VIOLA ADVISORY

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Initiation: Large-Cap Pharma / Biotech
3Q18 Earnings: NVS, BIIB, AMGN, CELG, AZN & GILD

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TABLE 1: Large-Cap Pharma/Biotech Coverage

	Mkt. Price 12/26/18	Fwd. P/E	YTD	Viola Advisory Rating	Viola Advisory PT	Upside Potential 52-Week High	Upside Potential PT	Dividend Yield
NVS	84.77	15.4	0.1%	Buy	90.00	11%	6%	3.53%
BIIB	295.17	10.5	-11.7%	Buy	350.00	32%	19%	n/a
AMGN	187.86	12.9	6.1%	Buy	205.00	12%	9%	3.14%
CELG	62.50	6.0	-41.1%	Hold	80.00	76%	28%	n/a
AZN	37.61	21.4	6.3%	Buy	42.00	11%	12%	3.68%
GILD	63.22	9.4	-14.7%	Buy	77.00	42%	22%	3.55%

Source: Yahoo Finance, Estimize.com, YCharts.com and Viola Advisory LLC

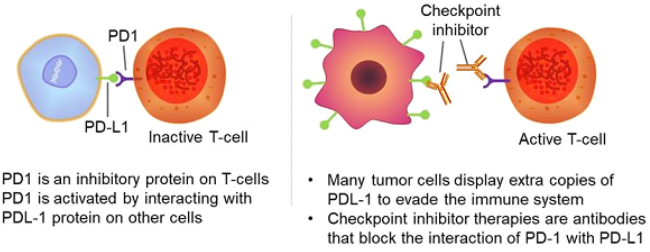
I. Major Themes FY2018: Innovative Cell & Gene Therapies and Overcrowded Immuno-Oncology Field

A. FY2018 Theme #1: Innovative Cell & Gene Therapies (CGT)

Cell & gene therapy (CGT) and its use in precision medicine cancer treatment has emerged as one of the top innovations in biotech research for 2018. The diversity of medical conditions that CGT are being evaluated for is growing, but oncological disorders remain the most commonly explored.

Dr. James P. Allison and Dr. Tasuku Honjo uncovered the role of checkpoint inhibitors in the body's immune response to cancer. Checkpoint inhibitors fight cancer by blocking mechanisms that the tumors use to protect themselves from being attacked by immune cells. The PD-1 receptor is an immune checkpoint on T cells that instructs them not to attack any cell carrying PD-L1. By blocking the interaction between PD-1 and PD-L1, the immune system's T cells attack tumor cells that produce PD-L1 in order to evade the immune system. The findings of Dr. Allison and Dr. Honjo have built the foundation for a new principle in cancer treatment – immunotherapy.

FIGURE 1: PD-1/PD-L1 Checkpoint Inhibitor: Mechanism of Action



Immunotherapy has led to a new class of drugs that has resulted in lasting remission for cancer patients. The first drugs to make it to market include Yervoy (metastatic melanoma), Opdivo (NSCLC – non-small cell lung cancer) and Keytruda (NSCLC). Dr. Allison discovered the checkpoint inhibitor CTLA-4 (the target of Yervoy) and Dr. Honjo discovered the checkpoint inhibitor PD-1 (the target of Opdivo and Keytruda).

Source: *A Killer(-T) Nobel Prize In Medicine,* Biotech Primer Weekly Newsletter #226, 10/11/18

B. FY2018 Theme #2: Immuno-Oncology (IO) Field Becoming Crowded

Immunotherapy is quickly becoming a popular therapeutic option for patients with some cancers: Its side effect profile can be mild, and when it does work in patients, it often works well. But the pipelines of biotech and pharma are quickly filling up with combination therapies for anti-PD-1 and PD-L1 antibodies. According to the Cancer Research Institute, there are currently over 1,500 clinical trials testing popular checkpoint inhibitors, an increase from 215 trials in 2016.

