IAM
Independent Asset Management

September 2021

Novartis

Market profile

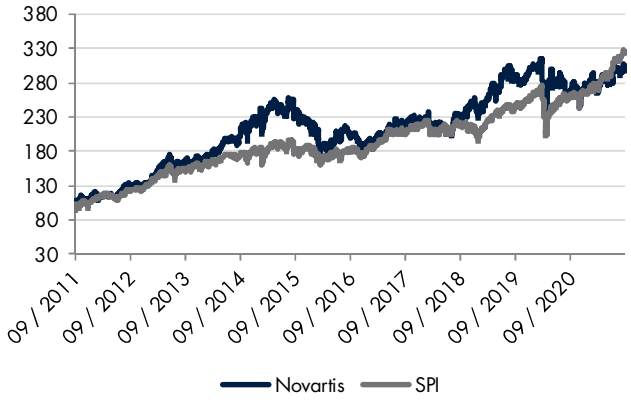
Country	Switzerland
Sector	Pharmaceuticals
Market cap (CHF bn)	206.7
52-week high / low (CHF)	87.16 / 70.42

Key metrics (CHF)

	2020	2021e	2022e
EPS	3.24	5.82	6.18
PE	25.8x	14.8x	13.9x
Dividend Yield	3.5%	3.9%	4.0%

Evolution of stock price with respect to benchmark (rebased)

Source: IAM



Executive summary

Novartis is a large multinational group of companies specializing in the research, development, manufacturing and marketing of a broad range of innovative pharmaceuticals, as well as cost-saving generic medicines (under the Sandoz brand).

Novartis is part of the elite group of 10 largest pharmaceutical companies in the world. With revenues of over USD 48 billion in 2020, the company is ranked 6th worldwide in the industry, which is behind its Swiss competitor Roche (3rd worldwide).

Novartis' business is split into 2 distinctive global operating divisions: Innovative medicines (which includes patent-protected prescription medicines) and Sandoz (generic pharmaceuticals and biosimilars). In 2020, Novartis had 14 drugs with net sales of over USD 1 billion each, so called "blockbusters".

Novartis wants to serve a progressive dividend (ie: rising each year) with a yield in a range of 3—5%. Clearly, the dividend policy is a high priority for management. Usually this indicates a stable and mature company which doesn't need the money to grow fast. The payout ratio is around 60%, with big variations when EPS is low.

Current consensus estimates 3% per annum top-line growth over the next 3 years. The growth rate may seem low, but it's in line with long-term historic growth. Obviously, Novartis is not a growth company anymore, that's why management focuses on dividends.

We believe the company is about fairly valued, as it neither deserves a premium nor a discount to the sector. A P/E multiple around its past average seems fair.

Novartis

Daniel Pfund, Senior Financial Analyst **September 2021**

Company description

Novartis is a large multinational group of companies specializing in the research, development, manufacturing and marketing of a broad range of innovative pharmaceuticals, as well as cost-saving generic medicines (under the Sandoz brand).

Novartis is part of the elite group of 10 largest pharmaceutical companies in the world. With revenues of over USD 48 billion in 2020, the company is ranked 6th worldwide in the industry, which is behind its Swiss competitor Roche (3rd worldwide).

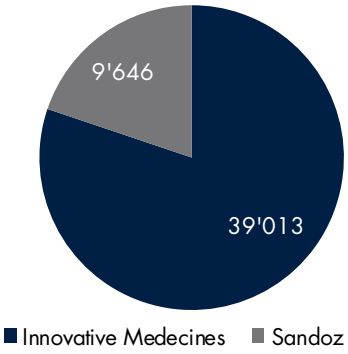
The company follows International Financial Reporting Standards (IFRS) and publishes its annual accounts in US dollars, with a traditional fiscal year ending 31st of December.

