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# **Pharmaceutical Innovation Index 2018**

**White paper:  
Celebrating the most innovative  
companies in pharma**

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# Pharmaceutical Innovation Index 2018 Top 10:

The PII ranks companies by their ability to bring products from Phase I/II to market and commercialize them successfully, and utilizes a range of clinical, regulatory and commercial metrics to do this, ranging from the corporate level down to individual products

2018	Companies	Change	2017
1	AstraZeneca	+14	15
2	Gilead	+1	3
3	Johnson & Johnson	+1	4
3	Novartis	+9	12
5	Abbvie	-3	2
6	BMS	+3	9
7	Merck & Co	0	7
8	Roche	+3	11
9	Pfizer	+10	19
10	Biogen	-9	1
10	Novo Nordisk	-2	8

To explore more fully which companies occupy Pharmaceutical Innovation Index (PII) positions 11-30, please visit our <http://ideapharma.com/pii>



# Company performance, Top 10:

**The Pharmaceutical Innovation Index (PII), now in its eighth year, provides a systematic and objective assessment of how well the top 30 companies perform in successfully bringing new medicines to market and commercialising them.**

The biggest shaker this year is AstraZeneca, coming from the middle of the pack in 2017 to take the 2018 PII Crown. Gilead also continued their PII ascent, becoming the runner-up in 2018, advancing from 2017's 3<sup>rd</sup>. Johnson and Johnson, having ceded the top spot last year after a 4 year run on top, was able to regain some of the lost ground in 2018, landing in a joint 3<sup>rd</sup> spot with a rapidly-improving Novartis.

## **ASTRAZENECA [1]**

How does a company catapult from the 15th spot in 2017 all the way to the top seat on the Pharmaceutical Innovation Index? A series of strategic and successful decisions that helped generate a substantial amount of robust positive data for their pipeline and began to stem the company's downward trend since the loss of several product exclusivities between 2011 and 2017. AstraZeneca managed to launch five significant new medicines in 2017, across their primary therapy areas, including Imfinzi in advanced bladder cancer, Calquence for r/r MCL, Qtern in T2D, Bevespi Aerosphere in COPD, and finally Fasenra for severe asthma. Significantly, 2 of these 5 launches received accelerated approval. In addition to these new drug approvals, AstraZeneca accumulated 14 other regulatory approvals across indication expansion and LCM projects in major markets. Over the past year AZ has also racked up 3 Breakthrough Therapy Designations (including 2 Orphan Drug Designations) and 6 additional Priority Review Designations.

These regulatory successes are mirrored strongly with a myriad of clinical trial success and advancement. Based on key internal guidance, the company has narrowed their R&D focus to provide deeper results from their prioritized therapeutic areas, most notably oncology. Shortly after Imfinzi received accelerated approval in advanced bladder cancer, AZ announced positive top-line results for the Phase III PACIFIC trial with Imfinzi demonstrating superior PFS in patients with locally-advanced, unresectable NSCLC. In addition to these major data readouts, AZ was able to bolster their pipeline with the advancement of 14 phase II trials in 2017.

2017 wasn't without its challenges however, as the MYSTIC trial did not meet its primary endpoint of improving PFS compared to standard of care (SoC) in PD-L1 >25% in patients with 1st line NSCLC. However, the MYSTIC trial continues as planned to assess the additional primary endpoint of overall survival – a data readout that is accumulated significant investor interest. In fact, by the end of year EP Vantage reported a 27% increase in AZ share price-demonstrating both confidence in MYSTIC's OS outcomes and the bright future of AstraZeneca's pipeline.



## **GILEAD [2]**

Gilead saw an exciting continuation of last years innovative success, climbing to the 2<sup>nd</sup> spot on the PII for 2018. Despite crumbling revenues from blockbuster Harvoni (a drop off of more than half, from \$9.08 billion in 2016 to \$4.37 billion in 2017) Gilead is reporting net product sales between \$24.5 billion and 25.5 billion in 2017, up from a range of \$22.5 billion to \$24.5 billion. This increase in revenue comes from new products, such as Vosevi, as well as external acquisitions which drove increasing market share from their core strategic therapeutic areas.

