BARCLAYS

Equity Research

Healthcare | European Pharmaceuticals

15 January 2016

Novartis

It's an uphill climb to the bottom

Earnings and execution headaches: With the sector at a 30% premium to the EU market (1yr fwd PE) earnings and execution uncertainties are not en vogue, which is why we now rate Novartis a relative UW (was EW). The company's top-line growth is >50% dependent on two launch products (Entresto in heart failure and Cosentyx in psoriasis), which both need to deliver on current expectations to justify today's valuation - failure would push the '15-20 EPS CAGR below sector average exposing 17% of '20 EPS and remove CHF9/share in valuation. With Alcon (second largest division) potentially declining in '16 we see little reason for the stock to shed its discount as earnings and growth trajectory are at risk; there isn't enough pipeline news flow to protect the multiple. UW rating, PT CHF85 from CHF90 (due to poorer Alcon outlook and slower Entresto ramp).

Launch dependency: Cosentyx and Entresto are estimated (company provided consensus) to deliver a combined $1.5bn in sales in '16. Our proprietary data suggests that is a tough ask. We are optimistic on Cosentyx but less on the Entresto uptake as even amongst specialists the new written prescription share remains low. Unfortunately before Medicare blocks are removed standard prescription trends remain a poor tracker of performance but worryingly Corlanor prescriptions (also HF) are showing no signs of inflection following the removal of NDC blocks. Should the same hold true for Entresto in the next few weeks questions will start concerning whether consensus estimates looking for $5bn in revenues in 2020 are reasonable. Halving the Entresto sales estimate removes 17% from '20 earnings and exposes CHF9/share in valuation.

Alcon headache: Alcon's innovation challenges and overall growth malaise now seems well understood but despite management's promise of a 'growth acceleration plan' announced with FY15 results there is no obvious quick fix in our view. Asset disposals that are earnings dilutive but margin and growth enhancing are not obvious and there seems little choice but to sit it out. Moving Alcon pharma into Novartis pharma is clearly an option but can do little in light of the exclusivity losses that face $300m of Alcon US pharma sales in 2016 alone.

Valuation and risk: We value Novartis through a DCF valuation, assuming a risk-free rate derived from the yield curve, an equity risk premium of 5%, an asset beta of 0.9, pre-tax cost of debt based on CDS spreads and a target debt ratio of 10%. These assumptions result in a dynamic cost of capital and our price target of CHF85.

NOVN.VX: Financial and Valuation Metrics EPS USD

FY Dec	2013	2014	2015	2016	2017
EPS	4.99A	5.19A	5.06E	5.34E	5.80E
Previous EPS	4.99A	5.19A	5.00E	5.32E	6.17E
Consensus EPS	5.01A	5.14A	5.09E	5.31E	5.99E
P/E	16.4	15.8	16.2	15.4	14.2

Source: Barclays Research.
Consensus numbers are from Thomson Reuters

PLEASE SEE ANALYST CERTIFICATION(S) AND IMPORTANT DISCLOSURES BEGINNING ON PAGE 16.

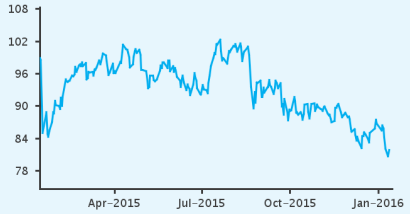
Stock Rating	UNDERWEIGHT from Equal Weight
Industry View	NEUTRAL Unchanged
Price Target	CHF 85.00 lowered -6% from CHF 90.00

Price (13-Jan-2016)	CHF 82.85
Potential Upside/Downside	+2.6%
Tickers	NOVN VX / NOVN.VX

Market Cap (CHF mn)	221789
Shares Outstanding (mn)	2676.99
Free Float (%)	84.99
52 Wk Avg Daily Volume (mn)	5.8
52 Wk Avg Daily Value (CHF mn)	474.48
Dividend Yield (%)	3.1
Return on Equity TTM (%)	11.37
Current BVPS (USD)	32.02

Source: Thomson Reuters

Price Performance	Exchange-LSE
52 Week range	CHF 103.20-80.60



Link to Barclays Live for interactive charting

European Pharmaceuticals

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European Pharmaceuticals — **Industry View: NEUTRAL**

Novartis (NOVN.VX)

Stock Rating: UNDERWEIGHT

Income statement ($mn)	2014A	2015E	2016E	2017E	CAGR
Revenue	57,996	50,404	50,663	52,472	-3.3%
Gross profit	39,175	33,513	33,767	34,930	-3.8%
EBITDA (adj)	16,202	15,263	15,806	16,768	1.2%
EBIT (adj)	14,616	13,563	14,004	14,870	0.6%
Pre-tax income (adj)	14,828	14,229	15,053	16,136	2.9%
Net income (adj)	12,757	12,114	12,771	13,695	2.4%
EPS (adj) ($)	5.19	5.06	5.34	5.80	3.8%
Diluted shares (mn)	2,470	2,446	2,433	2,402	-0.9%
DPS ($)	2.92	2.77	2.83	2.85	-0.8%

Margin and return data					Average
Gross margin (%)	67.5	66.5	66.7	66.6	66.8
EBIT (adj) margin (%)	25.2	26.9	27.6	28.3	27.0
Pre-tax (adj) margin (%)	25.6	28.2	29.7	30.8	28.6
Net (adj) margin (%)	22.0	24.0	25.2	26.1	24.3
ROIC (%)	13.2	12.9	12.8	13.8	13.1
ROE (%)	17.5	16.9	16.8	17.8	17.2

Balance sheet and cash flow ($mn)					CAGR
Tangible fixed assets	15,983	17,183	18,181	19,083	6.1%
Intangible fixed assets	53,143	54,575	51,010	47,445	-3.7%
Cash and equivalents	13,862	14,231	15,995	18,637	10.4%
Total assets	125,387	121,755	122,196	123,818	-0.4%
Short and long-term debt	20,411	21,291	21,334	21,413	1.6%
Other long-term liabilities	7,672	7,672	7,672	7,672	0.0%
Total liabilities	54,543	52,530	52,807	53,451	-0.7%
Total invested capital	92,441	90,977	89,743	88,726	-1.4%
Net debt/(funds)	6,549	7,060	5,339	2,777	-24.9%
Provisions	12,524	11,977	12,100	12,460	-0.2%
Minorities	78	68	48	28	-28.9%
Shareholders' equity	70,766	69,156	69,340	70,339	-0.2%
Change in working capital	-625	-389	-13	-23	N/A
Cash flow from operations	13,897	17,243	14,085	15,036	2.7%
Capital expenditure	-2,684	-2,900	-2,800	-2,800	N/A
Free cash flow	10,110	8,868	10,885	11,836	5.4%