The group's vision is to be a trusted leader in changing the practice of medicine. The company's strategy is to build a leading, focused medicines company powered by advanced therapy platforms and data science. To implement this strategy, Novartis has set five priorities to shape its future and help create value for their employees, shareholders, and society:

1. Unleash the power of their employees
2. Deliver transformative innovation
3. Embrace operational excellence
4. Go big on data and digital
5. Build trust with society

Novartis' business is split into 2 distinctive global operating divisions: **Innovative medicines** (which includes patent-protected prescription medicines) and **Sandoz** (generic pharmaceuticals and biosimilars).

Fig.1: 2020 Net sales by segment (USD million)
Source: Company data, IAM research



Innovative Medicines

Innovative medicines researches, develops, manufactures, distributes, and sells patented pharmaceuticals, and is composed of two global business units: Novartis Oncology (30% of the group's net sales) and Novartis Pharmaceuticals (50%). The Novartis Oncology business unit is responsible for the commercialization of products in the area of cancer and hematologic disorders. The Novartis Pharmaceuticals business unit is further organized into the following global business franchises responsible for the commercialization of various products in their respective therapeutic areas: Immunology, Hepatology and Dermatology; Ophthalmology; Neuroscience; Cardiovascular, Renal and Metabolism; Respiratory; and Established Medicines.

The Innovative Medicines division is the larger of Novartis' two divisions in terms of consolidated net sales. It reported consolidated net sales of USD 39.0 billion in 2020, which represented 80% of the group's net sales. The product portfolio of the Innovative Medicines Division includes a significant number of key marketed

products, many of which are among the leaders in their respective therapeutic areas.

The Innovative Medicines division sells products in approximately 140 countries worldwide. Net sales are primarily concentrated in the US (37% in 2020) and Europe (35%). Overall, net sales are split 76% in established markets and 24% in emerging markets.

Many of the Innovative Medicines products are used for chronic conditions that require patients to consume the product over long periods of time, ranging from months to years. However, certain of these marketed products and development projects, such as cell and gene therapies, are administered only once. Of course, the price is adjusted when a single dose can cure a patient. For example, Novartis sells the most expensive drug in the world, Zolgensma, which is a one-time intravenous gene therapy designed to address the genetic root cause of spinal muscular atrophy (SMA) by replacing the function of the missing or non-working SMN1 gene. The cost of this one-time therapy is USD 2.1 million. Because the price is so high, certain payers have received outcome-based agreements for Zolgensma. If the patient has a significant negative outcome during a five year period, Novartis will reimburse a percentage of the cost of the therapy relative to the time passed.

In 2020, Novartis had 14 drugs with net sales of over USD 1 billion each. The biggest revenue generators were Cosentyx (USD 4 bn, used for indications in psoriasis, ankylosing spondylitis, psoriatic arthritis, and axial spondyloarthritis), Gilenya (USD 3 bn, used to treat relapsing multiple sclerosis), and Entresto (USD 2.5 bn, used to treat chronic heart failure).

Sandoz

The Sandoz division is a global leader in generic pharmaceuticals and biosimilars, selling products in well over 100 countries. In 2020, the Sandoz Division achieved consolidated net sales of USD 9.6 billion, representing 20% of the group's total net sales. Sandoz develops, manufactures and markets finished dosage form medicines as well as intermediary products including active pharmaceutical ingredients.

Sandoz is organized globally into three franchises: Retail Generics, Anti-Infectives and Biopharmaceuticals. In Retail Generics, Sandoz develops, manufactures and markets active ingredients and finished dosage forms of small-molecule pharmaceuticals to third parties across a broad range of therapeutic areas, as well as finished dosage form anti-infectives sold to third parties. In Anti-Infectives, Sandoz manufactures and supplies active pharmaceutical ingredients and intermediates – mainly antibiotics – for internal use by Retail Generics and for sale to third-party customers. In Biopharmaceuticals, Sandoz develops, manufactures and markets protein- or other biotechnology-based products, including biosimilars, and provides biotechnology manufacturing services to other companies.

