PPIP

Pittsburgh Pharmacy Investment Portfolio

Reporting Committee

Monthly Report: February 2019

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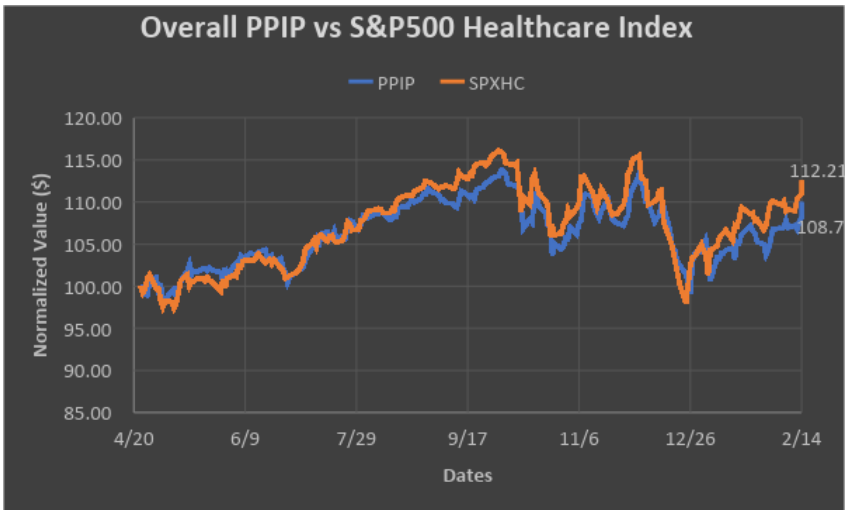
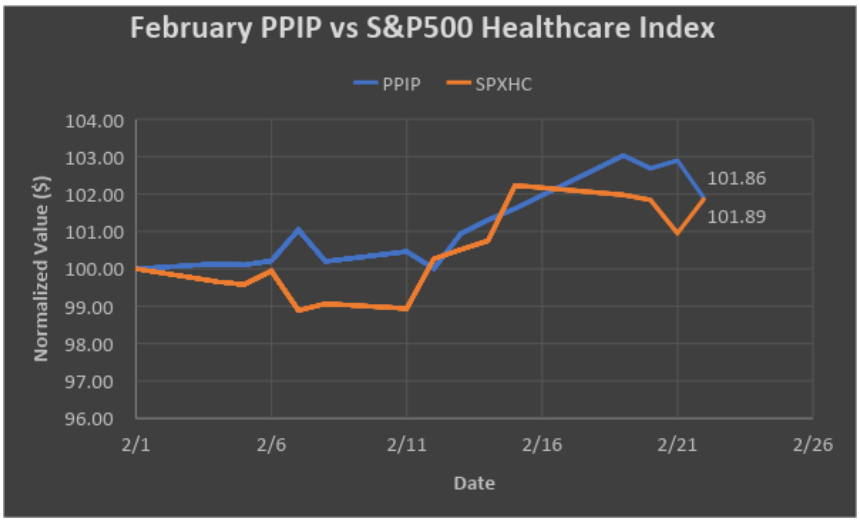
Market Comparison

From the initial investment date through February 22nd, 2019 the PPIP achieved an overall 8.73% gain. During this same period, the S&P 500 Healthcare Index (SPXHC) increased in value by 12.21%. In the context of the initial $50,000 investment, the PPIP has achieved a value of $54,365 as of February 22nd while investing in the comparator SPXHC would have yielded $56,105. Therefore, the SPXHC index has outperformed the PPIP by 3.48% during the period of 4/23/18 – 2/22/19.



From the period of February 1st through February 22nd, the PPIP achieved an overall 1.86% gain. During this same period, the SPXHC increased in value by 1.89%. In the context of a hypothetical initial $50,000 investment, the PPIP would have achieved a value of $50,930 during January while investing in the comparator SPXHC would have yielded $50,945. Therefore, the SPXHC index has outperformed PPIP by 0.03% during the period of 2/1/19 – 2/22/19.



Weakest Earners

AbbVie Inc. (ABBV): (-9.7%)

AbbVie Inc. has relied on Humira for a significant portion of its revenue, earning $19.9 billion off the product in 2018. However, biosimilars have attempted entered the market. Amgen and Samsung Bioepsis's products have already been approved in Europe, but have not yet launched because of litigation from AbbVie. While there is no direct competitor yet, AbbVie has significantly decreased the price of Humira in Europe. It is expected that a biosimilar will also be approved here in the U.S which could cause similar drops in revenue. Abbvie still owns the patent on Imbruvica through 2026- however, generics are already in development.