Valuation and leverage metrics					Average
P/E (adj) (x)	15.8	16.2	15.4	14.2	15.4
EV/sales (x)	3.7	4.3	4.3	4.1	4.1
EV/EBITDA (adj) (x)	13.4	14.2	13.7	12.8	13.5
Equity FCF yield (%)	6.3	4.9	5.6	6.1	5.7
P/FCF (x)	15.9	20.3	18.0	16.3	17.6
P/BV (x)	2.9	2.9	2.9	2.8	2.9
Dividend yield (%)	3.6	3.4	3.4	3.5	3.5
Total debt/capital (%)	22.4	23.5	23.5	23.3	23.2
Net debt/equity (%)	14.4	15.8	13.5	10.0	13.4

Selected operating metrics					Average
SG&A/sales (%)	28.6	28.6	28.1	27.3	28.2
R&D/sales (%)	17.3	17.8	18.0	17.8	17.7
R&D growth (%)	0.2	-2.8	3.2	2.6	0.8
SG&A growth (%)	-1.6	-5.2	0.2	0.4	-1.5

Source: Company data, Barclays Research
Note: FY End Dec

Price (13-Jan-2016)	**CHF 82.85**
Price Target	**CHF 85.00**

Why Underweight? Following a drastic portfolio restructuring the company had been on track for a smoothed earnings profile. However the recent weakness in Alcon and the heavy reliance on Entresto and Cosentyx to deliver growth and margin exposes 2016 earnings estimates as well as the growth trajectory to risk.

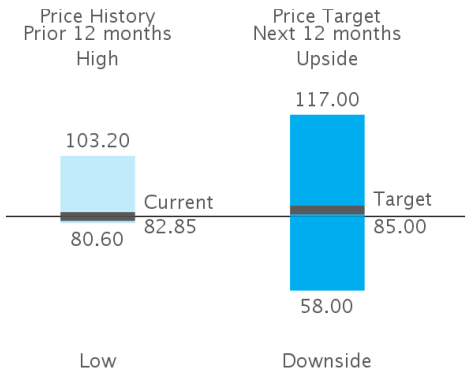
Upside case — **CHF 117.00**

The upside to our investment case resides mainly with restructuring where every $1bn in savings would add CHF3/share. A $3bn savings program would add 500bps to our margin estimate, driving the upside scenario.

Downside case — **CHF 58.00**

The downside to our investment case resides with an inability to protect the gross margin as Gleevec goes off patent (CHF6/share) as well as Entresto commercial failure in heart failure (CHF18/share). Residual downside resides with further Lucentis erosion..

Upside/Downside scenarios

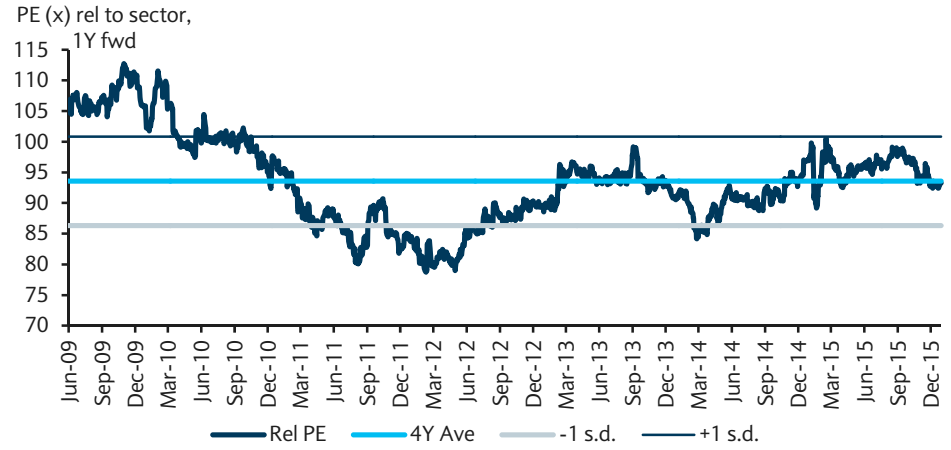


Investment summary

Novartis has de-rated over the last three months on the back of two main reasons in our view – continuing weak Alcon performance and a slower than hoped for (by the bulls) initial uptake of Entresto (Novartis' main pipeline/launch product) in heart failure. The stock has pulled back to below its 4 year average relative to the sector and we think it will struggle shed this discount as uncertainty about the growth outlook will unlikely subside anytime soon. The answer to the question 'has the valuation reached interesting levels' is a clear 'no' from our perspective.

FIGURE 1

Novartis has de-rates and given top-line exposure recovery seems unlikely

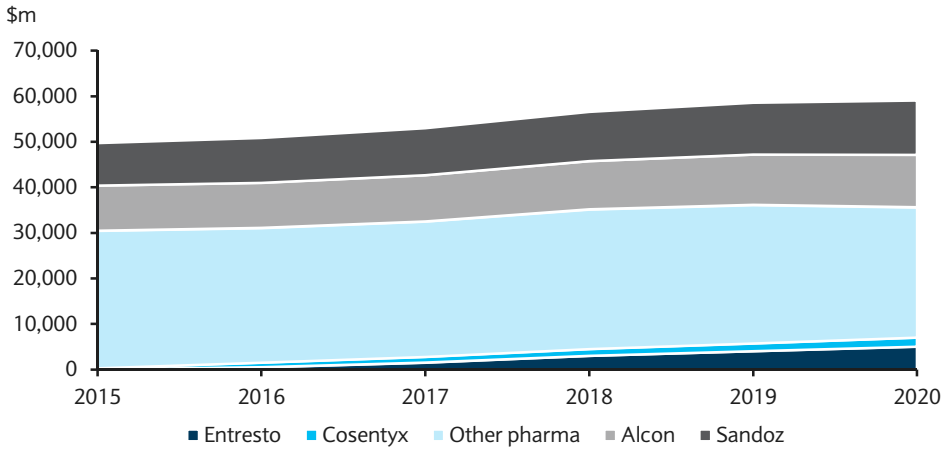


Source: Thompson DataStream, Barclays Research

Despite the promised Alcon 'growth acceleration plan' (due with FY 2015 late January) there is unlikely going to be a quick fix for the division and with >50% of 2015-20 top-line growth coming from only two products (Entresto in heart failure and Cosentyx in psoriasis) the ongoing lack of visibility especially for Entresto is going to be a major issue for the multiple in our view.