The Sandoz strategic ambition is to be the world's leading and most valued generics company (including biosimilars). Currently, Sandoz is the world's second generic company behind Teva. The company's divisional strategy focuses on three areas: developing a broad and consistent pipeline of off-patent launches across key geographies and across a broad range of therapeutic areas; positioning Sandoz to be "first in" by having a strong pipeline with a focus on being first to market and "last out" by way of competitive costs and stable supply; and instilling a true "generic mindset," with a focus on priorities, simple and rapid decision-making, and focused resource allocation.

Sandoz is the global market leader in biosimilars, with a total of eight approved and marketed products, and a pipeline of over 15 molecules. In addition to internally developed projects, Sandoz's biosimilar portfolio comprises publicly announced commercialization agreements with BioCon, Gan & Lee, EirGenix and Polpharma Biologics.

Sandoz is also the global market leader in generic antibiotics. Its Kundl, Austria, manufacturing site is the hub of the last vertically integrated antibiotics production chain in Europe, which offers certain competitive advantages including added supply chain resilience.

Net sales of Sandoz are primarily concentrated in Europe (54% in 2020) and the United States (22%).

Overall, net sales are split 73% in established markets and 27% in emerging markets.

History of the company

Novartis was created on March 7th 1996 when Sandoz and Ciba-Geigy decided to merge, turning it into one of the world's largest healthcare companies.

To celebrate the 25 years of the company, Novartis will create a new event center on the Novartis Campus in Basel named "Novartis Pavillon" which will be the home to the permanent exhibition "Wonders of Medicine".

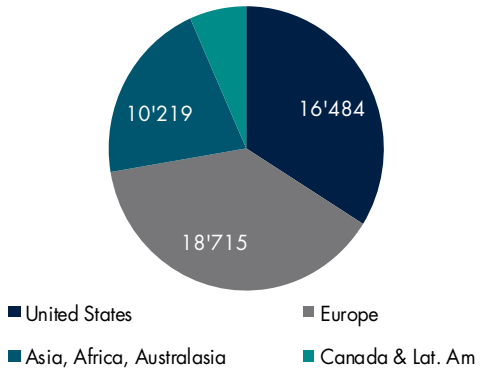
But the company can trace back its roots way further than 25 years.

Ciba started out in the 1850s as a silk-dyeing business and branched out into pharmaceuticals in 1900, by which time it was the largest chemical company in Switzerland. Geigy dates back even further, to 1758 when Johann Rudolf Geigy set up a chemist's shop in Basel and soon began manufacturing dyes for the textile industry.

Geographic exposure

The following pie chart shows Novartis' sales by region in 2020 (revenues in USD millions).

Fig.2: Revenues by region
Source: Company data, IAM research



We can see that Europe represents 38% of total sales (Sandoz is a larger proportion compared to Innovative Medicines), the United States is the second largest region, representing 34% of sales, while Asia, Africa, Australasia represents 21%. The rest of the world (regrouped under "Canada and Latin America") represents the last 7%.

Industry Overview & Competitive positioning

The global pharmaceutical market is highly competitive. Novartis competes against other major international corporations that have substantial financial and other resources, as well as against smaller companies that operate regionally or nationally. Competition within the industry is intense and extends across a wide range of activities, including pricing, product characteristics, customer service, sales and marketing, and research and development.

Like other companies selling patented pharmaceuticals, Novartis faces challenges from companies selling competing patented products. Generic forms of Novartis' products may follow the expiry of intellectual property protection, and generic companies may also gain entry to the market through successfully challenging Novartis' intellectual property rights.

To differentiate themselves, pharmaceutical companies need to invest massively into Research & Development (R&D). In fact, pharmaceutical companies cannot afford to stand still, as drug patents only last for a limited amount of years (usually 20). As soon as a medicine falls into the public domain, low-cost producers will make generics sold at much lower prices. Demand for the original branded product usually falls dramatically (at least 50%) the first year after patent expiry. Business economics indicate that the biggest margins are made on "blockbuster" drugs (those who have sales of over USD 1 billion per year).

