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4Q18 Earnings Large-Cap Pharma/Biotech: NVS, BIIB, AMGN, CELG, AZN & GILD

TABLE 1: Large-Cap Pharma/Biotech Coverage

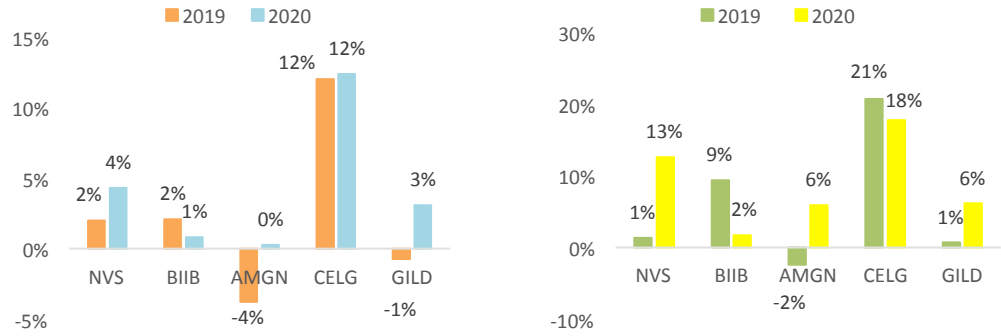
	Mkt. Price 2/5/19	Fwd. P/E	YTD	Viola Advisory Rating	Viola Advisory PT	Upside Potential 52-wk High	Upside Potential PT	Dividend Yield
NVS	88.95	15.1	5.8%	Buy	100.00	4%	12%	3.36%
BIIB	336.99	11.6	10.6%	Buy	350.00	15%	4%	n/a
AMGN	188.31	12.7	-1.9%	Buy	205.00	12%	9%	3.02%
CELG	88.14	7.0	32.3%	Hold	90.00	14%	2%	n/a
AZN	37.00	12.7	-2.1%	Buy	42.00	13%	14%	3.89%
GILD	67.68	9.5	6.7%	Buy	80.00	25%	18%	3.25%

Source: Yahoo Finance, Estimize.com, and YCharts.com

I. FY2019-2020 Revenue/EPS Growth and 4Q18 Earnings Summary: NVS, BIIB, AMGN, CELG, AZN & GILD

Both Figure 1 and Table 2 show the Street projections for both revenue and profit growth in FY2019-2020 for the large-cap pharma/biotech companies in our coverage space.

FIGURE 1: FY2019-2020 Revenue Growth (left) and EPS Growth (right)



Source: Yahoo Finance and YCharts.com

TABLE 2:

FY2019-2020 Revenue y/y Chg. (US$B) **EPS y/y Change**

	Rev. 2019	Rev. 2020	Rev. y/y Chg. 2019	Rev. y/y Chg. 2020	EPS 2019	EPS 2020	EPS y/y Chg. 2019	EPS y/y Chg. 2020
NVS	52.9	55.2	2%	4%	5.22	5.88	1%	13%
BIIB	13.7	13.8	2%	1%	28.6	29.1	9%	2%
AMG	22.8	22.9	-4%	0%	14.0	14.8	-2%	6%
CELG	17.1	19.2	12%	12%	10.7	12.6	21%	18%
AZN	23.5	25.9	6%	10%	2.11	2.92	5%	39%
GILD	21.9	22.6	-1%	3%	6.72	7.13	1%	6%

Source: Yahoo Finance and YCharts.com

Both revenue and profit estimates were generated shortly after the companies reported their 4Q18 / FY2018 earnings and provided guidance for FY2019. Both top- and bottom-line projections can serve as useful metrics for relative value comparisons as well as short-term performance indicators.