Gilead has made a habit of entering markets with the goal of generating step-wise change, exemplified by both Truvada in HIV and Sovaldi in hepatitis C. When Gilead purchased Kite to join the CAR-T race, it's clear their aspiration for game-changing therapeutics was a key driver. In October, Gilead was rewarded for their jump into the cell therapy market with the approval of Yescarta for 3<sup>rd</sup> line treatment in large B-cell lymphoma. Gilead has also continued to back their CAR-T bet with additional data readouts featuring compelling long term data in non-Hodgkin's Lymphoma and aggressive expansion of treatment center education and facilitation, hoping to reach 80% of centers over the next few years.

The huge investment in Kite's CAR-T was a bold and ambitious move by Gilead. Some critics argue that the potential issues with safety, manufacturing and other real world obstacles to treatment made the \$11 billion dollar price tag too steep. Gilead hopes to overcome these criticisms by expanding the label through a wide breadth of hematological indications and becoming the hematologist's first choice in CAR-T technology.

In 2017, Gilead's Selonsertib also continued to advance, initiating a pair of phase III trials. Non-alcoholic steatohepatitis (NASH) could represent an enormous opportunity by 2020, with an expected annual market size projected between \$20 and \$35 billion. Data from the late phase trials should be available early in 2019.

Gilead's decision to continue building and developing their HIV portfolio after the acquisition of Triangle Pharmaceuticals (and Truvada) led to continued success when they could have otherwise rested on the laurels of their initial success. After watching its U.S. HIV market share gradually decline to just over 70% in Q3 2015, Gilead has seen a resurgence to 78% market share in Q3 2017. These impactful strategic decisions have paved the way for Gilead's success in 2017.

## **JOHNSON & JOHNSON [3]**

Also notching a single rung higher for the 2018 PII is Johnson & Johnson. Over the course of 2017, J&J had a strong showing of regulatory milestones, clinical data read outs and drug specific revenues. Strong growth in new products include Darzalex, for the treatment of patients with multiple myeloma, Imbruvica, for use in treating certain B-cell malignancies, and Tremfya, for the treatment of adults living with moderate to severe plaque psoriasis.



Among the biggest stars of 2017 for Johnson & Johnson was Imbruvica, which notched an enormous win with the first ever approval in graft-versus-host by the FDA. The successes continued to mount as successful long term phase 3 data readouts helped solidify the Imbruvica market position in Mantle Cell Lymphoma (MCL). Shortly after the data was announced in December, J&J received further good news when NICE reversed their previous negative opinion of Imbruvica in MCL.

Additionally, Darzalex scored massive phase 3 data in front line myeloma, demonstrating a 50% reduction in disease progression or death in newly diagnosed myeloma patients. This monumental readout, coupled with the approval of Darzalex (in combination with dexamethasone and Celgene's Pomalyst) for late line multiple myeloma patients, highlight a successful year for the therapy, despite receiving a negative opinion from NICE in March. 2017 ended – and 2018 began – positively for the Darzelex brand team however, with the FDA accepting J&J's submission and subsequently prioritizing the sBLA for their therapeutic (in combo) for the treatment of newly diagnosed multiple myeloma patients.

In addition to growth from new products, J&J managed to preserve Remicade revenues, no easy feat in a ever-rising tide of biosimilars. Over the last year, revenues declined to \$6.32 billion, a 9.3% decline from the previous year, but fared beyond expectations with the launch of infliximab biosimilars entering the US market. Ex-US has been a different tale altogether, with Remicade's market share falling to 50% in the European market, which raises the question: how will the advance of biosimilars in the US in 2018 and beyond affect revenues?