The discovery and development of a new drug usually requires approximately 10 to 15 years from the initial research to bringing a drug to market. This includes approximately six to eight years from Phase I clinical trials to market entry. At each of these steps, there is a substantial risk that a compound will not meet the requirements to progress further. In such an event, Novartis may be required to abandon the development of a compound in which they have made a substantial investment. This is a major pitfall for healthcare investors, as a lot of decisions are binary: either products meet the study's endpoint

or not. Share price reactions can be brutal in case of disappointing results.

Novartis has approximately 5'600 full-time equivalent scientists, physicians and business professionals that work in the research department of Novartis (which they call the Novartis Institutes for BioMedical Research).

After initial assessment of drug candidates, the development team comes into play to execute the overall pipeline strategy. Novartis' global drug development organization oversees drug development for the group's innovative medicines division and works closely with the research organization. The development organization includes approximately 11'000 full-time equivalent employees worldwide.

The traditional model of development consists of three phases:

Phase I: The first clinical trials of a new compound – generally performed in a small number of healthy human volunteers – to assess the drug's safety profile, including the safe dosage range. These trials also determine how a drug is absorbed, distributed, metabolized and excreted, and the duration of its action.

Phase II: Clinical studies performed with patients who have the target disease, with the aim of continuing the Phase I safety assessment in a larger group, assessing the efficacy of the drug in the patient population, and determining the appropriate doses for further evaluation.

Phase III: Large-scale clinical studies with several hundred to several thousand patients, which are conducted to establish the safety and efficacy of the drug in specific indications for regulatory approval. Phase III trials may also be used to compare a new drug against a current standard of care to evaluate the overall benefit-risk relationship of the new medicine.

In each of these phases, physicians monitor volunteer patients closely to assess the potential new drug's safety and efficacy.

The vast amount of data that must be collected and evaluated makes clinical testing the most time-consuming and expensive part of new drug development. The next stage in the drug development process is to seek registration for the new drug.

The international pharmaceutical industry is highly regulated. Regulatory authorities around the world administer numerous laws and regulations regarding the testing, approval, manufacturing, importing, labeling and marketing of drugs, and review the safety and efficacy of pharmaceutical products. Extensive controls exist on the non-clinical and clinical development of pharmaceutical products. These regulatory requirements, and the implementation of them by local health authorities around the globe, are a major factor in determining whether a substance can be developed into a marketable product, and the amount of time and expense associated with that development.

Health authorities, including those in the US and the EU, have high standards of technical evaluation. The introduction of new pharmaceutical products generally entails a lengthy approval process. Products must be authorized or registered prior to marketing, and such authorization or registration must subsequently be maintained. In recent years, the registration process has required increased testing and documentation for the approval of new drugs, with a corresponding increase in the expense of product introduction.

To register a pharmaceutical product, a registration dossier containing evidence establishing the safety, efficacy and quality of the product must be submitted to regulatory authorities. Generally, a therapeutic product must be registered in each country in which it will be sold. In every country, the submission of an application to a regulatory authority does not guarantee that approval to market the product will be granted. Although the criteria for the registration of therapeutic drugs are similar in most countries, the formal structure of the necessary registration documents and the specific requirements, including risk tolerance, of the local health authorities can vary significantly from country to country. Even if a drug is registered and marketed in one country, the registration authority in another country may request additional information from the pharmaceutical company prior to registration or even reject the product. A drug may be approved for different indications in different countries.

The registration process generally takes between six months and several years, depending on the country, the quality of the data submitted, the efficiency of the regis-

tration authority's procedures, and the nature of the product. Many countries provide for accelerated processing of registration applications for innovative products of particular therapeutic interest. In recent years, the US and the EU have made efforts to harmonize registration requirements in order to achieve shorter development and registration times for medical products. However, the requirement in many countries to negotiate selling prices or reimbursement levels with government regulators and other payers can substantially extend the time until a product may finally be available to patients.

