Q1 2021 Biopharma earnings analysis and industry outlook

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Q1 2021 Earnings summary

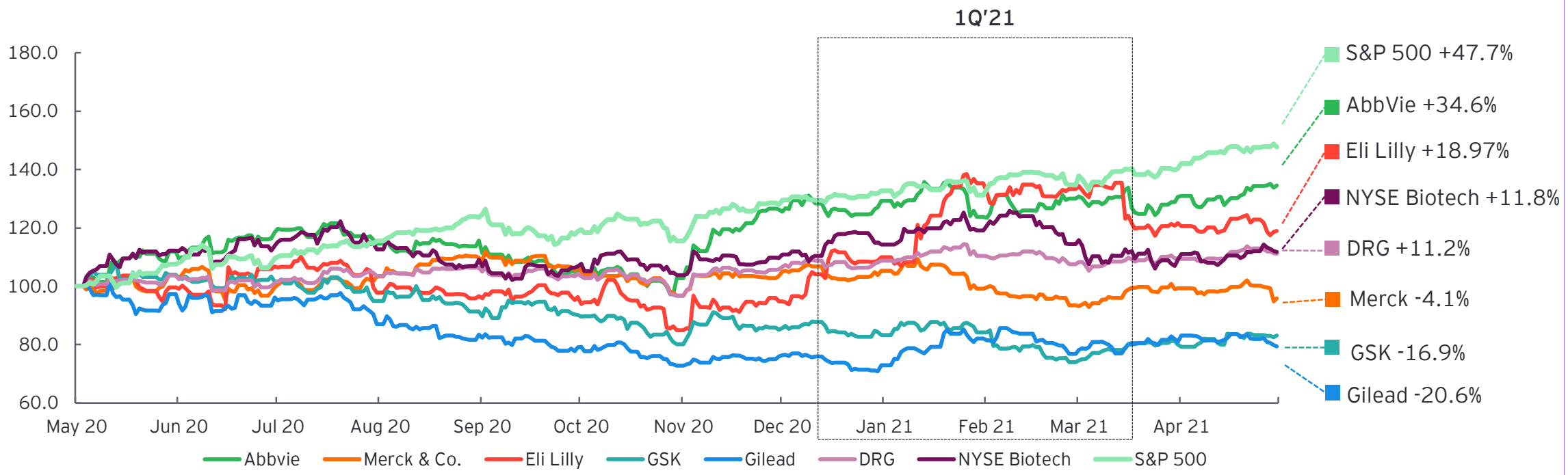
Company	Y-O-Y Revenue	Company sales vs. consensus	Change in analyst estimate for FY21 revenue	Y-O-Y change in EBITDA margin	EPS (US$)	EPS (%)	Analyst rating*
AbbVie	50.90%	1.30%	0.60%	2.4 pp	$2.00	-1.20%	Buy
Amgen	-4.20%	-5.70%	-1.60%	-2.5 pp	$2.90	-7.80%	Buy
AstraZeneca	15.20%	4.60%	-0.07%	-4.5 pp	$1.20	100%	Buy
Biogen	-23.80%	-1.70%	0.10%	-16.5 pp	$2.70	-66.60%	Hold
Bristol Myers Squibb	2.70%	-0.70%	-0.30%	-0.5 pp	$0.90	NA	Buy
Eli Lilly	16.10%	-2.20%	-1.50%	-0.6 pp	$1.50	-7%	Buy
Gilead	15.80%	-5.00%	0.00%	2.6 pp	$1.40	12%	Buy
GlaxoSmithKline	-9.70%	-6.00%	-0.50%	-2.3 pp	$0.30	-24.60%	Hold
Johnson & Johnson	7.90%	1.40%	0.60%	2.0 pp	$2.40	7%	Buy
Merck & Co.	0.20%	-4.50%	-0.40%	2.0 pp	$1.30	-1.60%	Buy
Novartis	-0.10%	-0.60%	-0.80%	-0.4 pp	$0.90	-4.40%	Buy
Novo Nordisk	6.80%	4.4%	0.30%	-2.9 pp	$0.90	15.3%	Hold
Pfizer	44.60%	7.10%	-0.03%	-3.5 pp	$0.90	44%	Buy
Regeneron	38.3%	-1.6%	2.2%	5.3 pp	$10.60	86%	Buy
Roche	-1.40%	-0.20%	NA	NA	NA	NA	Buy
Sanofi	1.90%	1.60%	0.10%	2.4 pp	$1.50	-0.50%	Buy
Teva	-8.60%	-1.60%	-0.01%	-2.4 pp	$0.10	11%	Hold

Source: S&P Capital IQ, Analyst reports

Biopharma stock performance

- AbbVie's stock outperformed, on the back of Allergan acquisition and significant investment by Berkshire Hathaway
- Gilead was significantly impacted by COVID-19 pandemic and pricing pressure
- Both the DRG Pharma and the NYSE Arca Biotech index underperformed the S&P 500, due to uncertainty about drug pricing and regulatory impacts on biopharma companies under the Biden administration

Stock price charts for LTM (May 2020 to April 2021)



Source: S&P 500, NYSE Biotech, DRG, Analyst reports

EY outlook

1. Revenue performance and earnings results in Q1 21 reflect a high degree of variability across the industry. “Steady as you go” can be a risky strategy.