These drugs generally target the same immune mechanisms and will likely have a similar effect in cancers. While a handful of drugs are needed, an additional 45 may not be productive since cancer patients will simply have too many drugs that just do the same thing. Moreover, an over-crowded field could also lower the average selling price of the drug leading to a lower ROI. By 2025, the market for PD-1 and PD-L1 inhibitors could reach €30 billion, a large amount for a still nascent market.

II. FY2019 Outlook: Payer Pushback could Reduce Drug Sales Forecasts for FY2019 and FY2024

A. FY2019 Outlook: Payer Pushback Limits Drug Manufacturer's Ability to Raise Prices for Costly New Therapies

Drugmakers are counting on sales from two new drugs, to grow their revenues in FY2019. The first drug is for treatments that help prevent migraines, and the second is for a little-known but widespread liver disease called NASH. PBMs and health insurers are also focusing on these two diseases because they affect broad populations. Analysts are forecasting $5 billion in sales just for the migraine market alone.

However, payers are likely to use competition among drugmakers to negotiate deep discounts, a similar tactic they employed in 2013 when a new generation of costly hepatitis C treatments came to market. PBMs used tough negotiations to limit hep C drug costs following the launch of Sovaldi and Harvoni by Gilead back in 2014 and 2015. After bringing in $19.1 billion in 2015, Gilead forecasts hep C sales will fall to $3.5 to $4 billion this year due to intense competition and discounting. Last year, Harvoni's actual selling price dropped by more than 50% since its launch across all payers. Both hep C drugs generated widespread criticism over pricing back when they launched.

Besides competition, formulary management is another strategy that PBMs will use to negotiate lower prices. Typically, PBMs decline drug coverage in cases where they were able to negotiate a better deal for alternatives. For 2018, Express Scripts removed 64 drugs from its formulary while CVS removed 17 medicines in 10 therapeutic classes. Express Scripts said its formulary management will save $2.5 billion in drug costs next year while CVS expects its management will bring clients $13.4 billion in savings between 2012 and 2018.

As a countermeasure, drugmakers are expected to demonstrate the therapeutic value that their new drugs can offer physicians and their patients. For example, Intercept Pharmaceuticals said its NASH drug can help prevent patients from undergoing costly liver transplants and that it plans to collaborate with payers and other healthcare stakeholders to deliver effective therapies that improve patient outcomes. Meanwhile, both Lilly and Amgen said they may pursue "value-based" contracts tied to how well their migraine drugs work. Amgen stated that it plans to make its case by showing how its new migraine drug helps to increase worker productivity.

B. Top 15 Therapy Areas in Worldwide Prescription Drug Sales 2017-2024

Table 2 below shows peak sales estimates for FY2024 of worldwide prescription drugs and market share forecasts by therapy area. Some of these projections may be at risk of a downward revision given the following factors discussed earlier:

1) the rush of drug manufacturers to develop new cell and gene therapies in an increasingly overcrowded immuno-oncology space
2) public outcry over high drug prices that has intensified in recent years
3) tension between payers and drugmakers as they negotiate drug prices post-FDA drug approval
4) increasing pricing pressures brought about by the market entry of the still nascent biosimilar market
5) the impending patent cliff in FY2024

TABLE 2: Worldwide Prescription Drug and OTC Sales, by Therapy Area (2017-2024)