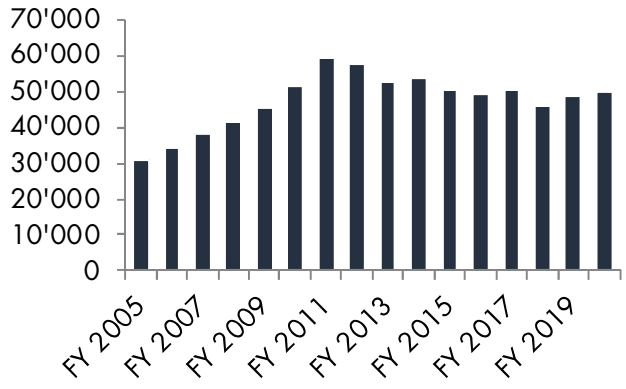
Financial analysis

Growth

The following chart shows Novartis' top line growth over time.

Fig.3: Novartis' revenues over time

Source: Company data, IAM research



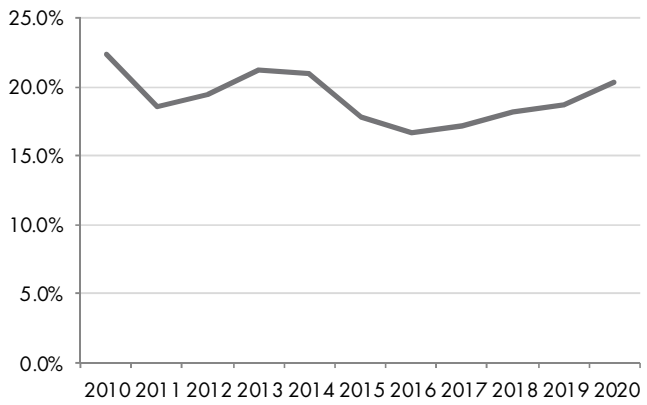
We can see that revenues seem to be stagnating or even falling since 2011. This is because these reported revenues include more than the equivalent of Novartis' businesses today (Innovative Medicines and Sandoz). Novartis has restructured itself over time and sold or spun-off several divisions (Consumer Health and Alcon for example) and has "lost" those revenues. In the future it may even be possible that the company sells the Sandoz division and could "lose" about 20% of revenues. Accounts are not re-adjusted in the past to reflect the current structure, so there is no way to obtain a "pro-forma" revenue growth.

Margins

The chart in figure 4 shows Novartis' published operating income margin.

Fig.4: Novartis' IFRS EBIT margin over time

Source: Company data, IAM research



These are non-adjusted figures, i.e.: not what Novartis calls "core operating income from continuing operations", where they deduct "extraordinary" costs like impairments of intangibles (recurring yearly) and legal charges. For us, these costs are part of doing business, and should not be excluded.

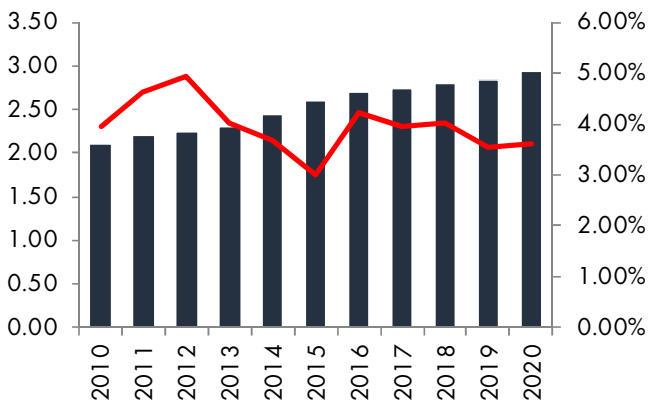
We can see that the overall margin lingers around 20%. (20.3% in 2020). Looking in detail however, Novartis discloses that the Innovative Medicines segment has a higher overall margin of 23.5% versus Sandoz's margin of only 10.8%.

