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Dr. Daniel Koller, Head Investment Team BB Biotech at Bellevue Asset Management

## Coveted drivers of innovation

The driving force for many new therapeutic approaches for drugs, yet with low stock market valuations – the biotech industry is going through a paradoxical development phase. This in turn is bringing it back on the radar of big pharma players with an eye for a takeover.

Viewed in fundamental terms, the biotech industry has never looked so well-positioned. According to a study published by the IQVIA Institute for Human Data Science, 65% all clinical studies underway in 2021 were conducted by smaller biotech companies, which IQVIA itself describes as «emerging». These are defined as companies with annual sales of below USD 500 mn that invest less than USD 200 mn annually in their research and development pipeline.

A key difference in the current situation compared to the past is the financial strength of today's biotechs. An increasing number of companies have sufficient liquid funds to drive forward the development of their clinical candidates through to market maturity under their own steam. In other words, they are moving away from the former dependency on development and marketing partnerships with the pharma industry. A clear indicator of this is another statistical finding of the above-mentioned IQVIA study: In 2021, “emerging pharma” companies submitted their own market approval applications for 76% of their products. Another plus point is that the biotech sector has become the pioneering force in the development of numerous new approaches such as gene therapies, cell-based therapies, and immuno-oncology.

What's more, there are plenty of signs that these companies are delivering the necessary price-driving news flow – a large number of clinical study results and approval decisions are expected this year, above all in the fields of cancer medicine, neurology and genetic disorders. Moreover, the pipeline looks very healthy, as the number of patients enrolled in studies is once again higher than it was prior to the coronavirus pandemic. The number of new study applications submitted to the US supervisory agency (Food and Drug Administration, FDA) has also risen further.

At the same time, the pressure is rising on pharma multinationals to generate new growth drivers. The majority of these companies have strategically repositioned themselves over the last decade by focusing their new drug development operations on just a few therapeutic fields. The innovative power of Big Pharma continues to be evident, with industry giants such as Roche and Bristol-Myers Squibb concentrating on cancer medicine and the likes of Novo Nordisk and Eli Lilly specializing in diabetes treatment. Nonetheless, the pharma industry will have to come up with solutions over the coming years in order to avoid a slump in revenues: according to the FDA, blockbuster drugs with total sales of more than USD 250 bn will lose their patent protection over the coming decade.

After two relatively quiet years, the M&A carousel is starting to spin again. Pfizer made the first move in May when it announced its acquisition of Biohaven for USD 11.6 bn, a markup of 80%. The deal gives Pfizer a migraine drug with a novel efficacy profile that was approved by regulatory authorities in the US in 2021 and, more recently, in Europe as well. Pfizer had already paid USD 6.7 bn to buy US biotech company Arena Pharma in a deal first announced in December. Arena Pharma's most advanced product candidate is a treatment for the chronic inflammatory bowel disease ulcerative colitis. Pfizer has accumulated a huge pile of cash, mainly from the billions in revenues it has earned from the COVID-19 vaccine Comirnaty. In

June, Bristol-Myers Squibb announced it had agreed to buy Turning Point Therapeutics for USD 4 bn, a premium of 120%. This deal gives the US pharmaceutical company a novel lung cancer drug that is expected to receive regulatory approval in 2023. BB Biotech's portfolio company Radius Health, which has a product in the market for the treatment of postmenopausal women with osteoporosis and high fracture risk, received a takeover offer from two investment companies, Gurnet Point Capital, LLC and Patient Square Capital, at the end of June.

In view of the low valuations that most biotech companies are trading on after a prolonged and sometimes steep correction over the past twelve months, it is certainly possible that more double-digit billion-dollar transactions could be announced before the year is over, targeting companies that already have products with blockbuster potential in the market. Pharma companies can be expected to focus above all on biotech firms that have received – or are about to receive – market approval for their initial products based on ground-breaking technologies. Among other things, this includes gene editing, where specific faulty gene segments in DNA strands are cut out and modified. Genes can be added, removed or disconnected with this technology, which has the potential to deliver complete and lasting solutions to various genetic disorders. In the second half of this year, Crispr Therapeutics and Vertex Pharma will unveil the first approval-relevant data in gene editing for the treatment of two genetically induced blood cell formation disorders. As the treatment costs of this as yet untreatable condition are very high, Crispr and Vertex would appear to have very high price-setting power. It is perfectly conceivable that Vertex, which is already a profitable biotech heavyweight, will attract a takeover offer given that its future potential revenues could run into billions of dollars.

RNA-based therapies such as SiRNA and AOs (antisense oligonucleotides), which have received market approval for drugs in connection with niche indications, represent another commercially attractive area for prospective corporate buyers. Alnylam and Ionis Pharma are two good examples of companies in this area that look to have takeover appeal in light of their first product authorizations and mature technology platforms. In the field of oncology, this is even more true of biotechs that play a pioneering role in the area of immuno-oncology – particularly if they possess products capable of activating the body's immune defences against tumor cells even better than combination therapies.

By contrast, for small biotech companies with promising technologies but as yet no active agents capable of demonstrating clinical effectiveness, there is still a huge discrepancy between the amount companies believe they are worth for takeover purposes and the price buyers are willing to pay. The equities of these companies have suffered the greatest price declines since 2021, and their corporate value has decreased accordingly. In order to secure financing for their most important clinical projects, these companies will have to enter into traditional development partnerships with Big Pharma which involve upfront payments and performance-linked milestone payments. If they turn out to be successful, these partnerships could then lead to takeover offers.

#### Author

Dr. Daniel Koller joined Bellevue Asset Management in 2004 and is senior portfolio manager in the biotechnology segment specialized in cardiovascular diseases. Since 2010 he is head management team of the listed investment company BB Biotech AG. Before joining the company he spent four years in the financial sector, initially as an equity analyst at UBS Warburg and then as a private equity investor at equity4life. Dr. Daniel Koller studied biochemistry at the Swiss Federal Institute of Technology and earned a doctorate in biotechnology while working at Cytos Biotechnology.

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#### Company profile

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