Although 2017 demonstrated some terrific success, the year was marred by the IL-6/IL-3 program failures. The FDA rejection and failure of the once-hopeful blockbuster candidate sirukumab and the discontinuation of the phase 3 trial of talacotuzumab were a low point of the 2017 year for Johnson and Johnson. To combat this pair of failures, Johnson & Johnson needed a considerable amount of help from the remainder of their established brands and pipeline to dig out – luckily for the big Pharma, many of their other therapeutic areas were able to deliver. Sales from Johnson & Johnson's 'Worldwide Pharmaceutical' unit tallied \$36.3 billion for the full-year 2017 - an increase of 8.3% versus the prior year.

## **NOVARTIS [3]**

During the last year, Novartis jumped a considerable 9 places and holds the third spot, tying with Johnson & Johnson in the 2018 PII. Major drivers for this upward movement include important new product launches and groundbreaking advancements in personalized cancer therapy.

Novartis reached three significant oncology milestones in 2017, perhaps the most important the significant milestone of achieving the first FDA approved chimeric antigen receptor T-cell (CAR-T) therapy. Kymriah, an innovative CAR-T therapy was approved in August of last year to treat children and young adults up to 25 years of age with acute lymphoblastic leukemia (ALL). The company is now in the process of seeking approval to extend the immunocellular therapy to treat adults with non-Hodgkin's lymphoma. CAR-T therapy is an innovative approach which



utilizes a patient's engineered healthy T-cells to target and kill cancer cells. Additionally, Kisqali received FDA approval as first-line treatment for (HR+/HER2-) advanced or metastatic breast cancer, and Rydapt was approved in the US for treatment of FLT3- mutated acute myeloid leukemia and three types of systemic mastocytosis.

Although Novartis faced generic competition from patent expiration of its cancer drug Gleevec/Glivec, the company's commitment to strengthening its oncology portfolio is evident with their recent developments and launches in this space. Additionally, in an effort to defend its psoriasis drug Cosentyx from new entrants, Novartis published phase 3 data indicating that 44% of patients had completely clear skin after one year of treatment and 41% maintained clear skin into the 5<sup>th</sup> year. Novartis delivered a solid financial performance in 2017 with net sales of \$49.1 billion (up 2% in constant currencies (cc)) and progressed its pipeline by delivering 16 major approvals, 6 FDA breakthrough therapy designations, and 16 major submissions.

## **ABBVIE [5]**

AbbVie, maker of 2017's global top seller Humira, holds 5<sup>th</sup> place on the 2018 PII. In 2017, AbbVie's delivered an admirable financial performance with net revenues of \$28.2 billion, a jump from \$25.6 in 2016. Humira brought in \$18.4 Billion in sales, an increase of 14.4 % on an operational basis from 2016. Its runner up, Imbruvica, for which AbbVie shares rights with J&J, brought in net revenues of \$2.5 billion, an increase of 40.5% from the prior year.

AbbVie's mega blockbuster Humira is expected to hold on to the number one spot in sales for 2018 and is on track for reaching forecasted peak sales figures of \$21 billion in 2020. This is largely thanks to last year's settlement that was reached to stave off competition in the US from Amgen's FDA approved Amjevita until Jan 31<sup>st</sup> 2023. However, Amgen is expected to launch its biosimilar in Europe later in 2018, where it may begin to steal away market share from Humira. Following its settlement with Amgen, AbbVie filled a suit for patent infringement against Boehringer Ingelheim for its FDA approved biosimilar.

The company is aggressively working towards growing its anti-inflammatory portfolio in preparation for future competition to Humira, which loses exclusivity in 2023. They announced top-line results from a phase 3 study investigating a JAK1 selective inhibitor upadacitinib (ABT-494) as a monotherapy for the treatment of patients with moderate to severe RA. In the study, 45% of patients in the 15 mg and 53% in the 30 mg group had low disease activity by week 14 of treatment. Additionally, the company reported positive results from a phase 3 study evaluating IL-23 inhibitor Risankizumab for treatment of patients with moderate to severe plaque psoriasis. Risankizumab achieved 84 to 88 percent response rates of clear to almost clear skin in patients at week 16; a response rate significantly greater compared to STELARA (ustekinumab) and HUMIRA (adalimumab).

