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BB Biotech

Media release as of July 20, 2018

Interim report of BB Biotech AG as of June 30, 2018

BB Biotech shares hold steady in the second quarter – Substantial portfolio adjustments, new investments in attractive small and mid-sized biotech firms

Major headwinds caused by various factors such as the talk of the US federal government imposing drug price controls and the general impression that the bull market is on its last leg weighed on investor sentiment in the healthcare sector during the second quarter. BB Biotech shares were not completely immune to these developments and delivered a return of -0.4% in CHF and 1.2% in EUR for the second quarter of 2018. Its Net Asset Value (NAV) fell by 2.8% in CHF, resulting in a net loss of CHF 98 mn. This compares to the net profit of CHF 103 mn reported for the second quarter of 2017. After a thorough review of all portfolio shareholdings, BB Biotech made several adjustments to its portfolio, guided by its time-tested strategy of investing in innovation leaders working on groundbreaking therapies and technologies. Valuations are now well off their highs from 2016 and 2017, which raises BB Biotech's confidence in future performance.

Overall, equities are roughly back to where they started the year. Yet the first six months of 2018 have seen market oscillations driven by a wide range of macro, sector- and stock-specific events.

The early-year market rally evaporated in association with the threat or actual start of international trade wars. After a good first quarter run, major US share indices have returned to early January levels – the S&P (+2.7%), and Dow Jones (-0.7%) were little changed (all values as total returns in USD) by mid-year.

European markets underperformed relative to the US indices, as the Euro Stoxx50 (-0.5%), the DAX (-4.7%, both in EUR) and the SPI (-4.0%, in CHF) ended June lower than at the start of the year.

Worldwide healthcare equities followed the broader US indices. The MSCI World Healthcare Index (+1.9%, in USD) was not appreciably changed at the end of 6 months, while pharmaceutical companies once again underperformed broad healthcare markets. The Nasdaq Biotechnology Index performed slightly better (+2.9%, in USD) driven by small and mid cap companies.

Sector concerns for drug stocks were fueled once more by political rhetoric, policy papers, and Presidential Tweets, variously pointing to potential US government-led price controls, and more likely setting up campaign platforms in anticipation of the midterm elections later this year.

Investors have been cautious about the risk of drug price control legislation (or its alternative executive orders or agency actions) – and this sentiment has been associated with continuous negative fund flows for the biotech sector. These generalist investor reactions are understandable, but as one of the biotech sector leaders, BB Biotech also believes that some of the strategic ideas being discussed in US healthcare are constructive, while others are not.

In the complex US healthcare system, improved transparency and the removal of inefficient incentives will ultimately spur innovation. The best innovation will create the best drugs, which, when priced for cost effectiveness and responsible budget-impact, will continue to create enormous value for shareholders.

BB Biotech's experts are less enamored with short term, under-informed snap judgements or irresponsible price hikes which threaten to undercut sustainable growth and curtail capital flows into one of the most important and exciting drivers of the global economy today – biotechnology.

The US Department of Health and Human Services (HHS) has proved to be a steadying influence on the White House so far. As for drugs (for which biotechnology drives the lion's share of innovation), the Food and Drug Administration (FDA) is leaning firmly in support of authentic innovation – despite FDA challenges of expert staffing and need for other resources. Both the FDA and its parent, the HHS, will play key roles in shaping the US government's position vis-a-vis the drug industry: Specifically, BB Biotech anticipates sensible executive actions to (a) reduce drug development timelines, lower complexity and contain costs; (b) administer intellectual property rights in ways which reward innovation; (c) call out price gouging; and (d) shine a light on some of the US

market's arcane incentives associated with the commercial value chain to reduce out-of-pocket expenses for patients and rebates for market intermediaries.

As indicated for several years now, BB Biotech sees smart evolution, not sizzling revolution in US drug access, pricing and reimbursement despite the leaders who are anxious to score popular votes. Over the foreseeable future, BB Biotech believes that the US healthcare system will restructure, reorganize and reassign capital steadily and successfully to create an increasingly competitive, information-rich, efficient and value-based market. In several ways, such change is already here. New players such as Alphabet, Apple, Amazon, Berkshire Hathaway and many others are driving novel ways of working to deliver care, with more to come. These ideas are more promising than punishing for smart biotech firms – because although the US government will be tough on the biotech sector, market forces will be more important than government intervention per se.