Dividends

The following chart shows Novartis' dividend history over the last decade. The bars represent the dividend per

Fig.5: Dividends per share in CHF and dividend yield (rhs)

Source: Company data, IAM research



share (in CHF) and the line is the dividend yield on the day of the payment.

We can see that Novartis wants to serve a progressive dividend (ie: rising each year) and that the yield is in a range of 3—5%. Clearly, the dividend policy is a high priority for management. Usually this indicates a stable and mature company which doesn't need the money to grow fast. The payout ratio is around 60%, with big variations when EPS is low (like in 2020).

Unfortunately, we would like to remind investors that dividends are not a tax efficient way to return capital. Indeed, the dividend comes from money the company already paid taxes on, as it cannot deduct it as an expense. Afterwards, the investor is also taxed on this same amount (35% at source), so there is a double taxation of the distributed dividend. In contrast, share buybacks are a more efficient way to return capital back to shareholders, as they are only taxed at the company level.

Fortunately, Novartis' management also understood this fiscal issue and proposes regular share buybacks. The latest of which was approved for an amount of CHF 10 billion at the 2019 AGM.

Free Cash Flow

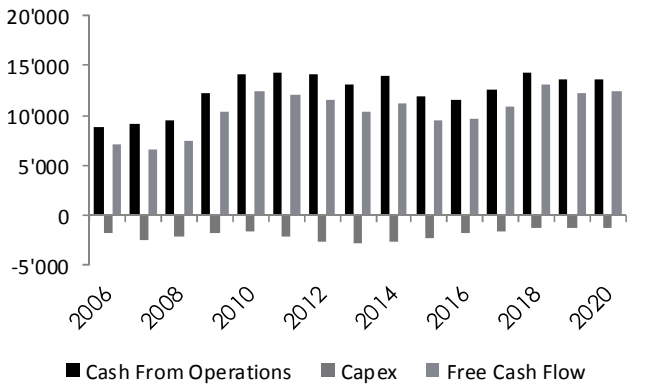
Free cash flow (FCF) is an essential component of any company and can be considered its life blood. Free cash flow refers to the cash a business generates after is has accounted for the outflow of money towards operations and maintaining capital assets. It is from FCF that the company can decide to either reimburse debt (capital allocation), make acquisitions (mergers & acquisitions), or distribute cash to shareholders (dividends and share buybacks).

The chart in figure 6 shows Novartis' Operating Cash Flow, Capital Expenditures and Free Cash Flow over the last 15 years.

What is clearly interesting, is that Novartis has very little capital expenditure requirements, which is reflected by its positive free cash flow in each year. This shows that Novartis does not need new factories to manufacturer more drugs, as either it can outsource increased demand, or re-use manufacturing capacities of declining drug products.

Fig.6: Novartis' cash flow over time

Source: IAM research



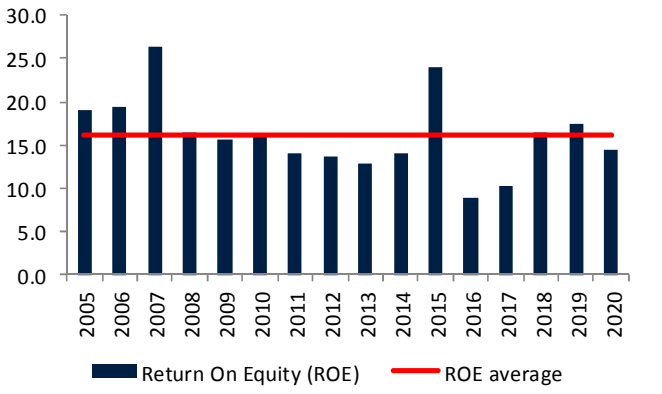
Return on Equity

The following figure shows Novartis' return on equity (ROE) over the last 15 years. The average is 16.2%.