Gilead Sciences, Inc. (GILD): (-4.1 %)

As a company, Gilead has struggled as of late because of declining sales in their Hepatitis C drugs Harvoni and Sovaldi. Many new treatments, such as AbbVie's Mavyret and Merck's Zepatier, have entered and flourished in the market while Gilead fell behind. The patent on their PAH drug Letairis will also be ending soon and it is expected that generics will be in the market competing for market shares. Gilead is attempting to pivot to oncology, following their 2017 purchase of Kite Pharma for $11 billion.

Top Earners

Abbott Laboratories (ABT) +6.36%

- The company reported 300,000 new users for the FreeStyle Libre in Q4, more than any competitor's entire user base. A new Libre device that contains the option to alarm the patient when their blood glucose is out of range was recently launched in Europe and is expected to come to the US market "shortly."
- In the Q4 earnings call, officials forecasted Q1 year-over-year revenue growth in the mid-to-high single digits for its pharmaceutical, diagnostics, and device segments. Abbott believes that an increasing elderly population in emerging markets, such as China and India, will provide potential for stable long-term growth for medical device companies.
- The US government entered into an ongoing lawsuit from 2013 with Abbott over Medicare fraud with a company Abbott had purchased in 2017, Arriva Medical LLC. Allegedly, the company mandated all new patients receive a new glucose meter, billing Medicare, but would provide kickbacks these patients. If guilty, under the False Claims Act, Abbott would be responsible for returning three times the amount of money the government lost, as well as an added penalty for each claim.
- Abbott entered a partnership with Novo Nordisk, allowing for digital collaboration between Novo's connected pens and Abbott's Libre system. By removing patient reporting, healthcare professionals will be given more accurate data about their patient's therapy adherence and health outcomes.
- Plans were announced for a $62 million expansion on the current manufacturing plant in Columbus, OH. 38 on-site jobs would be added as a result. Project completion is expected in late 2019.
- The company's Determine HBsAg 2 test for Hepatitis B detection has received CE Mark as the most sensitive rapid diagnostic test in the world.

Johnson and Johnson (JNJ) +2.68%

- Xarelto will become the first medication in the US to provide its list price and out of pocket costs on a television commercial. It will also include the website to locate the company's prescription savings card, a practice first used last month by Eli Lilly.
- The Justice Department and SEC began investigating the company due to speculation of asbestos contaminating baby powder. This news was met with an immediate 12% drop in stock price.
- JNJ purchased Auris Health, a robotic surgery firm, for $3.4 billion as the company's breakthrough into the robotics sector. They are also partnered with Alphabet's Verily.
- A FDA advisory panel voted in favor of esketamine for the treatment of Major Depressive Disorder in those who have failed at least two prior therapies. The FDA has already recommended for implementation of a REMS program due to ensure the medication is administered in a controlled setting. The FDA is set to make a decision by March 4th.

GlaxoSmithKline (GSK) +2.96%

- The company purchases the rights to molecule M7824 from Merck KGgA (not Merck and Co.) for $4.2 billion with potential for bonuses based on achieved milestones. The cancer immunotherapy is currently in Phase II clinical trials being compared against Merck and Co.'s Keytruda.
- Bharat Biotech buys Chiron Behring Vaccines from GSK to become the largest producer of the rabies vaccine. Financial details were not reported.
- Six molecules will be removed from the company's pipeline including five from respiratory and one from rare diseases. Though GSK currently has a major influence on the respiratory market, this does not come as a surprise since they have recently announced their vision to pull back from this market to focus more resources in oncology research. Discontinued molecules include:
    - GSK1325756 (aka danirixin) – COPD
    - GSK2269557 (aka nemiralisib) – COPD
    - GSK2398852 and GSK2315698 combination – AL/ATTR-CM
    - GSK2245035 (a TLR7 agonist) – asthma
    - GSK2798745 (TRPV4 antagonist) – ARDS
    - GSK3008348 (aVb6 antagonist) – IPF