In parallel, AbbVie is solidifying its presence in oncology with Imbruvica, a drug originally developed by Pharmacyclics, which was bought by AbbVie in 2015 for \$21 billion. The drug received expanded indication outside blood cancer in 2017, when it landed FDA approval for chronic graft-versus-host disease (cGVHD). This novel approval made Imbruvica the first drug



to ever be indicated in this space. Additionally, in oncology, AbbVie's phase 3 MURANO study evaluating Venclexta/Venclyxto (venetoclax) in combination with Roche's Rituxan in patients with relapsed or refractory chronic lymphocytic leukemia (CLL) met its primary endpoint. Venclexta is FDA approved for patients with CLL with 17p deletion. However, AbbVie has committed efforts towards expanding the role of Venclexta, seeking to become the go to therapy for patients who develop resistance to first line treatment with Imbruvica.

## **BMS [6]**

BMS holds the 6<sup>th</sup> place in the 2018 Pharmaceutical Innovation Index (PII). The company had a 7% growth in revenues from 2016, bringing in a total of \$20.8 billion in 2017. Sales for Opdivo, its star immuno-oncology drug, increased by 31% with sales of \$4.9 billion in 2017. A flurry of activity surrounded Opdivo in 2017 as BMS tried to maximize reach across global markets and expand use of the therapy across multiple cancer indications, both as a monotherapy and in combination with Yervoy.

Currently, Opdivo is approved for treatment in 9 tumor types and 15 indications. In addition to this impressive label, Bristol-Myers Squibb has recently released data that could lead to yet another approval in kidney cancer, demonstrating a 37% reduction in risk of death in patients treated with combination of Opdivo plus Yervoy. However, the biggest win for Opdivo alone or in combination (with Yervoy) would be the highly sought FDA approval in front-line treatment in non-small cell lung cancer. In international markets, the company filed a BLA for Opdivo to the China Food and Drug Administration and hopes to achieve this approval in the Chinese market where lung cancer is the most commonly diagnosed cancer.

In the cardiovascular space, Eliquis (the anticoagulant drug that BMS shares rights to with Pfizer) has seen tremendous growth in 2017. Sales of the drug increased by 46%, reaching \$4.9 billion in 2017. The next generation anticoagulant is on the way to dominating this market by steadily stealing away share from competition. Their rheumatoid arthritis drug, Orencia, had the third highest sales in 2017, followed by oncology drug Sprycel.

There is a lot to look forward to in 2018 for BMS. In oncology, BMS continues to advance its portfolio with numerous studies in phase 3. In immunoscience, the company is quickly advancing its TYK2 inhibitor in psoriasis. Finally, in fibrotic disease their FGF21 for the potential treatment of non-alcoholic steatohepatitis (NASH).

## **MERCK & CO [7]**

For Merck, Keytruda undoubtedly has stolen the spotlight in 2017. Having landed three approvals last May, for use in front-line combination therapy with chemo for patients with non-small cell lung cancer (NSCLC), first and second-line therapy in bladder cancer, as well as treatment of children and adults with microsatellite instability-high (MSI-H) or a mismatch repair deficient (dMMR) solid tumors, Keytruda's sales reflected its major regulatory successes. In 2017 the PD-L1's sales grew an impressive 172% from the previous year, bringing in \$3.8



billion in sales in 2017. Merck reported end year sales of \$40.1 billion, overall only a 1% change from prior year.

Not all news was good news for Keytruda in 2017 however, in July, Merck announced the Immuno-Oncology drug fell short of delivering a statistically significant advantage in overall survival over the current standard treatment in a phase 3 study in head and neck cancer. Later in the year, the company's ambitious attempt to move Keytruda into second line treatment for stomach-cancer was shot down by the FDA after the drug failed to meet its primary endpoint in a phase 3 trial. In addition, patient deaths in two Keytruda + chemo myeloma trials led the company to halt the trials and raised concerns in the medical and regulatory community.