FIGURE 2

Novartis top-line growth is heavily dependent on Entresto and Cosentyx



Source: Barclays Research

The problem is that with the Gleevec US erosion unavoidable from February and Alcon facing headwinds that are not going to be fixed on the quick the company may be forced

into investing less into the launches than hoped in 2016. In turn that means the launch trajectory may stay sub-optimal for now and if our assumption about heart failure guidelines is correct (we think it is unlikely that generic ACE inhibitors will be removed from guidelines which means tough pre-authorisation requirements are here to stay) there may be little evidence to boost confidence in the $5bn consensus (company provided) peak sales estimate for Entresto. For illustrative purposes should Entresto only reach half the estimated sales potential Novartis' EPS CAGR drops to 5% and below the sector average resulting in a PEG of almost 3x, which would screen expensive v the sector – in this scenario 2020 EPS estimates would fall 17%. This sort of execution risk we believe will hold the stock back in the absence of meaningful news flow in 2016 which is why we rate Novartis a relative UW (from EW).

FIGURE 3

Under scenario where Entresto reaches 50% of current estimates the stock is expensive

($m, except per share data)	2015E	2016E	2017E	2018E	2019E	2020E	CAGR
Barclays Entresto	36	350	1000	2000	3000	4000	
Consensus Entresto	100	850	1,750	2,900	4,000	4,950	
Basic EPS Barclays	5.06	5.34	5.80	6.67	7.25	7.35	*8%*
Basic EPS Consensus	5.11	5.31	6.06	7.06	7.57	7.92	*9%*
Basic EPS Scenario 50% Entresto	5.06	5.28	5.62	6.31	6.70	6.61	*5%*
% below consensus		*-1%*	*-7%*	*-11%*	*-11%*	*-17%*	

Source: Barclays Research, Company provided consensus

Entresto – we have three problems (market potential isn't one)

As mentioned above Novartis' top-line is heavily dependent on Entresto. Confidence in the product's performance will remain a significant contributor to the stock's multiple. IMS prescription trends remain a poor tool to track the product's outlook at the moment as 65% of the product's potential patient population is treated by Medicare and 10% by Medicaid, which means reimbursement blocks (NDC blocks) deny reimbursement in the first six months for the majority of patients before things start to normalise. This at least has been the excuse why prescription trends have been slow. For illustrative purposes assuming that the current US launch trajectory continues in a linear manner, IMS prescription data projects US Entresto revenues of c$350m in 2020E.

It is thought that the launch trajectory will pick-up

a) once Medicare/Medicaid reimbursement is achieved, and

b) after ACC/AHA guideline recommendation for Entresto in 2016.

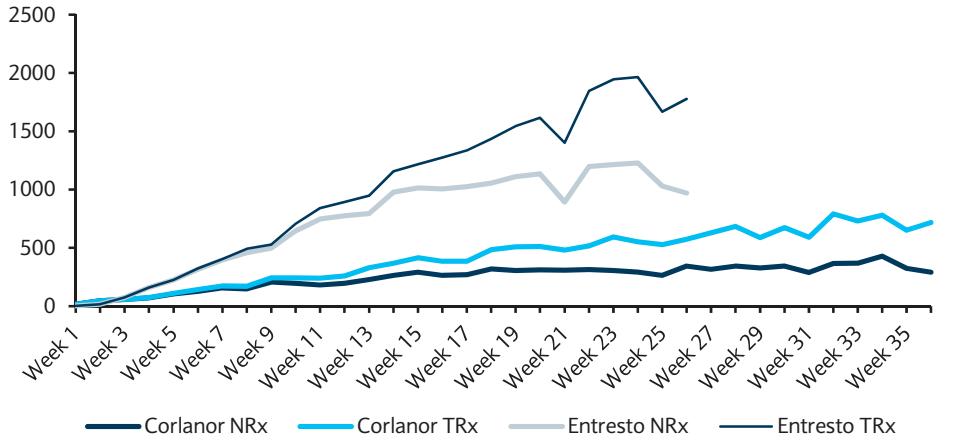
Unfortunately there has been no inflection for Amgen's Corlanor (also heart failure) which has worked through the majority of the National Drug Code (NDC) blocks and a Class1A/Class1B guideline recommendation for Entresto is unlikely to displace the Class1A recommendation for ACE inhibitors in symptomatic heart failure. It seems that at the moment pharmacy benefit managers (PBMs) have put tough pre-authorisation restrictions in place for Entresto (including prior failure on ACE inhibitors), which we believe will continue to dampen uptake especially in the primary care prescriber base which accounts for just under half of total written prescriptions. We would not be surprised to see Novartis management talk down the Entresto uptake in H1 2016 arguing for acceleration in H2 that then still will be slow.

Problem #1 – no inflection for Corlanor

Novartis estimates that the potentially eligible heart failure with reduced ejection fraction (HFrEF) patient population NYHA II-IV for Entresto is split 25% commercial, 65% Medicare Part D and 10% Medicaid/other. Whilst on the commercial side some formulary acceptance was achieved in 2015, PBMs have put tough pre-authorisation restrictions in place including prior failure on beta blockers and ACE inhibitors. For Medicare no reimbursement was anticipated for 2015 with National Drug Code (NDC) blocks in place. These NDC blocks result in significant out-of-pocket expenses for patients and even after formulary placement co-pays may represent costs up to 2-3x commercial co-pays (prior to falling into the Medicare doughnut hole) and normally these NDC blocks are removed after six (Entresto was launched in July 2015). This means in theory we should start to see an improvement in prescribing trends from January (gradual but improvement nevertheless).

