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Stock Watch: J&J's Q1 Earnings Untroubled By The IRA

Initial Earnings Euphoria Gives Way To Realism But IRA Impact Negligible

by **Andy Smith**

J&J's Q1 earnings announcement included challenges like the loss of exclusivity and competitive pressures, but the price renegotiation associated with the Inflation Reduction Act was not among them.

Expectations Were Not High

A sense of gloom preceded *Johnson & Johnson's* (J&J's) first-quarter results announcement, which opened earnings season for life science companies. The rising interest rates that scuppered Silicon Valley Bank have also raised the hurdle rate for virtually any investment.

This reminded me of the time I reported the results of the biotech fund I ran – which were positive, but not stellar – and an investor commented that he might as well have just held treasuries. The implication was that moving up the risk profile from assets like government bonds (the yields of which have been rising in an attempt to tame inflation) to biotech should be accompanied by higher returns to compensate investors for taking more risk. While this raises the bar for sales and earnings growth for the largest life science companies like J&J, the effect is magnified for earlier-stage and loss-making biotech companies where an elevated risk premium on top of base rates demands outsized returns.

Prior to J&J's results announcement, average first-quarter earnings per share (EPS) growth at S&P 500 health care companies was expected to fall by just over 20% year-over-year, although revenue growth was expected to be largely flat compared to the previous year. With that backdrop, J&J's first-quarter 2023 earnings report restored some sector pride with strong sales growth, although its EPS conformed to the pessimistic expectations

J&J Initially Positive

J&J reported first-quarter 2023 sales that grew by nearly 6% on the first quarter of 2022 and, probably due to early January pharmaceutical price increases, by over 4% on the final quarter of last year. On its conference call, J&J's CFO described pharmaceutical pricing as "not as unfavorable as we anticipated." J&J's first-quarter sales beat analysts' expectations by nearly 5% while non-GAAP EPS was nearly 8% ahead of analysts' estimates. This second facet not only managed to conform to the wider sector expectations of first-quarter EPS contraction – with J&J reporting a first-quarter of 2023 GAAP loss of \$68m due to a special talc litigation charge – but also indicated how well-briefed its analysts must have been ahead of the announcement. The analysts from Stifel's first reaction to J&J's results was "an encouraging start to 1Q23."

J&J's stock price traded up by over 1% in the premarket as investors basked in its first-quarter sales growth and increases to its full-year guidance and quarterly dividend. However, over the course of the day that enthusiasm bled away, perhaps because much of the first-quarter sales increase included contributions from the recent \$17bn acquisition of [Abiomed, Inc.](#) and the last COVID-19 vaccine sales J&J expects in 2023. Together these accounted for over 4% of J&J's first-quarter sales. The analysts from Morgan Stanley attributed the \$747m in first-quarter ex-US COVID-19 vaccine sales as driving "the majority of the beat" as they also helped propel J&J's pharmaceutical revenues beyond analysts' estimates by 6%. In addition, J&J's earnings guidance increases were 'adjusted' to exclude the first quarter's \$7bn special talc litigation expense but, unlike its sales guidance, included its COVID-19 vaccine revenues. J&J's stock price finished the day of its announcement down by nearly 3% compared to a fall of 1% for the NYSE Arca Pharmaceutical Index.

J&J Hedges On 2025 Pharma Revenue Outlook

By [Jessica Merrill](#)

18 Apr 2023

The company admitted it may not meet a goal set in 2021 to reach a \$60bn pharmaceutical revenue target in 2025.

[Read the full article here](#)

Details Chipped Away Positivity

Investors' change of heart may have also had something to do with the mention on its conference call that within its now "biggest franchise" – oncology – J&J's CFO was "very much looking forward" to the read-out of the Phase III MARIPOSA study later this year. MARIPOSA is a head-to-head study of J&J's third-generation EGFR inhibitor lazertinib plus its anti-EGFR antibody Rybrevant (amivantamab) that is pitted against [AstraZeneca PLC](#)'s multi-blockbuster EGFR inhibitor, Tagrisso (osimtinib), in non-small cell lung cancer patients. The implication was that MARIPOSA had passed an interim analysis without J&J's one-two EGFR knock-out punch demonstrating superior efficacy. (Also see "[J&J Rybrevant Update Could Bode Positively For AstraZeneca's Tagrisso](#)" - Scrip, 19 Apr, 2023.)