	Therapy Area	WW Rx Sales ($B)			WW Market Share			Rank
		2017	2024	CAGR	2017	2024	Chg. (+/-)	Chg. (+/-)
1	Oncology	104	233	12.2%	13%	19%	6.0%	0
2	Anti-diabetics	46	60	3.7%	6%	5%	-0.8%	+1
3	Anti-rheumatics	56	57	0.2%	7%	5%	-2.3%	-1
4	Vaccines	28	45	7.1%	3%	4%	0.2%	+1
5	Anti-virals	42	40	-0.9%	5%	3%	-1.9%	-1
6	Immunosuppressants	14	38	15.7%	2%	3%	1.3%	+5
7	Bronchodilators	27	32	2.5%	3%	3%	-0.7%	-1
8	Dermatologicals	13	30	13.0%	2%	2%	0.8%	+4
9	Sensory Organs	22	27	3.2%	3%	2%	-0.4%	0
10	Anti-hypertensives	23	24	0.8%	3%	2%	-0.8%	-3
11	Anti-coagulants	17	23	4.6%	2%	2%	-0.2%	-1
12	MS Therapies	23	22	-0.8%	3%	2%	-1.0%	-4
13	Anti-fibrinolytics	13	20	7.1%	2%	2%	0.1%	0
14	Anti-hyperlipidaemics	11	16	5.5%	1%	1%	-0.1%	0
15	Anti-anaemics	8	16	11.0%	1%	1%	0.4%	+3
	Top 15	445	683	6.3%	54%	55%	0.6%	
	Other	379	567	5.9%	46%	45%	-0.6%	
	Total WW Rx & OTC Sales	825	1,249	6.1%	100%	100%		

Source: World Preview 2018, Outlook to 2024, EvaluatePharma, 11th ed. June 2018

III. 3Q18 Earnings Summary & Core Therapy Areas for NVS, BIIB, AMGN, CELG, AZN & GILD

Novartis (BUY @ PT $90.00) 3Q18 Earnings Summary

Novartis = 40 drugs in portfolio	# of Drugs	% 3Q18 Sales	Trend
Oncology	14	38%	↗
Ophthalmology	4	13%	→
Neuroscience	3	10%	→
Immunology, Hepatology & Dermatology	5	10%	↗

Source: Company Financial Statements

We are bullish on Novartis heading into FY2019 based on the strength of its late-stage pipeline that has the potential to change the standard of care in high burden disease areas. The company has 3 highly advanced therapy platforms: 1) **cell-based therapy** (Kymriah as a CAR-T therapy), 2) **gene therapy** Zolgensma (formerly AVXS-101) treatment for SMA Type 1 with regulatory approvals expected in the U.S., EU and Japan in 1H19) and 3) **radioligand therapy** (Lutathera indicated for neuroendocrine tumors (NET) with developmental projects planned for indications beyond NET). Its potential blockbuster Zolgensma is on track to launch in 1H19 along with potential submissions of 7 late-stage candidates scheduled for FY2019. Furthermore, expect sales of Kymriah to re-accelerate in 2H19 once the drug's manufacturing issues are resolved.

Biogen (BUY @ PT $350.00) 3Q18 Earnings Summary

Biogen = 10 drugs in portfolio	# of Drugs	% 3Q18 Sales	Trend
Multiple Sclerosis	7	63%	→
Spinal Muscular Atrophy	1	14%	↗
Anti-CD20	1	11%	→

Source: Company Financial Statements

While investor sentiment remains downbeat driven by near-term uncertainty on Biogen's pipeline, we see a few bright spots heading into FY2019.

- First, Biogen's core MS business including Ocrevus royalties (67% of total 3Q sales) remains stable y/y. Tecfidera, Biogen's anchor MS medicine (32% of 3Q18 sales) continues to see some y/y gains despite increased competition from newer drugs.
- Second, Spinraza (14% of total 3Q sales), Biogen's newest blockbuster MS drug grew nicely posting a 73% y/y growth rate in 3Q. The number of commercial patients on Spinraza grew around 20% from last quarter as the drug continued to make progress with adults. In 3Q18, more than 50% of new starts were adults increasing the number of adult patients on Spinraza by more than 20% vs. last quarter.
- Third, the latest data readout on Biogen's Alzheimer's drug candidate BAN2401 (aducanumab) presented at CTAD in October allayed some investor concerns that the imbalance in the number of APOE4 carriers between the treatment and placebo arms was the reason for the treatment benefit on cognition that was first reported last July. Instead, the trial results may have underestimated BAN2401's effect on the cognitive endpoints. Biogen is in current discussions with the FDA on how to proceed with BAN2401 to the next Phase 3 trial.
- Fourth, biosimilars (4% of total 3Q18 sales) continues to grow at a healthy pace and will likely be a revenue stabilizer in the coming quarters, especially now that Imraldi is available in European markets. Imraldi is Biogen's adalimumab biosimilar referencing Humira. Humira sales in Europe is around $4 billion per year.