FIGURE 4

Whilst Entresto's launch remains ahead of Corlanor's the lack of inflection is worrying



Source: IMS Health, Barclays Research

Amgen's Corlanor in chronic heart failure was launched in April 2015 (three months before the roll-out of Entresto) and the removal of NDC blocks should already have led to a pick-up in prescription trends as reimbursement expanded from commercial to the Medicare/Medicaid segments. Unfortunately this has not happened. Whilst significant prior authorisations and step edits are being imposed, we understand that the majority of Corlanor claims are getting approved with the last NDC blocks (Kaiser and United Health) removed by the end of 2015/early 2016. However despite access to >70% of covered lives, the Corlanor launch trajectory has remained linear since May 2015 and there has been no inflection point as NDC blocks have been removed. There is a different method of action and there is debate how applicable the European SHIFT trial is for the US market for Corlanor, but the lack of inflection is noticeable. At this point we do not understand why the removal of NDC blocks would provide an inflection point for Entresto prescriptions and not Corlanor prescriptions. Continued linear performance of prescriptions trends would not only be an issue for 2016 estimates but also the longer term outlook.

Problem #2 – will guideline updates boost Entresto in 2016?

Entrestro was approved by the FDA 7 July 2015, based on positive data from the PARADIGM-HF study (study was stopped early due to an overwhelming benefit with Entresto compared to an active control of ACE inhibitor enalapril dosed 10mg BID). Whilst the enalapril dose used in the trial is within the recommended dose range (per guidelines 10-20mg BID) and in-line with the two trials that led to inclusion of enalapril in HF guidelines (16.6mg and 18.4mg in the COnSEnSUS trial and SOLVD trials, respectively), the

trial did not use the maximum recommended dose (40mg daily as a single dose or in two divided doses).

FIGURE 5

2013 ACCF/AHA Guideline for the Management of Heart Failure (published June 2013)

Class	Interpretation	Treatment recommendation
Class 1 LOE A	Conditions for which there is evidence and/or general agreement that this procedure is useful and effective. *Based on the presence of multiple randomized clinical trials.*	**In all patients with a recent or remote history of MI or ACS and reduced EF, ACE inhibitors should be used to prevent symptomatic HF and reduce mortality. In patients intolerant of ACE inhibitors, ARBs are appropriate unless contraindicated** In all patients with a recent or remote history of MI or ACS, statins should be used to prevent symptomatic HF and cardiovascular events In patients with structural cardiac abnormalities, including LV hypertrophy, in the absence of a history of MI or ACS, blood pressure should be controlled in accordance with clinical practice guidelines for hypertension to prevent symptomatic HF **ACE inhibitors should be used in all patients with a reduced EF to prevent symptomatic HF, even if they do not have a history of MI**
Class 1 LOE B	*Based on the presence of a single randomized trial or nonrandomized studies*	In all patients with a recent or remote history of MI or ACS and reduced EF, evidence-based beta blockers should be used to reduce mortality
Class 1 LOE C	*Based on expert consensus*	Beta blockers should be used in all patients with a reduced EF to prevent symptomatic HF, even if they do not have a history of MI
Class 2a LOE B	Conditions for which there is conflicting evidence and/or a divergence of opinion about the usefulness/efficacy of performing the procedure Weight of evidence/opinion is in favor of usefulness/ efficacy *Based on the presence of a single randomized trial or nonrandomized studies*	To prevent sudden death, placement of an ICD is reasonable in patients with asymptomatic ischemic cardiomyopathy who are at least 40 days post-MI, have an LVEF of 30% or less, are on appropriate medical therapy, and have reasonable expectation of survival with a good functional status for more than 1 year
Class 3 LOE C	Conditions for which there is evidence and/or general agreement that the procedure is not useful/effective and in some cases may be harmful *Based on expert consensus*	Nondihydropyridine calcium channel blockers with negative inotropic effects may be harmful in asymptomatic patients with low LVEF and no symptoms of HF after MI

Source: Barclays Research, ACCF/AHA Guidelines; LOE – "Level Of Evidence"

The ACCF/AHA treatment guidelines for the management of heart failure classify the level of agreement on whether a medicine or procedure should be used and the level of evidence to support the recommendation. The use of ACE inhibitors such as enalapril for the treatment of patients with symptomatic heart failure whether they have a history of myocardial infarction or not is given the highest Class 1A recommendation in the guidelines. We believe that the ACCF/AHA treatment guidelines for the management of heart failure could be updated in 2016 to include treatment with Entresto based on the PARADIGM-HF trial data. However whilst Entresto could be potentially given a Class 1A / Class 1B recommendation, it is unlikely that the use of ACE inhibitors will be entirely demoted in the guidelines from a Class 1A recommendation. As an example Brilinta demonstrated a 16% reduction in the risk of cardiovascular death, non-fatal myocardial infarction and stroke in secondary prevention acute coronary syndromes patients compared to clopidogrel (a treatment benefit not dissimilar to that seen with Entresto over enalapril) yet the ACCF/AHA treatment guidelines for the management of acute coronary syndromes (updated October 2014) equally recommended clopidogrel and Brilinta at a Class 1B level but accompanied by a Class2a LOE B guideline that "it is reasonable to choose Brilinta over clopidogrel" in patients with NSTE-ACS treated with an early invasive, ischemia-guided and/or coronary stenting strategy.

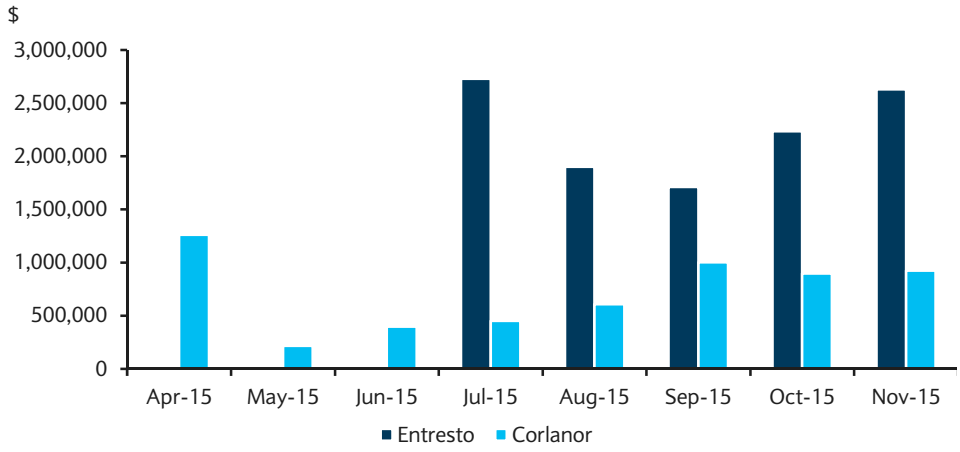
Therefore in our view, Entresto is likely to continue to be impacted by tough prior-authorisation restrictions put in place by PBMs and patients will have to fail on ACE inhibitors ahead of starting treatment with Entresto.