Elsewhere in J&J's biggest franchise, the picture was rosier. Sales of its second biggest pharmaceutical product Darzalex (daratumumab) for the treatment of hematological cancers continued their ascent, rising by 22% year on year and by nearly 9% on the last quarter of 2022, although they modestly missed analysts' expectations by 1%.

This sets up an interesting tussle for product and franchise leadership within J&J. While Darzalex may be going great guns and its quarterly sales may overtake those of J&J's biggest-selling product in the first quarter – the anti-inflammatory blockbuster Stelara (ustekinumab) – by next quarter, the oncology category is being held back by competition to J&J's BTK inhibitor Imbruvica (ibrutinib). Imbruvica's first-quarter 2023 sales fell by just over 20%, and by nearly 5% on the first and final quarters of 2022, respectively. Imbruvica missed analysts' estimates by 4% as competition from AstraZeneca's Calquence (acalabrutinib) and other BTK inhibitors crimped its global market leadership.

Silver Linings Eventually Have Clouds

Even the silver lining known as Darzalex will eventually have its own cloud – as [Pfizer Inc.](#)* has discovered with the declining sales of its pandemic-related products after the pandemic, and [AbbVie Inc.](#) is finding after the loss of exclusivity of its anti-inflammatory multi-blockbuster Humira (adalimumab). Indeed, J&J is also getting a sense of the tide going out on Darzalex's exclusivity in 2026 with first-quarter sales of Stelara that grew by a more modest (than Darzalex) 7% but beat analysts' expectations by 2% as either wholesalers demurred on stocking ahead of third-quarter biosimilar competition, or more likely payers contracted at lower prices for the year ahead of it.

IRA Avoided

There was no mention in J&J's announcement or conference call of the current bugbear among pharmaceutical executives – the inflation reduction act (IRA) – ironically because J&J's medium-term losses of exclusivity and competitive issues make the impact of Medicare price renegotiations in the IRA moot. With most of its sales in Crohn's disease and ulcerative colitis, Stelara is unlikely to be prescribed to seniors, so while not a big Medicare cost and despite having no biosimilar competition (yet), it is unlikely to be identified for price renegotiation.

The same cannot initially be said for Darzalex and Imbruvica, which as outpatient or orally administered drugs are covered by Medicare Parts B and D, respectively, and the average age at diagnosis for both multiple myeloma and chronic lymphocytic leukemia patients is about 70. J&J's two multi-blockbuster oncology drugs with large senior populations would likely catch the Centers for Medicare and Medicaid Services' (CMS) beady eye for a maximum fair price determination at the first negotiations in 2026 were it not for two reasons. Competition from AstraZeneca's better tolerated BTK inhibitor Calquence is likely to continue to pressure Imbruvica's pricing before its loss of exclusivity in 2027. Indeed, Calquence's 2022 US BTK inhibitor market leadership and Imbruvica as a lower priced comparator are likely to result in

AstraZeneca and not J&J being hauled into price re-negotiations with CMS. By contrast, Darzalex's loss of exclusivity and likely biosimilar competition would exclude it from Part B price renegotiations that start in 2028.

Facing loss of exclusivity for two of your largest pharmaceutical products does not usually feel like a good thing for a pharma company. However, bearing in mind the slow erosion in the US from biosimilar competition and the significant market shares retained by innovator companies' biologic products after loss of exclusivity, perhaps J&J's analysts are worrying too much about replacing lost sales in the future. This could well be the preferable outcome compared with entering into IRA price negotiations.

*Andy's pensions hold Pfizer

Andy Smith gives an analyst and investor's view on life science companies. He joined the independent research house Equity Development in October 2019 having previously been an analyst at Edison group and a Senior Principal in ICON PLC's Commercialization, Pricing and Market Access consulting practice. Smith has been the lead fund manager for four life science-specific funds, including 3i Bioscience, International Biotechnology and the AXA Framlington Biotech Fund, and was chief investment officer at Mannbio Invest. He was awarded the techMark Technology Fund Manager of the year for 2007 and was a global product manager at SmithKline Beecham Pharmaceuticals until 2000.