have a material adverse effect on our business, financial condition and results of operations.

### An inability to attract and retain qualified personnel could adversely affect our business.

We highly depend upon skilled personnel in key parts of our organization and we invest heavily in recruiting and training qualified individuals. The loss of the service of key members of our organization—particularly senior members of our scientific and management teams—may delay or prevent the achievement of major business objectives. In addition, the success of our research and development activities—especially in the area of biologics—is particularly dependent on our ability to attract and retain sufficient numbers of high quality researchers and development specialists. We face intense competition for qualified individuals from numerous pharmaceutical and biotechnology companies, universities, governmental entities and other research institutions. As a result, we may be unable to attract and retain qualified individuals in sufficient numbers, which would have an adverse effect on our business, financial condition and results of operations.

### Environmental liabilities may adversely impact our results of operations.

The environmental laws of various jurisdictions impose actual and potential obligations on us to remediate contaminated sites. In 2007, we increased our provisions for worldwide environmental liabilities by \$614 million following the completion of internal and external reviews. \$590 million of this increase was attributable to a Corporate charge primarily related to formerly-owned businesses including the Novartis-related share of potential remediation costs for landfills in the Basel region (including Switzerland, France and Germany). We have also been identified as a potentially responsible party under the US Comprehensive Environmental Response Compensation and Liability Act in respect to certain sites. Given the inherent difficulties in estimating liabilities in environmental matters, it cannot be guaranteed that additional costs will not be incurred beyond the amounts we have provided for in the Group consolidated financial statements. Should we be required to further increase our provisions for environmental liabilities in the future or fail to properly manage environmental risks, this could have a material adverse effect on our business, financial condition and results of operations. For more detail regarding environmental matters, see "Item 4.D Property, Plants and Equipment—Environmental Matters" and "Item 18. Financial Statements—note 19."

# Foreign exchange fluctuations may adversely affect our earnings and the value of some of our assets.

A significant portion of our earnings and expenditures are in currencies other than US dollars, our reporting currency. In 2007, 39% of our net sales from continuing operations were made in US dollars, 30% in euro, 6% in Japanese yen, 2% in Swiss francs and 23% in other currencies. During the same period, 36% of our expenses from continuing operations arose in US dollars, 28% in euro, 14% in Swiss francs, 5% in Japanese yen and 17% in other currencies. Changes in exchange rates between the US dollar and other currencies can result in increases or decreases in our costs and earnings. Fluctuations in exchange rates between the US dollar and other currencies may also affect the reported value of our assets measured in US dollars and the components of shareholders' equity. For more information on the effects of currency fluctuations on our consolidated financial statements and on how we manage currency risk, see "Item 5.A Operating Results—Effects of Currency Fluctuations" and "Item 11. Quantitative and Qualitative Disclosures about Non-Product—Related Market Risk."

# Earthquakes could adversely affect our business.

Our corporate headquarters, the headquarters of our Pharmaceuticals and Consumer Health Divisions, and certain of our major Pharmaceuticals Division production facilities are located near earthquake fault lines in Basel, Switzerland. In addition, other major facilities of our Pharmaceuticals, Vaccines and Diagnostics, Sandoz and Consumer Health Divisions are located near major earthquake fault lines in various locations around the world. In the event of a major earthquake, we could experience business interruptions, destruction of facilities and loss of life, all of which could have a material adverse effect on our business, financial condition and results of operations.

# We may be held responsible for the potential misconduct by our third party agents, particularly in developing countries.

We have operations in approximately 140 countries around the world. In many of these countries, particularly in less developed markets, we rely heavily on third party distributors and other agents for the marketing and distribution of our products. Many of these third parties are small and do not have internal compliance resources that are comparable to those within our own organization. In many emerging growth markets, the local legal systems have also undergone dramatic changes in recent years. In many cases, specific regulations on the marketing and sale of pharmaceutical products either do not exist or the interpretation and safeguards of the new regulatory systems are still being developed, which may result in legal uncertainty and in existing laws and regulations being applied inconsistently. In addition, many of these countries are also plagued by widespread corruption. Should our efforts in screening our third party agents and in detecting cases of potential misconduct fail, we could be held responsible for the non-compliance by these third parties with applicable laws and regulations, which may have a negative effect on our reputation and our business.

# Significant disruptions of information technology systems could adversely affect our business.

Our business is increasingly dependent on information technology systems, including Internet-based systems, to support business processes as well as internal and external communications. Any significant breakdown, invasion, destruction or interruption of these systems, whether due to computer viruses or other outside incursions, may result in the loss of data and/or impairment of production and business processes which could materially and adversely affect our business.

#### Risks Related To Our ADSs

# The price of our ADSs and the US dollar value of any dividends may be negatively affected by fluctuations in the US dollar/Swiss franc exchange rate.

Our American Depositary Shares (ADSs) trade on the New York Stock Exchange in US dollars. Since the shares underlying the ADSs are listed in Switzerland on the SWX Swiss Exchange (SWX) and trade on the European trading platform virt-x Exchange Limited (virt-x) in Swiss francs, the value of the ADSs may be affected by fluctuations in the US dollar/Swiss franc exchange rate. In addition, since any dividends that we may declare will be denominated in Swiss francs, exchange rate fluctuations will affect the US dollar equivalent of dividends received by holders of ADSs. If the value of the Swiss franc decreases against the US dollar, the price at which our ADS trade and the value of the US dollar equivalent of any dividend will decrease accordingly.

# Holders of ADSs may not be able to exercise preemptive rights attached to shares underlying ADSs.

Under Swiss law, shareholders have preemptive rights to subscribe for cash for issuances of new shares on a pro rata basis. Shareholders may waive their preemptive rights in respect of any offering at a general meeting of shareholders. Preemptive rights, if not previously waived, are transferable during the subscription period relating to a particular offering of shares and may be quoted on the SWX. US holders of ADSs may not be able to exercise the preemptive rights attached to the shares underlying their ADSs