Problem #3 – no help yet from heart failure with preserved ejection fraction

Entresto US revenues are currently annualising at $31m based on monthly IMS MIDAS data emphasising the difficult dynamics discussed above. Given the early stages of the roll-out, we analysed leading indicator data from AlphaImpactRx to hunt for clues as to what could be holding back the Entresto launch. These data suggest that the heart failure market is currently split 73% reduced ejection fraction and 27% preserved ejection fraction in terms of Total Written prescriptions (TWRx), which is somewhat different from the 50:50 split in terms of patients that Novartis has guided towards ahead of the PARAGON-HF study which is expected to complete May 2019. Whilst cardiologists make just over two thirds of New Written Prescription (NWRx) start decisions, TWRx's are split 56:44 between cardiologists and primary care physicians.

FIGURE 6

Entresto and Corlanor revenue progression has been slow



Source: IMS MIDAS

FIGURE 7

Entresto has captured a modest share of New Written Prescription starts in reduced ejection fraction heart failure patients

Parameter	Cardiologists	PCPs	Total
NWRx share			
HFrEF	7.6%	4.7%	6.9%
HFpEF	0.0%	0.0%	0.0%
TWRx share			
HFrEF	3.4%	1.0%	2.4%
HFpEF	0.0%	0.0%	0.0%
% HF market that is dynamic			
NWRx % TWRx	27.6%	14.5%	21.2%

Source: Barclays Research, AlphaImpactRx

This data suggests that there is no off-label use of Entresto in patients with preserved ejection fraction heart failure. As of November 2015, Entresto is capturing a 6.9% NWRx share of the reduced ejection fraction heart failure opportunity, with a TRWx share of just 2.4%. We believe that the primary care prescribing base is struggling the most with the

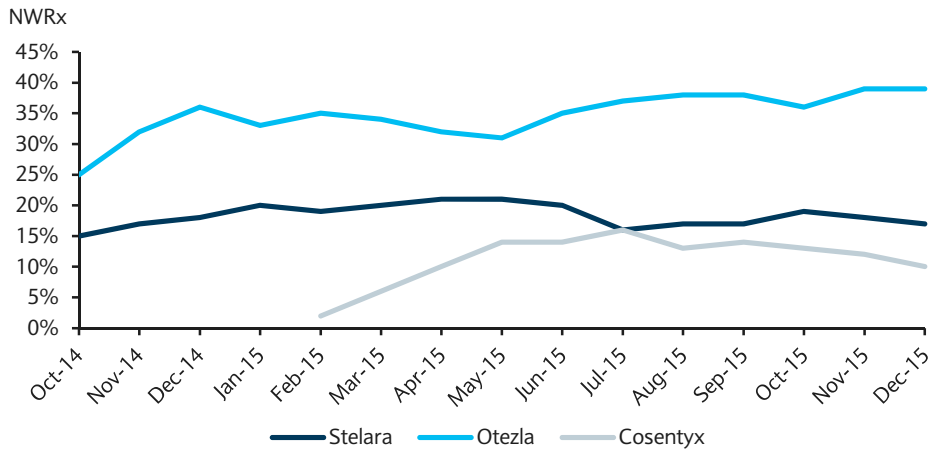
tough prior-authorisation restrictions put in place by PBMs, which is reflected in an NWRx share of 4.7%. We will continue to follow these data to see whether after capturing poorly controlled rEF heart failure patients, Entresto's NWRx share shows changes in dynamics. Whether the removal of NDC blocks and the potential for ACCF/AHA guideline changes will lead to a pickup in NWRx in 2016 remains to be seen. For now we are worried to see that even amongst specialists the new written prescription share is low (we would expect that specialists are more willing and able to get around pre-authorisation requests).

Cosentyx faring better (for now)

Cosentyx (psoriasis) is currently faring better than Entresto. Initial prescription trends may have been flattered by the loading dose of the product followed by a slight slowdown due to the monthly maintenance dosing (that is what our TWRx data suggests), and potentially there also is a small slowdown as the low hanging fruits of TNF/Stelara failures has been captured leaving the product to fight more for 1st line and methotrexate/Otezla failures. However, assuming the product continues to follow its linear launch trajectory that the IMS total prescriptions show, it is actually on track to make $1bn in 2016 revenues (our 2016 estimate v consensus $600m) in the US alone. IMS prescription volume suggests this market is expanding allowing for some share loss whilst still delivering overall growth.

FIGURE 8

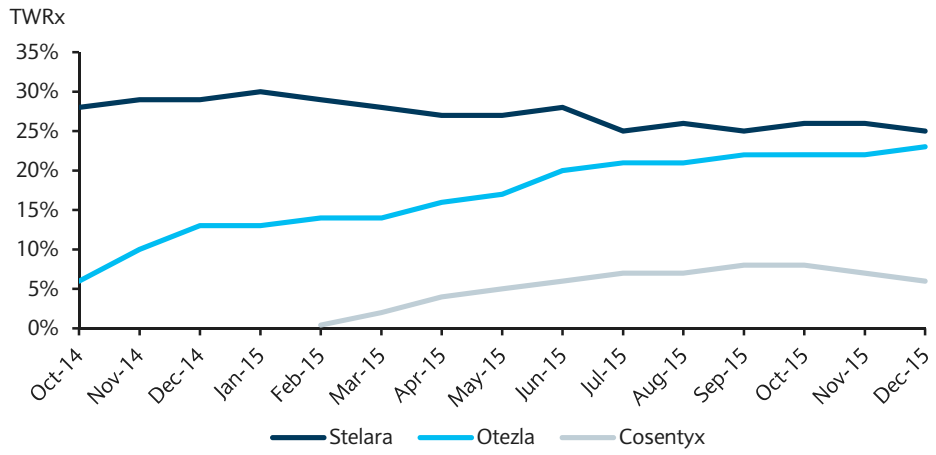
New written prescription share - dermatologists