- **Novartis (BUY @ PT $100.00)**

Shortly after becoming CEO in February 2018, Vas Narasimhan pushed Novartis towards a focus on innovative medicines and leadership in digital innovation. Novartis spent $8.7 billion on acquiring gene therapy company AveXis and radiotherapy specialists Endocyte for $2.8 billion. The company also announced cuts to its manufacturing operations and confirmed the spin-off of eyecare division Alcon, which could raise as much as $35 billion this year.

On its 4Q18 earnings call, the CEO highlighted Novartis' late-stage pipeline and announced its plans for the launch of 10 new blockbuster medicines between 2018 and 2020 (see Table 3). Some of these are new products while others are expected to be expansions of existing medicines into new indications.

One of the drugs in Table 3 is a potentially groundbreaking new gene therapy – Zolgensma, which is expected to gain FDA approval in 1H19 and later in the year in Europe. The one-time potentially curative treatment for SMA has attracted a great deal of controversy partly due to Novartis saying the treatment could cost as much as $4 million per patient.

TABLE 3: Novartis List of Potential Blockbuster Drugs

Year	Drug	Indication
2018	**Aimovig**	migraine
	Kymriah	DLBCL
	Lutathera	Radionuclide therapy for Gastroenteropancreatic NETs
2019	**BYL719**	advanced breast cancer
	Mayzent	secondary progressive MS
	RTH258	neovascular age-related macular degeneration (nAMD
	Zolgensma	spinal muscular atrophy (SMA) type 1
2020	**Cosentyx**	Non-Radiographic Axial Spondyloarthropathy (nr-axSpA)
	Entresto	Heart Failure with preserved ejection fraction (HFpEF)
	INC280	non-small cell lung cancer
	OMB157	relapsing MS
	PDR001 combo	metastatic melanoma
	QMV149	asthma
	SEG101	sickle cell disease

Source: Novartis 4Q18 earnings release

The Street seems to be overall positive on Novartis' growth assessment raising its 2019 revenue and EPS growth forecast by a modest 2% and 1% respectively. However, the Street seems most bullish on the company's growth outlook for 2020 raising both top-and bottom-line growth forecast at 4% and 13% respectively. Novartis is currently trading at a Fwd. P/E of 14.9x at a slight premium to the group's average Fwd. P/E of 11.4x.

- **Biogen (BUY @ PT $350.00)**

Biogen's valuation mainly depends on three catalysts: 1) Tecfidera, its MS medicine that made up roughly 32% of FY2018 sales, 2) Spinraza, its newest blockbuster SMA medicine that grew 95% y/y in FY2018 and 3) aducanumab, its most important pipeline asset indicated for Alzheimer's Disease.

1. **Tecfidera** – sales of Tecfidera grew to $4.27 billion in 2018, a growth rate of 1% y/y while total MS product revenues including Ocrevus royalties grew to $9.07 billion, a drop of around 1% y/y. Overall, MS product sales seem to have stabilized for FY18. However, Tecfidera is facing competition from newer treatments such as Ocrevus from Roche Holding and Biogen has been looking to Spinraza, its SMA treatment to drive future growth.
2. **Spinraza** – 4Q18 sales of Spinraza grew to $470 million, a growth rate of around 30% y/y but fell short of analysts' estimate of $488 million, mostly due to pricing pressure and dosing schedule. Overseas sales of Spinraza came under pressure from patients moving to a lower-priced maintenance dose from an induction dose in some mature markets in Europe. Biogen stated that it expects global Spinraza revenue to be relatively stable in 1Q19 and expects mid- to high-teen growth in sales this year.
3. **Aducanumab** – Biogen declined to answer analysts' questions about potential data readouts on its AD drug, aducanumab. However, management did announce plans to initiate another late-stage study that will evaluate whether early use of aducanumab can prevent or delay clinical onset of Alzheimer's Disease. Two Phase 3 studies of aducanumab in early AD are expected to finish by early next year. To make matters worse, Roche recently announced that it was discontinuing two Phase 3 studies on its lead AD drug candidate, crenezumab, after an interim analysis concluded that the drug was unlikely to meet its primary goal of stopping dementia progression as measured by the Clinical Dementia Rating-Sum of Boxes Score. However, Al Sandrock, Biogen's Chief Medical Officer cautioned about too much read-through stating that aducanumab and crenezumab differ in their binding sites, selectivity and effect on amyloid plaque burden.