Medtronic (MDT) +2.39%

- The FDA approved the expanded indication for the Resolute Drug-Eluting Stent for the treatment of CAD with de novo chronic total occlusion.
- The FDA approved the expanded indication for the Pipeline Flex embolization device to include patients with small or medium, wide-necked brain aneurysms from the petrous to the terminus of the internal carotid artery.
- The company announced the closure of the transformative solutions facility in Portsmouth, NH "most likely within the next 12 months." This comes as part of a restructuring plan which will invest more resources into their Louisville, CO facility. All 150 employees at the Portsmouth plant will be terminated. While the company said many of the positions will be transferred to Louisville, employees with be forced to apply if they choose to relocate.
- The FDA gave a Class I assignment, the most serious, to the company's January recall of a series of pacemakers, citing a software error which can cause a lack of pacing. A total of two patients have been affected by faulty devices, but no deaths have been reported. An

update is being worked on to correct this issue in the 13,440 devices currently being used.
- The first patient was enrolled in the Embrace TTD clinical study to measure efficacy of the Synchromed II intrathecal drug delivery system for non-malignant back pain management. The study aims to enroll a total of 100 patients in an attempt to prove an alternative pain relief strategy to eliminate chronic opioid use.
- The FDA approved usage of the Accurian RF system for ablation of nerve tissues via targeted radiofrequencies. This process is minimally invasive.

Bristol-Myers Squibb (BMY) +4.64%
- NOTE: All news related to the Celgene merger in the month of February was merely speculation. The vote for the $74 billion acquisition will take place on April 15th, at which point our outlook will be evaluated.
- The European Commission approved Sprycel for the treatment of Philadelphia chromosome-positive ALL in pediatric patients. This is the first oral suspension approved for pediatric ALL in Europe.
- Phase II results from the CheckMate-650 trial testing Opdivo and Yervoy in combination for metastatic castration-resistant prostate cancer returned promising, proving efficacy without any unplanned adverse effects.
- Phase III results from the CheckMate-214 trial testing Opdivo and Yervoy in combination for advanced/metastatic RCC also returned positive, showing a greater survival benefit when compared to Pfizer's Sutent.
- With the expected merger with Celgene approaching, Bristol Myers has ended three of their twelve discovery programs with CytomX Therapeutics. The news hit CytomX hard, dropping 30% in share price upon reveal; however, the company has a sturdy pipeline, including Phase I/II trials with BMS that will report preliminary data this year.

Novartis (NVS) +4.24%
- Formed partnership with Blackstone Group LP to form a new company, Anthos Therapeutics. Blackstone will contribute $250 million to control the development of Novartis molecule MAA868, indicated to treat blood clots via targeting factor XI and XIa. Novartis had been in the process of designing Phase II clinical trials to compare the molecule against class leaders, such as Bristol-Myers' Eliquis, but all studies have since been withdrawn. Former head of Novartis' CV team, John Glasspool, has been named the CEO of Anthos.
- The company exercised their rights to purchase CV molecule TQJ230 from Ionis Pharmaceuticals for $150 million. The molecule is ready for Phase III clinical trials in CVD patients who are unable to lower their Lipoprotein A by diet or lifestyle changes. Novartis aims to add to their relatively depleted CV portfolio, which currently only contains Entresto as a large revenue stream. Expected timeline for commercialization is set for 2024.
- English health authorities approved the use of Kymriah for DLBCL, reversing last year's decision. The medication is now available in 10 European countries, but is still a distant second in terms of sales to Gilead's Yescarta ($76 million vs $183 million in 2018.)
- Clingen Group purchased the rights to Proleukin, a human recombinant IL-2 used for metastatic renal cell carcinoma, for an agreed $210 million. Clingen had already owned the ex-US rights to the medication. Proleukin had accrued $60 million in US revenue in 2018.
- The FDA approved Egaten for the treatment of fascioliasis in patients over the age of 6. This is the only medication currently indicated for the disease. While Novartis has been donating Egaten since 2005, its approval will allow for easier access worldwide. It is currently listed on the WHO's Essential medication list and is the only WHO

recommended medication for fascioliasis, a disease which currently affects 2.4 million patients worldwide.

- Novartis struck a deal with antibody discovery company, AbCellera, to be provided with up to 10 new discovery targets for an undisclosed price. This will shorten development timelines for Novartis and allow the company to allocate resources in other departments. AbCellera has a client list including: Pfizer, Merck, GSK, and Teva.