Source: AlphaImpactRx

FIGURE 9

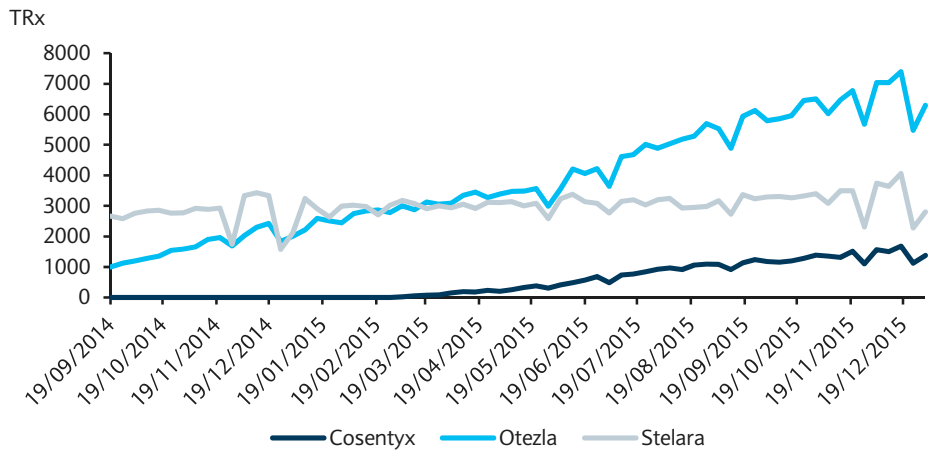
New written prescription share - dermatologists



Source: ImpactRx

FIGURE 10

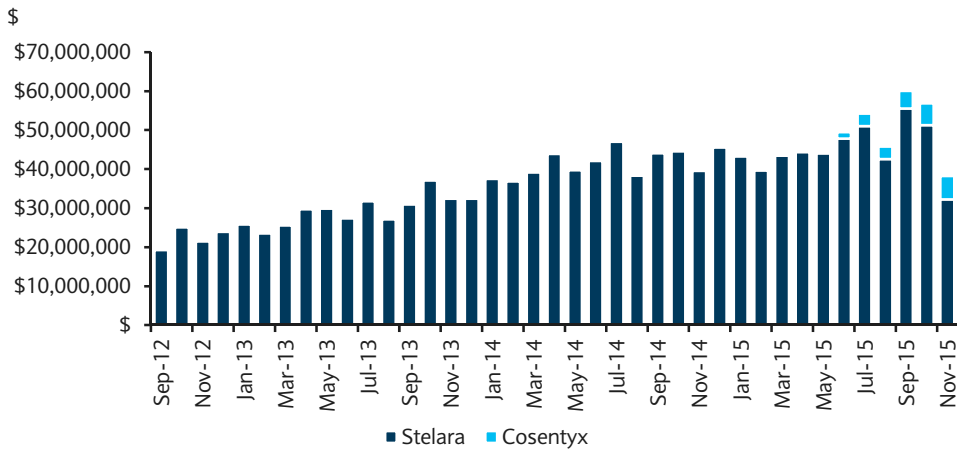
Psoriasis market prescription trends - IMS



Source: IMS Health

Cosentyx' performance in Europe is harder to grasp for now (early days) but performance in countries like Germany is encouraging (33% value share).

FIGURE 11
Cosentyx v Stelara EU revenues



Source: IMS MIDAS

As US weekly prescriptions continue to deliver, confidence in Cosentyx estimates should increase in the next few months at least ahead of the launch of competitor ixekizumab (Lilly) in H1 2016. This launch of Lilly's competing anti-IL17 agent will provide an important focus point in the roll-out of Cosentyx, with additional share of voice providing an opportunity for the IL-17 class to make further inroads into the share of incumbents Stelara, Humira and Enbrel. However on the flip-side, an important focus will be how much market share ixekizumab captures from Cosentyx based on its efficacy and more convenient dosing profile.

FIGURE 12
Cosentyx and ixekizumab dosing schedule

	Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8	Wk 9	Wk 10	Wk 11	Wk 12	..	Wk 16
Cosentyx	2x150mg	2x150mg	2x150mg	2x150mg				2x150mg				2x150mg		2x150mg
ixekizmb	2x80mg	1x80mg		1x80mg		1x80mg		1x80mg		1x80mg		1x80mg		1x80mg

Source: Barclays Research

Cosentyx is administered as two 150mg injections at the initiation of therapy, week 1, 2, 3, 4 and then monthly ie 8 individual injections in the first four weeks of treatment (10 in the first eight weeks). In the pivotal psoariasis trials at 12 weeks, Cosentyx demonstrated a PASI75 score (simplistically, 75% skin clearance) in 67-87% of patients and PASI90 score in 59% of patients. Lilly's ixekizumab is expected to be available in an autoinjector at launch, administered as two 80mg injections on treatment initiation followed by a single injection at week 2, 4, 6, 8, 10, 12 (four injections in the first four weeks and six in the first eight weeks) or a single injection at week 4, 8, 12 followed by a single 80mg injection every 4 or 12 weeks. Despite a lower injection burden, ixekizumab was able to demonstrate a PASI75 score in 87-90% of patients, a PASI90 score in 68-71% and a PASI100 in 35-41% of patients. The catch-22 is that just as the 2016/17 Entresto estimates may start to look shaky, confidence in Cosentyx might also take a hit as Lilly's product takes share.