It seems that the Street is not so confident in Biogen's future FY2020 performance especially as it relates to aducanumab's future FDA approval. It is only projecting a 1% y/y sales growth and profit to grow by just 2% y/y in 2020. BIIB currently trades at 11.3x Fwd. P/E roughly in line with the group average of 11.4x Fwd. P/E.

- **Amgen (BUY @ PT $205.00)**

TABLE 4: Total Sales Value of Amgen Drugs Exposed to Biosimilars (US$ Million, % of Total FY18 Sales)

	FY2018	% of FY18
Oncology/Hematology		
Neulasta	4,475	20%
Aranesp	1,877	8%
Neupogen	365	2%
Total	**6,717**	**30%**
Nephrology		
Sensipar	1,774	8%
Epogen	1,010	4%
Total	**2,784**	**12%**
Inflammation		
Enbrel	5,014	22%
Total Drugs	**14,515**	**64%**
FY18 Total Product Sales	**22,533**	

Source: Amgen 4Q18/FY2018 earnings release

The current theme in Amgen's 4Q18 earnings call was the increase in biosimilar competition for their best-selling blockbuster drugs whose patents are about to expire in the near term. Management mentioned that Amgen's strategy for growth this year would be driven by volume, not price. The company projected that net selling prices for Amgen's drugs fell in 2018 and would decline further in 2019. The company reminded investors of their recent decision to lower the list price of Repatha, their best-selling high cholesterol drug, by 60%. Moreover, the company stated that there are currently no planned price increases for many of Amgen's medicines.

The FDA has currently approved 17 biosimilar products so far, this year. Of those, six biosimilars are copies of Amgen's medicines. These medicines are listed in Table 4 left.

Our analysis shows that Amgen's Oncology/Hematology group ($6.72 billion in sales) has a 30% exposure to biosimilar competition this year with Neulasta ($4.48 billion in sales) having about a 20% sales exposure. The Nephrology group ($2.78 billion in sales) has about a 12% exposure and Amgen's biggest blockbuster Enbrel ($5.01 billion in sales), the sole drug in the Inflammation Group with about a 22% sales exposure to biosimilar competition this year. Overall, the 6 drugs exposed to biosimilar competition had sales of about $14.52 billion representing around 64% of total FY2018 sales.

As a result of stiff price competition and near-term biosimilar entry, the Street is projecting Amgen's sales to decline by 4% this year and for sales to stay flat in 2020. Moreover, the Street expects Amgen's profitability to decline by 2% y/y this year and to grow by around 6% y/y in 2020.

- **Celgene (HOLD @ PT $90.00)**

Investor sentiment over Celgene seems to have improved since 3Q18 when concern over Revlimid's patent cliff seems to have dominated the stock's valuation. This quarter, the Street seems to have been convinced that strong management execution will now drive pipeline momentum and the company's dominance in the multiple myeloma space.

Management guided for FY2019 revenue ($17.0-17.2 billion) to grow at around 12% y/y supported by strong growth in Celgene's 4 blockbuster in-market drugs (see Table 5):

TABLE 5: Celgene's In-Market Blockbuster Drugs

Drug	FY2019 Guidance	Y/Y Change
Revlimid	$10.8B	+ 12%
Pomalyst/Imnovid	$2.4B	+18%
Otezla	$1.9B	+18%
Abraxane	$1.1B	+4%

Source: Celgene 4Q18 earnings release

Furthermore, management stated that in 2018, the company achieved 11 positive phase 3 clinical trials spanning hematology, oncology, immunology and new products. Moreover, management also re-affirmed that they were on track to bring 5 near-term product launches with U.S. approvals expected by the end of 2020. Each of these 5 pipeline candidates presumably could have the potential to bring in around $1 billion per year. These 5 drug candidates include:

1) Ozanimod – for multiple sclerosis
2) Fedratinib – for myelofibrosis
3) Luspatercept – for various blood disorders
4) bb2121 – for multiple myeloma
5) Liso-cel – for blood cancer

Of the 5 drug candidates, Ozanimod has the potential to bring in the highest annual peak sales revenues with the Street projecting sales at around $3 billion per year. Management believes it is on track to submit Ozanimod for regulatory approval in the U.S. by March 2019. They also believe Ozanimod has the potential to become a best-in-class medicine and they are currently in the process of building out the infrastructure necessary to ensure a world class launch.

The Street was clearly receptive to management's positive outlook, projecting Celgene's revenue to grow by 12% y/y for both 2019 and 2020 and profits to grow by 21% and 18% y/y for 2019 and 2020 respectively.

- **Gilead Sciences (BUY @ PT $80.00)**

Gilead finished FY2018 with continued weakness in their Hep C/B franchise (down 57% y/y and comprising 18% of FY2018 total product sales) and HIV portfolio (up 5% y/y and comprising 69% of FY2018 total product sales). This had the cumulative effect of decreasing FY2018 total product sales to $21.68 billion (down 16% y/y). Management gave FY2019 product sales guidance of $21.3-21.8 billion (down 2% to flat relative to FY2018) missing Street estimate of $21.8 billion.

Two positive highlights of the 4Q18 earnings call included both Biktarvy (HIV/AIDS triplet) and Yescarta (r/r DLBCL), two recently approved blockbuster medicines in 2018. Biktarvy continued to outperform in 4Q18 generating $551 million in revenues and remaining the No.1 prescribed regimen for both treatment-naïve and switch patients. Yescarta, Gilead's first CAR-T therapy, also continued to see steady growth with management projecting revenues to double this year as the number of treatment centers in the U.S. (68 centers) and Europe (12 centers) that are authorized to provide treatment with Yescarta, continues to grow.

We believe the market is valuing GILD on its upcoming data readouts. The company has announced it is anticipating data readouts from five Phase 3 clinical trials in the first half of this year (see Table 6).

TABLE 6: Gilead's Upcoming Phase 3 Clinical Trial Data Readouts

Drug	Indication	Clinical Trial	Status
Selonsertib (GS-4997)	Non-alcoholic steatohepatitis (NASH)	STELLAR 3	Phase 3 data due 2Q 2019
Selonsertib (GS-4997)	Non-alcoholic steatohepatitis (NASH)	STELLAR 4	Phase 3 data due 1Q 2019
Filgotinib	Rheumatoid arthritis (RA)	FINCH 1	Phase 3 data due 1Q 2019
Filgotinib	Rheumatoid arthritis (RA)	FINCH 3	Phase 3 data due 1Q 2019
F/TAF (Descovy)	Pre-exposure prophylaxis (PrEP)	DISCOVER	Phase 3 data due 2Q 2019

Source: Gilead 4Q18 earnings call and www.biopharmcatalysts.com

Investors are hoping that Selonsertib (indicated for NASH) and Filgotinib (indicated for RA, PsA, UC and Crohn's Disease) will be the blockbuster drugs that will help stem the revenue erosion from Gilead's legacy Hep C/B portfolio and HIV franchise. The market is anticipating the potential revenue growth from these two drug candidates to materialize in 2020 with revenue growth of 3% y/y and EPS growing at 6% y/y (see Figure 1 and Table 2). For the current year, the market is basically expecting no material changes from last year with 2019 revenue declining 1% y/y and EPS growing at just 1% y/y.

- **AstraZeneca (BUY @ PT $42.00)**

AstraZeneca (AZN) is expected to report 4Q18/FY2018 earnings on Thursday, February 14, 2019.

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Analyst Certification

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