2. Concerns about drug pricing, reimbursement and tax reforms coming from a new administration are weighing on share prices, and this is likely to continue.

3. A renaissance of scientific innovation continues to drive a favorable growth outlook.

4. The health of the capital markets, as well as IPOs, follow-ons, SPACs and M&A, will significantly impact growth strategies.

EY outlook

1 Revenue performance and earnings results in Q1 21 reflect a high degree of variability across the industry. "Steady as you go" can be a risky strategy.

The far-reaching business implications of COVID-19 will continue to influence corporate performance and shape the biopharma industry's strategic direction. The seismic shifts of the last year will continue to reverberate. Additionally, the agenda of the new Democratic Biden administration could challenge growth strategies, with tax policy, potential pricing and reimbursement reforms, and more stringent regulatory oversight. This includes the FDA's approach to product reviews, approvals and manufacturing inspections, as well as tighter scrutiny from the FTC.

While organic revenue growth was largely positive, performance varied markedly by company, as a function of whether product mix benefitted or was penalized by the pandemic, the extent of losses of exclusivity and shifts in buying patterns. Some companies have seen significant, if not record-breaking growth tied to the unprecedented rapid development of COVID-19 vaccines and therapeutics. Whether this trend is sustainable will depend on the need for potential booster shots to address emergence of future variants. At the same time, sales of therapeutics requiring in-office administration or diagnostic testing at the hospital or in doctors' offices, or where treatment can be deferred, continue to lag. Yet companies are reporting that with the rapid adoption of vaccines in Q1 2021, late March showed signs of improving trends and a "return to normalcy."

Industry considerations

1 Revenue performance and earnings results in Q1 21 reflect a high degree of variability across the industry. "Steady as you go" can be a risky strategy. (cont.)

Although it appears in the US that the pandemic is beginning to ebb, **the long-term impacts of COVID-19 will influence biopharma leaders' strategic agenda for years to come.** Business continuity was threatened, and now is the time to reimagine the future of the pharmaceutical supply chain, through re-onshoring or near-shoring the manufacturing of certain therapeutics and especially essential medicines. However, this could have negative implications for major capital investment, gross margins and tax rates. At the same time, the inevitable losses of exclusivity emphasize that companies must have a diversified and effective strategy to innovate and replenish their pipelines through internal R&D productivity and external assets. Investments in R&D and M&A continue to climb, and the companies with the best financial performance and strong balance sheets will have an enhanced competitive advantage.

This means that **industry performance could become more stratified over time**, with a clear emergence of front-runners and laggards. With bifurcated results, the laggards may struggle, and increased activist pressure will require a close watch. Executives should consider a vigorous offense as the best defense.

Given this outlook, **biopharma executives must challenge their current playbook** and identify how they can operate differently. From exploring digital capex to piloting hybrid commercial and operational models, enterprises should focus on efforts to maximize efficiency and ensure strong and sustainable performance. Human capital plays a part, too — a dearth of senior talent across the industry, and the challenge to attract and retain the best will tie directly to a company's financial and stock price performance. For companies that experience a slowdown in earnings or miss consensus expectations, aggressive actions are necessary, not optional. Rigorous attention across the industry to asset allocation, diversification, internal and external R&D investments, M&A, stringent cost management, productivity and efficiency will be critical to ultimate performance.

EY outlook

2 Concerns about drug pricing, reimbursement and tax reforms coming from a new administration are weighing on share prices, and this is likely to continue.

"Drug pricing policy under the Biden administration is a prevailing concern for pharma leaders," says Heather Meade, a principal with Washington Council EY, Ernst & Young LLP. At the heart of current drug pricing proposals endorsed by the Biden administration is Medicare price negotiation, including excise penalties for affected companies that fail to reach an agreement with the government.

Previous legislative proposals that could be considered again in 2021 include limiting drug price increases relative to inflation and ordering pharmaceutical companies to pay an increased portion of costs to limit out-of-pocket spending in Medicare Part D. This segment is three times larger than Medicare Part B, for which certain pricing restrictions already exist.

Industry considerations

2 Concerns about drug pricing, reimbursement and tax reforms coming from a new administration are weighing on share prices, and this is likely to continue. (cont.)

Biopharma executives should closely track policy developments in the coming months, **but more importantly, proactively and strongly advocate for the high costs of and risks to R&D and innovation.** The rapid development of effective vaccines clearly demonstrates the profound benefits that successes can have on individual patient lives and even the global economy. Legislation to regulate drug pricing and reimbursement could have the unintended impact of stifling innovation across the industry, and this message should be at the forefront of company communications and those of its leaders.