In the vaccines space Merck continues to strengthen its Gardasil franchise; a Merck-funded study found that the Quadrivalent HPV vaccine Gardasil could provide protection against vaccine specific HPV types 6, 11, 16, and 18 for 10 years. Additionally, in a large phase 3 trial the newer vaccine Gardasil 9 delivered protection in subjects for at least 6 years. On the other hand, Merck's Zostervax was not viewed favorably by a CDC advisory committee on immunization practices. The group voted 8 to 7 in favor of GSK's Shingrix over Zostervax, and further expanded the recommendation in people 50 years and older. In 2018, the company is expected to file for approval for its Ebola vaccine. Last September, the company announced the termination of their Hepatitis C treatment development efforts, but with numerous programs in phase 3, we'll continue to watch closely as they progress in 2018.

## **ROCHE [8]**

Roche had a steady flow of positive news in 2017, driving the Swiss drugmaker up 3 spots in this year's PII rankings, to number 8. Their upward trend can be attributed to a combination of factors, including: a significant number of positive trial readouts, an impressive regulatory performance and solid revenue growth.

Roche's total sales rose 5% in 2017 to \$56.32 billion. Both the pharmaceutical and diagnostics divisions increased revenue by 5% from 2016. Key drivers of the pharmaceutical divisions growth came from newer drugs, mainly Ocrevus, Tecentriq, Perjeta and Alecensa, contributing \$1.48 billion in new sales.

In 2017 Roche received a number of key approvals, including two new medicines, namely Ocrevus for the treatment of relapsing and primary progressive multiple sclerosis, and Hemlibra for haemophilia A. Roche also received a number of additional approvals for existing products. These additional approvals include: Perjeta for adjuvant, as well as for neoadjuvant, use in HER2-positive breast cancer, Alecensa for 1st line treatment in ALK-positive NSCLC, Zelboraf in Erdheim-Chester disease, Gazyva for untreated advanced follicular lymphoma, Lucentis for the treatment of all forms of diabetic retinopathy, and Avastin for Glioblastoma in adult patients whose cancer has progressed.

Roche also received approval in 1st line metastatic bladder cancer for its IO therapy, Tecentriq. However, in a twist of fate, it later went on to fail a Phase III trial in its 2<sup>nd</sup> line trial in UC. Although





the failure has yet to result in the removal of Tecentriq, it did have dramatic negative impacts on Tecentriq's UC market share. Some fear could this developmental misstep could lead to future negative impacts on the assets performance in other large indications, such as NSCLC, where there is little to clearly differentiate Tecentriq from the other IO therapies.

Roche also had a number of positive clinical read outs in key areas in 2017. Of particular note were Roche's positive phase III IMpower150 and IMmotion151 studies, which both met their primary endpoint of PFS. The IMpower150 study demonstrated that the combination of Tecentriq and Avastin plus chemotherapy significantly improved PFS compared to Avastin plus chemotherapy in the first-line treatment of people with advanced non-squamous non-small cell lung cancer. The IMmotion151 study demonstrated that the combination of Tecentriq and Avastin provided a significant improvement in PFS in people who expressed PD-L1 compared with sunitinib for first-line metastatic renal cell carcinoma. Both were significant as they help to bolster Roche's newest potential blockbuster, Tecentriq, while renewing the utility of one of its historical blockbusters, Avastin, creating a very valuable cancer-fighting dynamic duo. Other positive data read outs for Roche included: positive data for Hemlibra, which delivered "clinically meaningful" reductions in the number of bleeds for hemophilia A patients, positive data for polatuzumab vedotin in combination with bendamustine plus Rituxan (BR) in r/r diffuse large B-cell lymphoma and positive data for Venclexta plus Rituxan for r/r chronic lymphocytic leukaemia (CLL).

Despite a solid year of positive news, Roche did face some challenges in 2017. One such concern came from declining sales of Tarceva and Avastin. Avastin sales declined for the first time in the US, largely due to increasing use of newer immunotherapy agents. Rituxan/MabThera also suffered a 11% revenue decrease in the EU in 2017, due primarily to the entry of biosimilars.