Alcon – waiting for the growth acceleration plan

The loss of exclusivities within Alcon pharma has already impacted 2015 but an additional $300m in US revenues alone are exposed in 2016. On top of that Alcon's surgical division continues to struggle with a negative mix effect as patients are opting for mono-focal lenses instead of the higher priced multi-focal lenses (on top of that reimbursement systems

outside the US still don't really help). In general Alcon is facing an innovation problem that has driven a 2% decline in revenues (in constant currencies) in Q3, is likely to drive a further decline in Q4 and with the above mentioned loss of additional exclusivities means 2016 is also facing an uphill battle as headwinds will not annualise until late in the year. In response to this management has promised a 'grow acceleration plan' (read restructuring plan?) to be announced with the FY results. As this mostly seems to be an innovation problem though we struggle to see how aggressively management would be able to drive growth in absence of new product launches (that will take time) unless products are in-licensed (Roche opting into ex-US Fovista rights in November clearly did not help). Here are the potential options we currently see none of which really deliver the quick fix the company may want given that 2016 is already a challenging year for the group given the Gleevec US patent expiry:

- Move Alcon pharma into Novartis pharma – there may be synergies to be had from the Lucentis and Alcon pharma sales set-up/overlap but ultimately this would equate to watering the issue down by hiding it in the much larger Novartis pharma unit. Unfortunately unless the surgical division starts to grow significantly faster the impact on Alcon sales growth would be limited in the near term
- Dispose of contact lens solutions – the structural shift to daily contact lenses has had a negative effect on lens solution revenues particularly as the EM growth has not been strong enough to offset this. Novartis could look to dispose of the solutions business but given its size (we estimate $556m in 2015 or 6% of Alcon) this is not enough to move the needle from a growth perspective. It would however slightly benefit the margin
- Cost efficiency program – whilst management has previously stated that the focus for Alcon must be on the top-line and not the margin all bets may be off given things have not gone according to plan. Given that Alcon seems to be facing an innovation problem cuts to R&D seems unlikely in our view so efficiency gains would be limited to COGS and SG&A. An efficiency program is possible but with headwinds annualising in H2 we suspect management may take a watchful waiting approach before implementing such a program

Overall whilst management has options, it seems unlikely they will move the needle drastically or quickly and impacts in 2016 are likely going to be limited.

News flow – not enough in the tank

2016 is an execution year (Gleevec erosion v new oncology products acquired from GSK v Entresto and Cosentyx launch). What 2016 isn't really is a pipeline year. Overall there are only few items that we believe could cause some excitement (Tasigna treatment free remission data, LEE011, Tekturna ATMOSPHERE, serelaxin RELAX-AHF2) but there is enough controversy around each one of those items for the execution risk to remain in the driving seat. What % of Tasigna patients reaches sustained MR4.5 over 2 years and how does this stack up against Gleevec generics and tolerability being the main driver of switches in the CML market? Will Pfizer convert the accelerated Ibrance approval into full approval prior to LEE011 filing and will Lilly steal the show with abemaciclib (breakthrough status)? Would ATMOSPHERE overcome the Tasigna renal safety concerns? Who would pay for serelaxin (ER product)? Novartis' CEO is probably right that the company's early pipeline is not appreciated enough but this pipeline keeps moving out a year every year which means the near term challenges are a bigger concern for now.

FIGURE 13

Novartis near-term news flow

Date	Event	Impact	Comment
H1 2016	PKC412 filing in AML	Low	Event driven pIII trial so pushed into 2016
2016	PKC412 filing in aggressive systemic mastocytosis	Low	Filing has shifted to 2016 to allow longer follow-up time for the pivotal Phase II trial
2016	Afinitor approval in advanced non-functional carcinoid tumors	Low	Filed Q3 2015 in US, Japan and EU
2016	Signifor filing in Crushing's disease	Low	
mid 2016	Tasigna treatment free remission filing	High	Patients with MR4.5 with >2 yr of Tasigna and 1yr of sustained MR4.5 discontinued treatment and were monitored for 1 year
2016	LEE011+letrozole filing in HR+/HER2- postmenopausal advanced breast cancer 1st line breast cancer (MONALEESA-2)	Med	Phase III study enrolled but no pII data and Pfizer gained accelerated approval for Ibrance and has survival data H1 2016. Lilly's abemaciclib has breakthrough status and does not require treatment holiday (data 2017)
2016	Serelaxin RELAX-AHF2 trial in acute heart failure	High	Designed to replicate the mortality results from RELAX-AHF. Trial significantly larger than RELAX-AHF. Not stopped at interim
2016	ATMOSPHERE: Tekturna chronic heart failure outcome study results	Med	Impact of aliskiren on cardiovascular morbidity and mortality in patients with acute and chronic congestive heart failure on top of standard therapy
2016	CTL019 filing in Leukemia	Low	In Aug. 2012, Novartis acquired rights from University of Pennsylvania to CART-19 now identified as CTL019
2016	BYM338 filing in sporadic inclusion body myositis	Low	Phase II data presented at American Neurological Association October 2013. Received FDA Breakthrough Therapy designation, Q3 2013
2016	Ilaris/ACZ885 filing in hereditary periodic fevers	Low	Registration trial FPFV June 2014
2016	Fovista (OAP030A/E10030) filing in wet AMD	Med	Roche has opted in as of November 2015
2016	Gilenya filing in chronic inflammatory demyelinating polyradiculoneuropathy	Low	
2016	Arzerra CLL filing (relapsed)	Low	
2016	Afinitor filing TSC seizures	Low	
2016	Afinitor filing DLBCL	Low	Was meant to be 2017 but lower than expected event rate pushed filing out but now saying 2016 again
2016	BKM120+fulvestrant filing in mBC ER+ AI resistant/mTOR naïve	Low	BELLE-2 data disappointing - Novartis press release said no benefit overall but looking at subgroups
2016	BKM120+fulvestrant filing in 3rd line mBC ER+ (BELLE-3)	Low	
2016	Promacta/Revolade filing myelodysplastic syndrome / AML associated thrombocytopenia	Low	
2016	Tafilnar/Mekinist filing in V600+ NSCLC	Low	

2017	Tafilnar/Mekinist filing in V600+ adjuvant melanoma	Med	
2017	Zykadia/LDK378 ALK+ NSCLC post chemo, crizotininb naïve filing	Low	Phase III trial initiated 2014. Novartis has entered into a clinical collaboration with BMY to evaluate Zykadia, INC280 and EGF816 in combination with BMY's nivolumab in Phase I/II trials in NSCLC
2017	Promacta/Revolade filing myelodysplastic syndrome	Low	
2017	Gilenya pIII in chronic inflammatory demyelinating neuropathy	Low	
2017	Ilaris/ACZ885 filing secondary prevention of CV events	Med	Interim analyses mid 2015 and H2 2016
2017	LCI699 filing in Cushing's	Low	Study design changed from single arm to randomized double-blinded trial
2017	KAE609 filing in malaria	Low	
2017	CTL019 filing in DLBCL	Med	
2017	Arzerra NHL (refractory) filing	Low	
2018	Arzerra NHL (relapsed) filing	Low	
2018	Cosentyx/AIN457 filing in non-radiographic axial spondyloarthritis	Low	
2018	EGF816 filing in solid tumours	Low	
2018	INC280 filing in NSCLC	Low	
2018	LEE011+tamoxifene+goserelin or NSAI+goserelin filing in HR+/HER2- premenopausal advanced breast cancer 1st line (MONALEESA-7)	Med	
2018	QMF149 asthma filing	Low	ICS/LABA
2018	QVM149 asthma filing	Low	Triple combo
2018	Zykadia/LDK378 ALK+ NSCLC (brain mets) filing	Low	
2018	LEE011 filing in solid tumors	Low	