Contrary to overall market sentiment, we believe 3Q18 results point to Biogen continuing to execute well on its turnaround plan.

Amgen (BUY @ PT $205.00) 3Q18 Earnings Summary

Amgen = 14 drugs in portfolio	# of Drugs	% 3Q18 Sales	Trend
Oncology/Hematology	7	41%	→
Bone Health	2	18%	↗
Nephrology	3	14%	→
Inflammation	1	23%	↘

Source: Company Financial Statements

Amgen delivered mixed 3Q18 earnings amidst a highly competitive market driven by unit volume growth, pricing pressures and increased gross-to-net rebating. All this does not bode well for Amgen's in-line drug portfolio, especially their oncology/hematology segment and nephrology segment, which face near-term headwinds of falling market share and increased pricing pressures from an influx of biosimilars entering their market niches.

The oncology/hematology portfolio comprised 41% of total 3Q sales and includes Neulasta, Aranesp and Neupogen. Neulasta, which made up 19% of total 3Q sales, saw sales drop 6% y/y driven by lower net selling price and lower unit demand due to biosimilar competition in the U.S. market. Moreover, there was also a slight reduction in market share in the quarter. There is currently one biosim in the market and Amgen expects several more to enter by the end of next year which could pressure Neulasta sales.

The nephrology business segment makes up 14% of total 3Q sales and is comprised of Sensipar, Parsabiv and Epogen. Epogen declined 5% y/y due to lower net selling price in a category that is becoming increasingly competitive. Moreover, the company expects the potential launch of a biosim in the U.S. which would lead to a further decline in the selling price. Sensipar which made up 7% of total 3Q sales, is currently undergoing patent litigation with Sandoz, which is hoping to introduce its own biosimilar. The outlook for Sensipar is uncertain given that generic competition may enter the market in the near term.

Meanwhile, Amgen's first-in-class cardiovascular drug Repatha (around 2% of 3Q sales) is having problems accessing the Medicare Part D market (65% of the total market) because too many Medicare patients cannot afford the high copay. This is causing them to abandon their treatment at a rate as high as 75%. To make the drug more affordable and accessible, Amgen created a new NDC (National Drug Code) for Repatha at a list price of $5,850/year down from its original list price of more than $14,000/year. The company justified the roughly 60% price reduction through higher volume growth particularly as payers begin to update their Part D plans.

On a more positive note, Amgen is also developing its own biosimilar agents. The company currently has 10 biosimilars, two of which launched recently. Kanjinti, a biosimilar referencing Herceptin already launched in the EU while Amgevita, a biosimilar referencing Humira also launched across several European markets in October. Management expects biosimilars to be a blockbuster growth category and is continuing to advance 8 biosimilar programs with one biosimilar ABP 710 (Remicade) planned for U.S. and EU regulatory submission by 1Q19 and a second biosimilar ABP 959 (Soliris) advancing to a Phase 3 pivotal study.

Amgen is also working on an innovative BiTE platform (Bispecific T cell Engager) which has the potential to challenge CAR-T, the latest technology in immuno-oncology cell therapy. BiTE drugs are off-the-shelf therapies whose goal is to bring off-the-shelf medicine that an average oncologist can deliver at an academic setting or in a community hospital as opposed to specialized CAR-T centers. Because these BiTE drugs are off the shelf, they are also cheaper and less complicated to manufacture and therefore more affordable and accessible to patients who need them.