Overall, Roche delivered an impressive 2017 performance, with a remarkable set of new medicines and expansions into new indications where true unmet needs exist. As Roche looks to the future, they will continue to try and rejuvenate their oncology portfolio with new, innovative medicines that can help take the place of former blockbusters. Their current pipeline of oncology products is diverse and should help in their efforts to drive their continued success in the coming years.

## **PFIZER [9]**

Pfizer had quite a productive 2017, jumping up 10 spots from their 2016 ranking (19), landing at number 9 on this year's PII. Their solid performance was the result of several factors, including: significant progress on several pipeline programs, a decades best, ten approvals from the FDA, and continued strength from several core brands, including Ibrance, Eliquis and Xeljanz. Notably, global revenue for Eliquis increased by 43%, while global Xeljanz revenue grew by 47% from 2016. Against these must be balanced increased competition for the immunology blockbuster Enbrel and a lukewarm performance by the company's best-selling product, pneumococcal vaccine Prevnar 13. Overall, total revenue for Pfizer increased by 1%, with revenue from their Innovative Health Business up by 5% from 2016.



2017 was a particularly strong regulatory year for Pfizer, with a total of 10 new approvals. Particularly noteworthy was the approval of their anti- PD-L1 immuno-oncology agent, avelumab, receiving approval for the treatment of urothelial carcinoma (UC) and Merkel cell carcinoma (MCC), both coming within a span of two months. While Pfizer will face stiff competition as the 5th IO to market in UC, avelumab is the first and only IO in MCC, making it a truly innovative approval. Some of Pfizer's other key approvals this year included: Bosulif (bosutinib), Steglato (ertugliflozin), a new indication for Xeljanz (tofacitinib) in PsA, and a new indication for Sutent (sunitinib maleate) as an adjuvant treatment in RCC.

Also of note, was Pfizer's growth in emerging markets, with total revenue growth at \$1.1 billion, or 11% from 2016. Pfizer showed a continued commitment to emerging growth markets with deals like the one it made with Basilea Pharmaceuticals. In the agreement, Pfizer was given exclusive development and commercialization rights for Cresemba (isavuconazole), a novel antifungal medicine in China and several countries in the Asia Pacific region.

Some of Pfizer's biggest setbacks in 2017 came from losses of exclusivity, which negatively impacted 2017 revenues by \$2.1 billion. This included loss of exclusivity for Enbrel in Europe, Pristiq and Viagra in the U.S., and Lyrica and Vfend in Europe. A second noteworthy setback came with Pfizer's failed attempt to bolster the Lyrica franchise, when the FDA rejected Lyrica CR in the treatment of fibromyalgia.

Pfizer's biggest clinical setback came with the failure of avelumab in its phase 3 trial in advanced stomach cancer. Two of its regulatory failures in 2017 included the rejection of its Epogen biosimilar and Xtandi in breast cancer.

Also of note in late 2017 was Pfizer's decision to end its internal neuroscience discovery and early development program. Likely a result of decades of failures, Pfizer decided to shut down the program in order to re-allocate funding to other areas where the company has stronger scientific leadership.

Overall, Pfizer had a productive 2017, with a decades-high 10 new approvals that should provide solid additional revenue for years to come. Looking ahead to 2018, Pfizer is hoping for more positive outcomes in a series of upcoming regulatory decisions and clinical data readouts across their pipeline as they continue to build toward its next wave of innovative treatments.

## **BIAGEN [10]**

Despite an appreciable year of revenue growth (up 7% from 2016), Biogen dropped from 1st in 2017, to 10th on this year's PII. While still 2nd on the freshness index (percent of sales from drugs launched in the previous 5 years), a regulatory set back in their core therapeutic area (MS), a lack of positive news, and strong performances from other companies led to Biogen's drop on this year's index.

Biogen achieved 4% revenue growth in 2017, with over 90% of its revenue coming from its core MS business, despite an increasingly competitive environment in MS, led primarily



by Tecfidera.