Source: Company data, Barclays Research

Q4 preview

FIGURE 14
Novartis 4Q15 preview

	Actuals	Barclays	
Continuing ($m except per share data)	**Q4 2014 A**	**Q4 2015E**	**% Q4 chg**
Net sales	13,131	12,769	-3%
Other revenues	224	220	-2%
COGS	(4,417)	(4,574)	4%
Gross profit	**8,938**	**8,415**	-6%
margin %	*68.1%*	*65.9%*	
Marketing & sales	(3,229)	(3,174)	-2%
% of revenues	*24.6%*	*24.9%*	
Research & development	(2,537)	(2,370)	-7%
% of revenues	*19.3%*	*18.6%*	
G&A	(736)	(683)	-7%
% of revenues	*5.6%*	*5.3%*	
Other income & expense	(88)	(138)	57%
Operating income	**2,348**	**2,050**	-13%
% margin	*17.9%*	*16.1%*	
Core operating profit	**3,226**	**3,089**	-4%
% margin	*24.6%*	*24.2%*	
Income from associate companies	582	146	-75%
Net financial income	(175)	(102)	-42%
Income before tax	**2,755**	**2,094**	-24%
Taxes	(308)	(308)	0%
Tax rate	*11.2%*	*14.7%*	
Net income	**2,447**	**1,786**	-27%
Minority interest	3	5	67%
NI attributable to Novartis shareholders	2,450	1,791	-27%
Average number of shares outstanding	2,406	2,405	0%
Core EPS (basic)	1.19	1.19	0%
Sales by division			
Pharmaceuticals	7,860	7,850	0%
Sandoz	2,512	2,492	-1%
Alcon	2,703	2,452	-9%
Core EBIT by division			
Pharmaceuticals	1,977	2,077	5%
% margin	*25.2%*	*26.5%*	
Sandoz	416	435	5%
% margin	*16.6%*	*17.5%*	
Alcon	895	660	-26%
% margin	*33.1%*	*26.9%*	
Corporate/Other	(62)	(118)	90%

Source: Company data, Barclays Research

FIGURE 15
Novartis 4Q15 preview

$m	Q4 2014 A	Q4 2015E	% chg
Diovan	379	278	-27%
Gleevec	1,237	1,246	1%
Tasigna	428	457	7%
Promacta	0	121	
Votrient	0	181	
Mekinist/Tafilnar	0	144	
Femara	98	71	-28%
Lucentis	588	0	-100%
Sandostatin	416	406	-2%
Exelon	240	142	-41%
Sandimmun/ Neoral	164	135	-18%
Xolair	200	193	-4%
Voltaren	172	174	1%
Exforge	298	236	-21%
Exjade	243	236	-3%
Comtan/Stalevo	89	73	-18%
Ritalin	128	84	-35%
Myfortic	131	120	-9%
Galvus	295	280	-5%
Gilenya	666	704	6%
Afinitor	426	415	-3%
Onbrez	56	42	-25%
Seebri	42	37	-12%
Ultibro	51	66	29%
Cosentyx	0	132	
Misc. Other	1,513	1,879	24%
Total Pharma sales	**7,860**	**7,850**	0%

Source: Barclays Research, Company data

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Primary Stocks (Ticker, Date, Price)

Novartis (NOVN.VX, 13-Jan-2016, CHF 82.85), Underweight/Neutral, A/C/D/E/J/K/L/M/N

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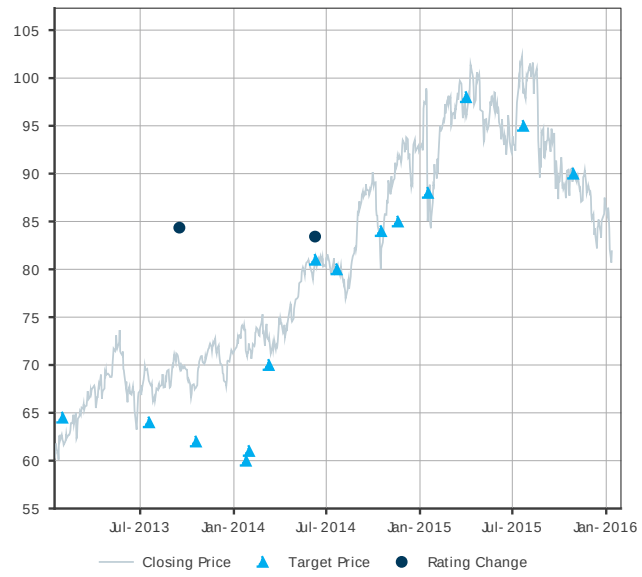
Novartis (NOVN VX / NOVN.VX)

Stock Rating	Industry View
CHF 82.85 (13-Jan-2016)	**UNDERWEIGHT**	**NEUTRAL**

Rating and Price Target Chart - CHF (as of 13-Jan-2016) — **Currency=CHF**



Date	Closing Price	Rating	Adjusted Price Target
28-Oct-2015	89.65		90.00
22-Jul-2015	98.40		95.00
01-Apr-2015	96.45		98.00
16-Jan-2015	85.05		88.00
18-Nov-2014	91.75		85.00
16-Oct-2014	80.00		84.00
21-Jul-2014	79.65		80.00
09-Jun-2014	79.60	Equal Weight	81.00
10-Mar-2014	72.60		70.00
30-Jan-2014	72.25		61.00
24-Jan-2014	71.50		60.00
18-Oct-2013	67.60		62.00
16-Sep-2013	69.90	Underweight	
18-Jul-2013	68.35		64.00
29-Jan-2013	62.40		64.50

Source: Thomson Reuters, Barclays Research

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Source: IDC, Barclays Research

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