Based on the blockbuster potential of Amgen's BiTE platform as well as their biosimilar program, we believe Amgen has enough levers to withstand competitive and pricing pressures it faces heading into FY2019.

Celgene (HOLD @ PT $80.00) 3Q18 Earnings Summary

Celgene = 9 drugs in portfolio	# of Drugs	% 3Q18 Sales	Trend
Hematology/Oncology	8	88%	↗
Inflammation/Immunology	1	11%	↗

Source: Company Financial Statements

Investor sentiment for Celgene has always been less than positive given concerns over the huge patent cliff it faces when Revlimid's patent expires in FY2022 and how the company can offset the roughly $8 billion in annual revenues from Revlimid once generic competition enters the market. Management stated during the

3Q18 earnings call that they would be bringing 5 pipeline candidates to market within the next 12 to 18 months that 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, we believe that Ozanimod has the potential to bring in the highest annual peak sales revenues. This is because when approved, Ozanimod would compete directly with Gilenya, Novartis' MS drug. In its Phase 2 trials, Ozanimod helped reduce MS relapses and did so without the safety concerns commonly associated with Gilenya. Because Gilenya generates over $3 billion in annualized revenue and Ozanimod is considered the better drug, peak sales projections for Ozanimod are around $3 billion per year. Celgene expects to submit Ozanimod for regulatory approval in both the U.S. and Europe in 1Q19.

Another potential blockbuster drug could be Luspatercept which received a pair of clinical trial wins for second-line myelodysplastic syndrome (MDS) and another for treating patients with transfusion-dependent thalassemia (TDT). Consensus estimates are projecting FY2025 sales of Luspatercept to be around $1.2 billion in MDS and another $530 million in thalassemia, but with the potential to bring in an additional $1.5 billion if early take-up is faster than expected.

However, there remains one major concern around Luspatercept that involves its dosing schedule. Luspatercept requires chronic dosing via subcutaneous injection and there is a likelihood that it can be eventually replaced by gene therapies from companies such as Bluebird Bio, which aim to permanently treat diseases like thalassemia with a one-off intervention. Bluebird Bio presented an update to its TDT trial at the American Society of Haematology (ASH) meeting which showed eight out of 10 patients receiving its LentiGlobin therapy were able to become free of transfusions for at least 12 months. If that data holds true, then patients currently on Luspatercept will likely switch to Bluebird's LentiGlobin therapy for the dosing convenience.

AstraZeneca (BUY @ PT $42.00) 3Q18 Earnings Summary

AstraZeneca = 32 drugs in portfolio	# of Drugs	% 3Q18 Sales	Trend
Oncology	9	30%	↗
Cardiovascular, Renal & Metabolism	10	32%	↘
Respiratory	7	22%	↗

Source: Company Financial Statements

AstraZeneca CEO Pascal Soriot believes that 3Q18 sales growth of 9% y/y marks an inflection point in the company's turnaround plan. Moreover, he sees AZN entering a period of sustained growth driven by new medicines in oncology, CVRM and respiratory as well as an increasing footprint in the growing China drug market. The main uncertainty around AZN is whether the growth in new medicines is enough to offset the slow decline of AZN's legacy drugs. Given the 3Q results, new medicine sales grew 27% y/y while legacy drugs declined by 19% y/y. Moreover, for YTD results, new medicine sales contributed over $1.8 billion in incremental sales. In addition, 3Q18 sales in China grew 32% y/y reaching $954 million putting AZN on a pace to hit close to $4 billion in FY2018. So far, it looks as though 3Q18 results confirm that AZN's revenue trajectory is on a positive trend putting it on track to meet its full-year guidance of low-single digit growth.