A significant portion of this year's growth also came from Biogen's newly launched Spinraza (approved in December, 2016), which generated over \$880 million in revenue. The launch represents one of the most successful rare disease launches of all time, for which Biogen received the 2017 Prix Galien USA Award for Best Biotechnology Product.

2017 was also a year of renewing focus for Biogen. In February, Biogen completed the spin-off of its hemophilia business, Bioverativ Inc., as an independent company. In October, Biogen approved a corporate restructuring, intended to create a leaner and simpler operating model. Both efforts were intended to allow Biogen to strategically reallocate resources towards its core competencies and emerging growth areas (all in neuroscience).

Biogen also made significant progress with its emerging biosimilar business in 2017. Benepali, an etanercept biosimilar, and Flixabi, an infliximab biosimilar, both showed wide acceptance and adoption in the EU. In August, 2017 the EC also granted marketing authorization for Imraldi, an adalimumab biosimilar.

Unfortunately Biogen's latest MS asset, Zinbryta (daclizumab), failed to live up to its expectation of becoming the next best follow-up therapy for patients who stop Tysabri (natalizumab). The EMA decided to significantly restrict its use in patients just one year after its approval due to safety concerns (in March, 2018, Biogen announced a voluntary worldwide withdrawal of the product, though this was not factored into this year's PII). Though the asset was not expected to be a major blockbuster, this represents a significant setback for Biogen in its core therapeutic area (MS).

Although Biogen faced some stagnation in 2017, it is still well placed for future performance in the coming years. In 2017, Biogen added seven clinical programs to its neuroscience pipeline, indicating continued commitment to the future of its core business. Biogen's most promising pipeline asset, aducanumab, is currently in phase 3 clinical trials for prodromal AD. A positive readout as a DMT in AD would propel Biogen closer to its stated goal of becoming the fastest growing large cap biotech. Thusly, the next 12-18 months will see pivotal data readouts that will have major implications on Biogen's future success.

## **NOVO NORDISK [10]**

Tied for 10th spot on the 2018 Pharmaceutical Innovations Index is Novo Nordisk. With the change in top leadership, 2017 could have been fraught with trouble for the leader in diabetes management. To the contrary, Lars Fruergaard Jørgensen assumed the role of president & CEO on the 1st day of 2017 and has mitigated the potentially negative effects of leadership change, pricing pressures on long-acting insulins and ever increasing competition in its primary markets.

The new CEO reports that Novo Nordisk has strategically unified their efforts behind key growth drivers to ensure the company will be more competitive in the evolving diabetes market. Accordingly, sales growth in 2017 was primarily driven by Tresiba, Victoza and Saxenda- core



strategic products in Novo's portfolio- and accumulating sales growth of 2% and 5% growth in operating profit. Novo Nordisk expects these therapeutics to continue as major growth drivers in the coming years.

Regulatory approvals also highlight Novo Nordisk's performance. With the approval (and subsequent EMA recommendation) for Ozempic, the company hopes to add a new core strategic product to their diabetes portfolio. The GLP-1 was approved in December with lofty expectations for its future- with predictions ranging as high as \$2.2 billion in sales in 2022. The approval comes on the heels of data from the Sustain-7 trial which provided impressive head to head data of GLP-1 with key type-2 diabetes competitor Trulicity (Eli Lilly). The superiority data was strong in terms of both safety and efficacy, laying the ground work for a successful launch in a crowded and price-pressured environment. In addition to the success of Ozempic, Novo Nordisk received approval for Fiasp (a new fast-acting insulin) in both the US and EU. 2017 was also marked by the strengthening of data and labels for their major diabetes hallmarks, Victoza and Tresiba.

The continued specialization and innovation of Novo Nordisk within diabetes has enabled them to continue their market leadership; as evidenced by their 27% global value market share in diabetes care. We anticipate this trend to continue into 2018 and beyond.

## **Final thoughts on PII performance...**

Of the companies outside this year's top 10 rankings, most had relatively modest movements between 2017 and 2018's PII (with the exception of one). This likely speaks to the industry's lack of dynamic risk taking as a whole in 2017, with little in terms of dramatic catastrophes or major paradigm shifts.