Further, we should **expect to see increased price pressure outside of the US,** given austerity measures in some countries due to the devastating impacts of COVID-19. Maximizing the efficiencies of operations, commercial infrastructure and tax structures will help blunt these effects.

Finally, the industry **needs to continue to lift its public image** and build on its recent successes largely fueled by its ability to bring a handful of novel vaccines to market in record time. The public debate, however, has already shifted towards invoking the Bayh-Dole Act and foregoing patents to accelerate scaling up vaccines for the rest of the world.

EY outlook

3 A renaissance of scientific innovation continues to drive a favorable growth outlook.

Innovation is continuing at a rapid pace, with 53 new molecular entities (NMEs) approved in 2020. As of late April 2021, 18 NMEs have been approved thus far, ahead of this time last year, with a record number of products under review at the FDA. The pace of innovation and NME submissions continues to increase. This momentum is a bullish indicator for future industry performance.

The acceleration in the successful development of truly novel platform technologies and therapeutics offers the opportunity for higher returns on investment and are driving pipeline priorities. Gene therapy, mRNA vaccines and therapeutics, cell therapy and gene editing once seemed like science fiction but are now a reality — as evidenced by the mRNA COVID-19 vaccines and the production of personalized therapeutics.

Industry considerations

3 A renaissance of scientific innovation continues to drive a favorable growth outlook. (cont.)

Industry leaders must critically assess their R&D programs, pipelines, teams and pace of development to ensure that their new products which will be competitive both now, and in the future, as the bar on value-adds is clearly rising.

Alongside the development of novel therapeutics, **pharmaceutical manufacturers must also rethink their approach to ensuring manufacturing capacity and production quality.** The economic, regulatory and societal impacts of missteps in drug manufacturing, both internal and outsourced, are far-reaching — as evidenced by recent news. Manufacturers should find efficiencies, maintain rigorous compliance protocols and anticipate potential quality issues before they occur. Quality performance must be integrated with safety and pharmacovigilance information, providing a comprehensive view throughout the complete therapy life cycle.

EY outlook

4 The health of the capital markets, as well as IPOs, follow-ons, SPACs and M&A, will significantly impact growth strategies.

M&A remains fundamental to the industry's growth strategy, as do the equity capital markets. In 2020, $52b of equity capital was raised in biopharma: double the amount in the prior year. With more than $170b in dry powder at the top 12 companies by market cap, industry leaders continue to aggressively seek opportunities to expand existing therapeutic franchises and diversify into other growth areas. Most companies cite corporate development as critical to future success.

Multiple factors suggest an active M&A year in 2021, driven by lots of free cash, rising losses of exclusivity and a high level of innovation. While it is currently a seller's market, that could change quickly if the capital markets window begins to close. Therapeutic focus remains an important long-term driver of deals, but many companies are seeking to expand into new areas as successful innovations increase their attractiveness. Growth gaps always create an urgency for deals among the largest companies. Because many biotechs are flush with the $52b in cash raised last year, they are funding through multiple milestones and value inflection points, hence deal premiums are likely to remain high.

Source: PharmExec; EY analysis

Industry considerations

4 The health of the capital markets, as well as IPOs, follow-ons, SPACs and M&A, will significantly impact growth strategies. (cont.)

Portfolio optimization is no longer a choice — it's an imperative. Given valuations in the market, now might be a good time for some to consider selling or spinning off non-core or lower-performing assets. Innovation will continue to be a target for M&A.

Leaders must **evaluate how to deploy excess cash flow beyond M&A strategies** with discipline. While returning excess cash through share repurchases and increasing dividend pay-outs have long been core to improving shareholder returns, they must not be at the expense of the pursuit of M&A or deploying capex toward building strategic capabilities, which could dramatically change enterprise values as well as the perception of the company in the marketplace. Doing a successful and smart strategic deal will make doing the next one much easier.

Appendix

Focus of analyst questions in Q1 2021 earnings calls

Growth outlook

- Impact of COVID-19 on FY2021 guidance
- Expected growth drivers for long-term and expected growth rates
- Forecasts for current pipeline products
- Expected improvement in margins and EPS, in line with revenue growth
- Forecasted growth in particular subsegments vs. remaining company

Drug pricing

- Drug pricing reforms under Biden administration
- Decline in product sales due to price erosion
- Impact of value based pricing contracts
- Price erosion due to launch of generics
- Pricing impact on company's profit margins

Product approval

- Optimism on pending FDA approvals
- Expansion in other geographies outside the US
- Timeline for expected product approvals
- Additional data required by regulators
- Expected product labeling by the FDA

R&D and clinical trials

- Patient enrollment rates during the pandemic
- Uncertainty about reaching clinical trial endpoints
- Unexpected clinical events during the trials, including adverse events
- Locations of trials and expanding geographic location
- Efficacy of pipeline product vs. competitor drugs

Sentiment: Positive Neutral Negative

Source: Earnings transcripts

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