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Stock Watch: Big Trouble In Small Biotech

Overpromising, Underdelivering, Workforce Reductions And Dilution Take Their Toll

by Andy Smith

While the stock prices of a few biotech companies have advanced significantly as a result of their pandemic efforts, a broad biotech stock index has underperformed the pharmaceutical index. Why?

Something happened towards the end of September that caused the biotechnology and pharmaceutical stock indices to diverge. Subsequently, in the year to date, the pharmaceutical stock index has now beaten the biotechnology index by more than 12%.

Biotech Should Be Ahead

In a rising stock market, conventional wisdom suggests that the shares of biotechnology companies – where higher growth and even frequent acquisitions are expected – should outperform their larger and more sedate potential pharmaceutical acquirers. But the NASDAQ Biotech Index (NBI) finished last week up just 1.5% on the year, compared to a gain of nearly 14% for the NYSE Arca Pharmaceutical Index (DRG).

While the pandemic has posed great challenges for life science firms, causing disruptions to activities ranging from running clinical trials to in-person sales calls, the 20-month delay for the divergence between the biotech and pharmaceutical stock indices might point to non-pandemic causes. Within a stock index like the NBI, there are hundreds of constituents and some have seen great gains, notably *Moderna, Inc.* and *BioNTech SE*, which have seen their stock prices rise by over 100% and 200%, respectively, in the year to date. So, for the NBI to finish the year to date close to flat is quite an indictment of the index's other companies.

Esperion Cuts One Way

On the face of it, there was nothing to dislike about *Esperion Therapeutics, Inc.*'s third-quarter earnings report. Revenues from its lipid-lowering drugs grew by nearly 230% on the same quarter

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of 2020 and both revenues and loss per share were better than analysts' consensus estimates. Despite commentaries last year that detailed the difficulties of launching a new product in the middle of a pandemic, the two factors that Esperion highlighted in its third-quarter call that were responsible for "prescription growth of 10% during the third quarter" were its "inadequate access to HCPs" [healthcare professionals], and prior authorizations." The first factor appeared to be entirely of Esperion's own making as a recent 40% workforce reduction will have cut the number of calls it makes to HCPs. The second, the squeeze on Esperion's products by payers, was illustrated by the comparison of its 10% prescription growth in the third quarter, but 2.7% net product sales growth. The fact that Esperion's drugs compete against generic statins, which are cheap, and the PCSK9 inhibitors, which have positive cardiovascular outcomes claims, has enabled payers to restrict Esperion's third-quarter revenues. These look much less impressive than the headline growth rate, at only \$11m. Esperion's revenues were generated by its \$39m in selling, general and marketing expense. Esperion's 71% stock price fall in the year to date probably reflects its investors finally waking up to it having developed a small product. The move to a more virtual marketing organization appears to be part of a wider trend that has included <u>Clovis Oncology, Inc.</u> in the oncology therapeutic area (Also see "<u>Stock Watch: AstraZeneca And</u> Clovis Diverge In Oncology Sales Recovery" - Scrip, 15 Nov, 2021.), and, also in the cardiovascular space, Amarin Corporation plc.

Amarin Hopes For Pandemic-Hit Germany

Amarin's third-quarter revenues from its lipid-lowering drug Vascepa (icosapent ethyl) fell by 9% on the same quarter of 2020, by 8% on the second quarter of 2021, and missed analysts' estimates by 13%. Staring down the barrel of generic competition in the US for its only product Vascepa, Amarin made the decision in September to reduce its salesforce from 750 to 300 and, like Esperion and Clovis, concentrate on more digital marketing in the US. At least Amarin's salesforce reduction is partially aligned with typical pharmaceutical marketing practice – where all marketing is cut when a product goes generic – although the continued promotional efforts in the US are reliant on skinny label restrictions for generics and indication-specific exclusivity. (Also see "*Generics Bulletin Editor's Picks For Q3 2021*" - Generics Bulletin, 14 Oct, 2021.)

At the beginning of the year, while Amarin was confident that supply issues would constrain generic competition and Vascepa would continue to expand in the US, the analysts from Jefferies correctly predicted that revenues would decline as generics gained market share. On the one hand, the reduction in sales and marketing investment as a result of the generic impact on Amarin's sales is a logical contrast to Esperion and Clovis where their salesforce reductions are for small, but still patent-protected products. On the other, Amarin's bonfire of tragedies continues as its first European market launch, Germany, is in the midst of a fourth pandemic wave. Amarin's stock price is down over 20% in the year to date.

FibroGen: Same Pressures, Different Reasons

Like Esperion, *FibroGen, Inc.* reported third-quarter revenues and earnings per share that both

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beat analysts' estimates. Despite total revenues growing by 254% on the same quarter of 2020, and by 540% between the end of the second and third quarters of 2021, FibroGen also announced a restructuring that will reduce expenses by \$100m annually for the next three years. About 75% of FibroGen's third-quarter revenues were a \$125m milestone from partner *Astellas Pharma, Inc.* for the EU approval of FibroGen's product Evrenzo (roxadustat) for anemia in chronic kidney disease patients. Evrenzo's approval in Europe was in stark contrast to the complete response letter from the FDA that requested more safety data from FibroGen and its US partner *AstraZeneca PLC*. The stock price of FibroGen finished the year to date down 67%.

The rash of cost cutting at commercial-stage biotech companies seems to be accompanied by tacit admissions that the products they developed are either past their best (in Amarin's case), or have not lived up to their lofty expectations. This contrasts with an earlier stage in the biotech sector's evolution, when savage cost-cutting was usually associated with clinical failure. This has also occurred recently with a 75% workforce reduction after sequential pipeline failures at *Theravance Biopharma Inc.*., and a 55% stock price fall in the year to date. (Also see "*Theravance To Slash Headcount By 75% After Latest Clinical Trial Setback*" - Scrip, 15 Sep, 2021.)

The Pandemic Takes And Takes

No single factor can explain the underperformance of the NBI compared to the DRG in the year so far, but the dawning realization among investors that many biotech products are never going to be anywhere near as big as once billed may have had a greater effect than the usual, and expected, rate of clinical failures. In addition, the oversupply of new early-stage biotech companies and the rash of dilutive secondary offerings are archetypical depressants of a biotech stock market.

But the pandemic also brought the opportunity for the sector to shine, and the stock prices of both Moderna and BioNTech, as well as some bigger pharmaceutical companies, have basked in that reflected glory. However, many other biotech companies had jumped on this same bandwagon during the early phase of the pandemic. In the last week, Amarin and <u>Molecular</u> <u>Partners AG</u> announced Phase III failures, while <u>Roche Holding AG</u> exited its partnership with <u>Atea Pharmaceuticals, Inc.</u> after a Phase II failure – all with treatments for COVID-19. One thing that guarantees stock market underperformance is to overpromise and underdeliver.

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.