Takeda is the exception to this, having a precipitous fall from 5<sup>th</sup> in 2017 to 31<sup>st</sup> in this year's PII. CEO Christophe Weber warned of this potential decline in the company's mid-year statement when he stated "we expect headwinds in the second half of the year". While a couple of breakthrough designations were seen, Takeda scored near the bottom on all key PII metrics, including a disappointing year in terms of R&D, regulatory approvals, key data readouts, HTA failures and key financial measures. Overall, Takeda is one of the least 'fresh' companies in terms of revenue from recently launched drugs.

Allergan and Valeant were notable new entrants to this year's PII, coming in at 16 and 18, respectively. Allergan had a solid and steady year, with middle-of-the-pack performances across all key PII metrics. Valeant had a more mixed set of PII metrics, with a very strong regulatory performance (in the top 5), but a poor freshness index (one of the worst), which taken in combination, prevented it from moving any higher than 18<sup>th</sup> in its debut on the PII.

The largest movers outside the top 10 were Teva, up 7 spots to 23<sup>rd</sup>, and Eli Lilly, up 8 places to 13<sup>th</sup>. Lilly was punching above its weight in terms of approvals, R&D and regulatory but with a low Freshness Index and poor key financial metrics. Teva, by contrast punched slightly above its weight in all metrics bar NME approvals, where it was in the top 10.

In terms of the overall PII, a key shift from 2016 to 2017 was the reclaimed supremacy of big pharma in the top 10 rankings, pushing out smaller companies.



Another key trend of 2017 was the near record number of NMEs approved by the FDA in rare diseases and oncology. While these innovative medicines are providing true clinical value to patients, they also come with an exorbitant price tag and continue to put extreme pressure on payer organizations. A key example of this came in 2017 with the launch of Luxturna, a single injection for a rare ophthalmic condition at the price of \$425,000. While some can argue that the price is justifiable given that the intervention quite literally can cure blindness, it could be the next source of backlash from both commercial payers, governmental systems and the general public. Only time will tell.

**To see what companies occupy PII positions 11-30, please visit the dedicated website at <http://ideapharma.com/pii> . And do not hesitate to get in contact should you wish to discuss anything.**



## PII Methodology

### Hypothesis:

If two companies each had the same NCE at the same stage of development (end of Phase 1), which company would do the best job of commercialising the product?

### Constraints:

Cannot measure this directly, therefore need to deploy surrogate measures.

Each measure or index must exist (somewhere), be gettable (either full or derivable), be useable (compare like with like, transferable), be available across ALL companies under consideration.

### Indices identified to date to rank top 30 pharma include (non-exclusive list):

1. Global sales – a measure of the funding available for commercialisation efforts
2. Regulatory efficiency: regulatory success ratio, investment vs company size, progression of assets to next phase, major study successes/ failures, return vs investment, etc.
3. Value proposition, need for product:
  - a. Did products achieve reimbursement, HTA approvals?
  - b. Did FDA grant expedited processing or breakthrough status?
  - c. Developing first in class NCEs or novel mechanisms of action
4. Commercialisation acumen: Sales and marketing spend, overall operating costs, vs turnover, etc.
5. 'Freshness Index' - percentage of company sales generated by products launched in the last three and five years (a measure of a company's ability to "refresh" its portfolio in the face of patent loss, providing a comprehensive portfolio, etc)
6. Snapshot of analyst rankings
7. In addition, IDEA Pharma monitors company websites, annual reports and industry sites to identify single or short- term events that would increase or decrease a company's PII ranking, e.g.
  - a. Changes in R&D strategy, research collaborations, etc.
  - b. Company restructuring to capitalise on areas of strength, optimisation of portfolios/ franchises
  - c. Innovative commercialisation or sales strategies (including social media)
  - d. Mergers and acquisitions which would increase a company's ability to generate commercial success

Each of the above are collated by company and weighted to produce the PII.