For a company to add economic value, its ROE should be above its cost of equity. The cost of equity can be calculated with the risk free rate, the market return and the beta. Which beta to use can be subjective, so this is not a science. With current risk free rates close to zero (if not negative), we can calculate the cost of equity as the beta times the market return. Using an adjusted beta of 1.0 and historic market return of 8%, we find a cost of equity of 8%. This means that Novartis is adding economic value with its average ROE of 16.2%.

Fig.7: Return On Equity (ROE %)

Source: Company data, IAM research

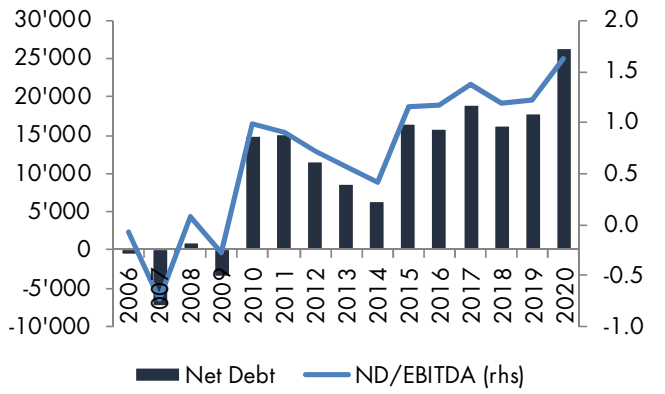


Balance Sheet

The chart in figure 8 shows Novartis' Net Debt, as well as their Net Debt to EBITDA ratio.

Fig. 8: Net Debt (ND) and ND/EBITDA

Source: Company data, IAM research



Since 2015, we see that management was willing to take on more debt as the ND/EBITDA ratio steadily increased. In an environment with low interest rates, this is to be expected. 2020 showed another increase in debt due to the pandemic, and we would consider 1.5 ND/EBITDA to be the upper limit. About a third (USD 10 bn) of Novartis' long term debt will need to be renewed in the next 5 years.

Investment case

Investing in a company implies discounting the future cash flows the company can generate. In the case of Novartis, this is essentially a bet on management's capability of discovering new drugs/treatments that will be able to replace old treatments whose patents inevitably expire. So there is a double hurdle: successfully find innovative new drugs to replace old treatments whose revenues decline/disappear and then grow revenues.

When analyzing pharmaceutical companies, it is quite difficult to evaluate the potential of even late-stage assets. Not only does the drug need proof that it works, it needs to be approved by the authorities, and finally it needs to be paid for by the insurers. And there is also an external factor whereby competitors may well bring out a superior product shortly after approval. For these reasons, investors have fairly large disparities in peak sales per drug, so uncertainty is high. In order to avoid such extremes, we take the consensus forecasts for the pipeline of new products.

Current consensus estimates 3% per annum top-line growth over the next 3 years. The growth rate may seem low, but it's in line with long-term historic growth. Obviously, Novartis is not a growth company anymore, that's why management focuses on dividends.

Valuation

The chart in figure 9 depicts Novartis' price to earnings (P/E) multiple over the past decade and its average (12.8x).

Fig.9: 12M forward P/E over last decade

Source: IAM research

We believe the company is about fairly valued, as it neither deserves a premium nor a discount to the sector. A P/E multiple around its past average seems fair.

Risks

Risks are numerous and mostly already discussed.

One important risk that needs to be mentioned is a reputation risk, which we could classify as Governance in ESG. Indeed, Novartis has been subject of several court cases where they were accused of bribery and corruption, mishandling of pharmaceuticals studies, illegal marketing practices, market price collusion, and other product liability claims. Past case settlements have cost the company several hundreds of millions of USD, so these cases are not irrelevant. For example, in relation to the US investigation of alleged kickbacks to doctors at educational events between 2001 and 2011, Novartis has put aside USD 700 millions in cash reserves to settle.