



27th May 2019

## NOVARTIS

Healthcare  
Pharmaceuticals

## BUY

Fair Value CHF96 vs. CHF93 (+13%)  
Share price CHF84.70  
EPS 3Y Cagr 7.7%

## Zolgensma and Piqray approved by the FDA on the same day

## Happy end of the week for Novartis

At the Meet-The-Management meeting, the understanding was clear that discussions were coming to an end with the agency about Zolgensma and that only the spectrum of the label was still being debated. Actually it could well be that Novartis was the one to advocate in favour of a certain limitation, not to scare off payers and also to be able to fully serve demand from a manufacturing standpoint.

With Piqray, it seems that it even took Novartis by surprise but the company will get ready to launch the drug quickly. It is not the first PI3K inhibitor to be approved by the FDA since Aliqopa (copanlisib, Bayer) was approved 18 months ago but Piqray (alpelisib) is an alpha-specific PI3K inhibitor which may prove highly beneficial from a safety perspective and is approved for PI3K-mutated HR+/HER2- breast cancer and with hopes in other solid tumours (whereas Aliqopa is for an advanced form of NHL).

## Zolgensma receives a broad label from the FDA

About 24 hours after the MMM ended, the FDA approved Zolgensma with a very broad label that basically mentions it is for paediatric patients with SMA without any reference to the form/type of the disease. Actually the limitation is more likely to come from either the age or the weight of the patient. Where SMA is diagnosed early (including in states where it is now systematically used in pre-borns or in newly borns and not only when it is symptomatic), Zolgensma can be expected to capture a very significant share of the incidence market (Novartis expects that 100% of States will do the test by 2021). Here, the drug will be injected iv and the label introduces a limit of 13.5kg which also more or less corresponds to the upper-limit age of 2 years. This is more favourable than the initial 8.5 kg. With this label, not only will the vast majority of SMA type 1 be covered, but a significant share of the SMA type 2 market could also be addressed since it often becomes symptomatic in the first years.

The question mark relates to those who have already been diagnosed and treated with Spinraza: how many will be candidates to switch and receive Zolgensma, which may add a meaningful cohort of young patients to the list, and pretty quickly.

## Zolgensma's price is responsible

Zolgensma's price approaches the ICER recommendations i.e. USD2.125m for the single injection, able to be divided into five equal parts over five years if required for cash constraints. As of the fifth year, Spinraza becomes more expensive than Zolgensma. We took USD2.5m recently and so we are adjusting downwards but we are slightly increasing the penetration both in prevalence and in incidence to adjust for the label, thus resulting in the end in a slightly positive overall impact.

## Piqray early approved and very highly priced

There is less to say about Piqray except that the approval came very early. Actually, the main surprise came from the WAC price of USD201,500 for a year, which is well above the CDK4-6 inhibitors we took in reference. We are increasing from USD100k to USD150k the worldwide average price and move the PoS to 100%. This is mainly where our new upgrade in FV comes from since PS go up from USD1.2bn to USD2.1bn.

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## Market Data

Bloomberg / Reuters	NOVN SW/NOVN.VX
Market Cap.	CHF214,069m
E.V.	CHF215,505m
Free Float	100%
Avg. Daily volume (6m)	4,802
12m high / low	CHF84.9 / CHF64.0
Ytd Perf.	0.8%

usdM	12/18	12/19e	12/20e	12/21e
Sales	51,900	46,484	49,246	51,168
% Change		-10.4%	5.9%	3.9%
EBITDA	8,199	16,232	17,698	18,046
% Change		98.0%	9.0%	2.0%
EBIT	8,199	10,232	11,698	12,546
% Change		24.8%	14.3%	7.3%
Net Income	12,641	8,585	9,941	10,776
% Change		-32.1%	15.8%	8.4%
ROE	0.17	0.11	0.13	0.13

	12/18	12/19e	12/20e	12/21e
EV/Sales	4.2x	4.7x	4.3x	4.0x
EV/EBITDA	26.5x	13.4x	11.9x	11.2x
EV/EBIT	26.5x	21.2x	18.0x	16.2x
EPS	4.71	5.04	5.55	5.88
% change		6.9%	10.2%	6.0%
P/E	18.1x	16.9x	15.4x	14.5x
Div Yield	3.3%	3.1%	3.3%	3.4%

Next Catalyst: Today @4.30pm - Conf. Call

## Last rating Change:

[2018-7-2, If Alcon is worth USD22-23bn, then our FV is CHF95](#)

## Last FV Change:

[2019-5-24, There is more upside than downside to our central-case scenario](#)

## Last Reports:

[2019-5-24, There is more upside than downside to our central-case scenario](#)

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### Distribution of stock ratings

BUY ratings 50.3%

NEUTRAL ratings 42.9%

SELL ratings 6.7%

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