Whether or not top-line growth is sustainable depends on the quality of AZN's mid- to late-stage pipeline and whether they have any innovative drug technology in mid-stage clinical trials that they are currently working on. A review of AZN's late-stage pipeline in the oncology segment shows some label expansions for existing oncology medicines and only one new compound, selumetinib that was granted orphan designation in the EU. The late-stage pipeline for the CVRM segment also shows a label expansion for existing diabetes drug Farxiga in a Phase 3 trial for the treatment of patients with heart failure but no new chemical compound. The respiratory segment looks more promising with a new drug candidate tezepelumab, indicated for severe asthma, being awarded Breakthrough Therapy Designation in the U.S. An additional compound PT010 indicated for COPD is also under regulatory submission in Japan and China.

For AZN to sustain growth, it needs to have an innovative technology platform. Fortunately, the company has formed partnerships with two biotech firms, Ionis and Innate Pharma, that are currently involved in innovative drug programs in the early- to mid-stage development. AZN formed a partnership with Ionis to develop antisense therapies for metabolic, cardiovascular and renal diseases. And as a follow up, AZN also struck a deal with Innate Pharma to in-license its anti-NKG2A antibody monalizumab and secure an option on five other pre-clinical drug candidates. Innate has shown in clinical data that monalizumab can possibly make PD-1/L1 checkpoint inhibitors such as AZN's Imfinzi more effective in cancer treatments. This has the potential of growing AZN's oncology patient pool.

Gilead Sciences (BUY @ PT $77.00) 3Q18 Earnings Summary

Gilead = 19 drugs in portfolio	# of Drugs	% 3Q18 Sales	Trend
HIV/AIDS	10	68%	↘
Liver Diseases	5	18%	↘
Hematology/Oncology	2	2%	↗

Source: Company Financial Statements

Gilead has been under pressure to prove that sales of its newer HIV products (Biktarvy and Descovy) and cancer cell therapy (Yescarta) will be strong enough to offset the faster-than-expected decline of its hepatitis C franchise. However, despite management statements that the HCV market has stabilized, the high-end of next quarter's 4Q18 guidance still shows a sequential decline in revenue. The decline in HCV sales can be attributed to the 20% decline in patients treated by Gilead's HCV medicines and competition from the likes of AbbVie's Mavyret. To restore revenue growth, the company will need additional levers to pull besides its HIV portfolio to fill the HCV void.

One potential lever is Asegua Therapeutics, a newly created subsidiary launched to sell generic versions of two HCV medicines, Epclusa and Harvoni, in the U.S. starting January 2019. The company believes that generic sales will drive volume growth by lowering out-of-pocket costs especially for Medicare patients. Moreover, lower HCV prices could also increase access for patients covered by Medicaid, which is projected to be the largest growing patient segment in the future. Management believes Asegua Therapeutics could help stem the tide of revenue erosion in the HCV portfolio in the short term.

Another lever is Yescarta, their lead CAR-T medicine for treating r/r DLBCL. However, Yescarta uptake has been slow due to billing and reimbursement issues with payers and the CMS as well as the complicated logistics required in the treatment process. Recently, CMS approved an NTAP, new technology add-on payment, to assist hospitals in the reimbursement of CAR-T therapy. CMS is also in the process of creating a CAR-T specific DRG (diagnosis-related group) which should help to cover all in-patient charges involving CAR-T treatment. However, the Street is forecasting Yescarta to grow at a 50% clip over the next 4 quarters while Gilead's projection calls for a gradual build-out in sales.

It is also difficult in the short term to be constructive on Gilead especially since their current CEO of 29 years is retiring this year and the company just chose a new CEO to start in FY2019. Investors will be waiting for a new turnaround strategy to be announced which could add to more uncertainty for both revenue and profit estimates in the coming year.

IV. Market Competitiveness, Pipeline Analysis & Future Growth Drivers: NVS, BIIB, AMGN, CELG, AZN & GILD

For the full report contact Viola Advisory, LLC at:

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