Overall at this time one sees more attractive emergent biotech innovation, which carries the potential to improve health, than ever before in our 25-year successful run. BB Biotech's leading companies are paying careful and explicit attention to the very real question of value for money in healthcare and it remains highly attentive to the opportunities created by and for sector experts in these remarkable times. Despite turbulence, this is a time to invest judiciously, not a time to retrench and eschew innovation.

BB Biotech second quarter and half year 2018 performance

Yet progress is not necessarily linear nor is it assured for every reporting period. And the second quarter of 2018 serves as a reminder of the complexity inherent with investing in the biotech sector.

Second quarter 2018 share return for BB Biotech was -0.4% in CHF, 1.2% in EUR and -3.9% in USD. The NAV pulled back 2.8% in CHF, 1.1% in EUR and 6.2% in USD. Consequently, second quarter net loss was CHF 98 mn, compared to a gain of CHF 103 mn for the same period in 2017.

Half year 2018 performance was consequently mixed. The total return for the share price including the dividend (+8.4% in CHF, +8.2% in EUR and +6.6% in USD) was higher than the portfolio's Net Asset Value return (-2.5% in CHF, -1.3% in EUR and -4.1% in USD) which led to a half year 2018 net loss of CHF 70 mn, compared to a gain of CHF 478 mn for the same period in 2017.

The disconnect between share price and NAV was the result of a continued modest share price premium through the first six months of the year.

Some of the portfolio companies also had a challenging first half of 2018. Important holdings such as Incyte and Esperion announced imperfect clinical trial results for key pipeline compounds. In a short-term investor environment, such results can drive aggressive generalist selling – as it did for these two firms. Other large cap holdings such as Celgene also performed sub-par.

Thorough review of portfolio positions

Given these and other challenges of biotech markets, the companies have been re-analyzed once more and the portfolio has been adjusted promptly and decisively. BB Biotech remains highly committed to best-of-breed innovators with exciting new technologies as follows:

First, it continued to build up its RNA-platform positions – by buying back shares in Alnylam that had been sold at higher levels, and by adding to the position in Wave Life Sciences. Drugs that rely on RNA are here to stay.

Second, it bought additional shares in its gene therapy holding, Voyager, given the company's progress – and the US FDA's positive stance in support of such ambitious innovation.

Third, it took advantage of short term market overreactions. As Esperion and Tesaro gave up around half of their respective valuations during the first half of 2018, BB Biotech increased its exposure to both, confident that they have meaningful products and potential for value creation. By contrast significant profits were realized from positions in Agios, Novo Nordisk and Halozyme – and some of the position in Probiodrug was sold in response to the company's change in strategy.

Fourth, BB Biotech reaped the rewards of its commitment to innovation when Novartis offered USD 218 per share in cash for Avexis, valuing the company at USD 8.7 bn. An initial investment in Avexis in late 2016 resulted in an exit at almost 5-fold the invested capital. Central to this successful investment was the novelty and transformative potential of AVX-101, a gene therapy for newborns with the most severe form of spinal muscular atrophy.

Fifth, the value of a long term view was illustrated once more with the disinvestment of the remaining position in Idorsia – spun out from Actelion as part of the Johnson & Johnson deal in June 2017. This ends a long and very successful strategic investment cycle.

Finally, other decisive steps were taken. The position in Prothena was closed after the Elan spinout company reported that their development candidate NEOD001 failed in Phase II clinical trials – resulting a rare overall loss on this investment.

BB Biotech's investment experts then set about deploying the capital released by these moves – initiating four new positions in cutting-edge, authentic innovation assets in potentially high growth rate, smaller cap companies: G1 Therapeutics, Exelixis, Nektar Therapeutics and Myokardia.

G1 Therapeutics focuses on the discovery and development of cancer treatments with selective inhibitors of cyclin-dependent kinases 4/6 (CDK4/6 inhibitor), trilaciclib and G1T38. The lead candidate, trilaciclib, is an intravenous CDK4/6 inhibitor designed to preserve myeloid cells in cancer patients undergoing chemotherapy.

Nektar Therapeutics is focused on developing novel drugs for oncology, autoimmune disease, and chronic pain. The most important product in their pipeline is NKTR-214, a CD122-biased agonist designed to stimulate the patient's own immune system to fight cancer.

Exelixis'primary focus is on small molecule tyrosine kinase inhibitors (TKIs). Cabozantinib is approved in two indications, renal cell carcinoma (Cabometyx tablets) and medullary thyroid cancer (Cometriq capsules).

Myokardia is one of only a few small biotech companies in the cardiovascular disease area. The company's initial focus is on the treatment of inheritable cardiomyopathies, a group of rare, genetically-driven forms of heart failure that result from biomechanical defects in cardiac muscle contraction. The most advanced pipeline asset is MYK-461 (mavacamtem).

Overall portfolio restructuring during the first half of 2018 increased the investment grade from 103% at the beginning of 2018 to 109% at the end of the first quarter and to 110% at the close of the first half of 2018.

Milestones in the second quarter
Important clinical trial results were reported by portfolio companies in the second quarter.

Incyte and partner Merck announced that epacadostat, an IDO inhibitor being tested in combination with Keytruda, did not add clinical benefit in patients with unresectable or metastatic melanoma. The companies decided to discontinue ongoing registration studies of the combination in other cancer types as well. This was disappointing, but the market reaction was overblown and so BB Biotech picked up more Incyte shares at a low price. It has high conviction that the company is temporarily undervalued.

Esperion failed to impress all investors with its top line release for their Phase III, long-term study, testing bempedoic acid (BA). The "bad cholesterol" (LDL-C) lowering effect of BA was adequate, but investors were apparently concerned by what they saw as disappointing safety data. While the results were not pristine, BB Biotech believes that the trial's underlying population characteristics, background treatment (e.g. with statins) and small frequency of adverse events provide reasonable confidence that Esperion has a useful drug on its hands for a meaningful segment of an enormous global market – atherosclerotic cardiovascular disease. As the Esperion share price was, like Incyte's, cut in half, BB Biotech assessed the information in detail and took the opportunity to increase the position.

Meantime, Novo Nordisk announced further positive clinical studies for the oral semaglutide program, announcing significant lowering of both HbA1c, a measure for blood glucose control, as well as weight loss with good performance relative to injectable drugs. The medication shows considerable promise in diabetes – and BB Biotech is keen to see how this and potential strategic moves signaled by the company during the first half of 2018 play out.

Celgene and Acceleron announced positive results from a Phase III study for Luspatercept. Patients with low-to-intermediate risk myelodysplastic syndromes benefited from Luspatercept with more patients achieving red blood cell transfusion independence. This is welcome news given Celgene's dependence on Revlimid and recent missteps. BB Biotech continues to follow Celgene very closely indeed.

Product approvals remain an important driver of BB Biotech's above-industry-average growth rates. During the second quarter of 2018, BB Biotech was pleased to see Eli Lilly and Incyte announce the FDA approval of Olumiant (baricitinib), as a once-daily oral medication for adults with moderate-to-severely active rheumatoid

arthritis who have had an inadequate response to TNF inhibitors. Olumiant was readily approved in Europe and Japan, while the US approval has been more convoluted. Advisors to the FDA recommended – and FDA agreed – that the agency should approve the lower, but not the higher and more efficacious dose of Olumiant. The competitiveness of the product label may be sufficient nevertheless – and in addition Eli Lilly and Incyte continue to test Olumiant for other indications such as atopic dermatitis, alopecia and moderate to severe psoriasis.

Gilead won CHMP recommendation for European approval of Biktarvy to treat HIV-infected individuals. The same meeting of CHMP came up with a positive recommendation for Akcea's Tegsedy to treat patients suffering from hereditary transthyretin amyloidosis (TTR).

In the US, Akcea received a positive FDA advisory committee vote for another product – Waylivra – to treat patients with familial chylomicronemia syndrome (FCS), an ultra-rare disease characterized by severe elevation of triglycerides. The anticipated date for US approval is August 30, 2018.

Outlook for the second half of 2018
More pipeline progress including important product approvals and Phase III data reports for new drugs in US and Europe is anticipated during the second half of 2018. News flow should come from:

- Alnylam (Patisaran) and Akcea/Ionis (Inotersen), who seem set to receive US FDA approvals for treating transthyretin amyloidosis
- Sage Therapeutics is expected to gain FDA approval for Brexanalone to treat post-partum depression
- Agios should achieve FDA approval for Ivosidenib to treat relapsed and refractory AML patients carrying an IDH1 mutation
- Esperion is expected to report Phase III data for the fixed-dose combination of bempedoic acid and ezetimibe to treat patients with high levels of LDL-C as well as the final Phase III safety study for monotherapy
- Alnylam is expected to report interim Phase III data for givosiran to treat patients with acute hepatic porphyria
- Incyte is likely to report Phase III data for its FGF123 inhibitor to treat cholangiocarcinoma

Despite Takeda's challenging offer for Shire, sector M&A activities did not meet investors' expectations in the second quarter of 2018. Some large pharma companies have declared interest in acquisitions, but no other major deals were struck.

Since valuations are now well off their 2016-17 highs, BB Biotech's analysis shows no reasons for despondency. One can reasonably expect selective M&A events to offer attractive exits for some positions in the portfolio. In the meantime, BB Biotech looks forward to attractive fundamental growth in the sector and will continue to marshal its portfolio including further new investments in leading smaller and mid cap positions which promise high growth rates.

As always, BB Biotech is following an innovation-driven investment strategy. It will continue to seek leading companies working on technologies which address unmet medical needs, cost-effectively – with the goal to produce superior returns for BB Biotech shareholders.

The complete interim report as at June 30, 2018 is available on www.bbbiotech.com.

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Company profile
BB Biotech invests in companies in the fast growing market of biotechnology and is one of the world's largest investors in this sector. BB Biotech is listed in Switzerland, Germany and Italy. Its investments are focused on listed companies that are developing and commercializing novel medical treatments and cures. BB Biotech's investment selection process is guided by the fundamental research and analysis of physicians and molecular biologists. Its Board of Directors has many years of experience in industry and science.

Composition of BB Biotech's portfolio as of June 30, 2018
(in % of securities, rounded values)

Ionis Pharmaceuticals	9.9%
Neurocrine Biosciences	8.9%
Celgene	7.2%
Incyte	6.9%
Vertex Pharmaceuticals	6.5%
Agios Pharmaceuticals	5.1%
Radius Health	5.0%
Gilead	4.6%
Sage Therapeutics	4.6%
Alexion Pharmaceuticals	4.6%
Halozyme Therapeutics	3.8%
Esperion Therapeutics	3.4%
Alnylam Pharmaceuticals	3.1%
Tesaro	3.0%
Novo Nordisk	2.9%
Regeneron Pharmaceuticals	2.6%
Myovant Sciences	2.2%
Moderna Therapeutics[1)]	1.9%
Akcea Therapeutics	1.6%
Macrogenics	1.5%
Voyager Therapeutics	1.4%
Intercept Pharmaceuticals	1.3%
Wave Life Sciences	1.2%
Intra-Cellular Therapies	1.1%
Argenx SE	1.0%
Alder Biopharmaceuticals	1.0%
Nektar Therapeutics	0.7%
Myokardia	0.7%
Exelixis	0.6%
Five Prime Therapeutics	0.4%
G1 Therapeutics	0.4%
Cidara Therapeutics	0.3%
Novavax	0.3%
Achillion Pharmaceuticals	0.1%
Probiodrug	0.1%
Radius Health Warrants, 19.02.2019	<0.1%
Total securities	**CHF 3 607.6 mn**
Other assets	CHF 43.6 mn
Other payables	CHF (365.7) mn
Net Asset Value	**CHF 3 285.5 mn**

1) Unlisted company

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