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Testo del comunicato

Vedi allegato.

Media release as of July 19, 2019

Interim report of BB Biotech AG as at June 30, 2019

Consolidation leaves a mark on results in the second quarter

BB Biotech's stock price and Net Asset Value decline in Q2 2019

The healthcare sector was unable to keep up with the European and US equity indexes, which hit new record highs in the second half of 2019. Despite a renewed increase in M&A activity, the Nasdaq Biotechnology Index dropped 2% (in USD) in the second quarter on the heels of its impressive first-quarter rally. Fears of government efforts in the US to block M&A transactions and lower drug prices weighed on investor sentiment for biotech stocks. BB Biotech does not share these concerns. Both the volume and the number of IPO transactions and share capital increases in the biotech sector have reached unprecedented levels. M&A activity is expected to pick up even more and this could have positive implications for the sector's innovation leaders. Initial statements by Norman Sharpless, the acting head of the FDA, stressing his commitment to further reforms and innovation were likewise encouraging. BB Biotech was not shielded from the broader market developments in Q2. Its stock price declined by 4.8% in CHF and EUR, while Net Asset Value fell 9.4% in CHF and 8.8% in EUR, resulting in a second-quarter net loss of CHF 336 mn compared to a loss of CHF 98 mn in the year-ago period. Its portfolio management team has largely completed the strategic, future-ready reallocation of portfolio assets to next-generation players that was initiated in the previous year. The aim is to lock in upside potential over the long run. Management thus continues to pursue its time-tested, long-term investment strategy with a focus on innovation leadership.

Equity markets reached new highs in the second quarter of 2019 in anticipation of further interest rate cuts by the Federal Reserve Bank and hopes of trade agreements. United States equity indices ended the quarter with year-to-date gains in USD of 18.5% and 21.3% for the S&P 500 Index and Nasdaq Composite Index respectively. European markets followed suit with EUR returns of 17.2% and 17.4% for the Stoxx Europe 600 and the Dax respectively; 21.2% in CHF for the SMI.

Healthcare equities did not keep pace with overall markets. Although the MSCI World Health Care Index was up 10.1% in USD year-to-date by mid-year, the Nasdaq Biotechnology Index followed its impressive first quarter rally with a second quarter decline of 2% – resulting in a first half-year return of only 12.9% in USD. There were reports of sector fund outflows among generalists – perhaps reflecting new concerns about US government inhibition of M&A transactions, and ongoing concerns about US drug pricing. BB Biotech's view differs. It was encouraged by the range and scope of biotech public offerings and capital increases, which reached unprecedented levels. In addition, M&A activities (albeit driven by large cap company challenges) have increased once more – and management believes this will have a positive knock-on effect for more innovative firms. Also encouraging were the early statements of the new FDA commissioner Norman Sharpless, who has expressed continuing commitment to innovation – including patient centricity, accelerated drug development and measures to increase competition. BB Biotech remains unfazed by potential US price control measures under discussion in Washington. Most of the ideas focus on improving patient access and affordability – which would ultimately improve market conditions for the innovation its managers support.

BB Biotech second quarter and half year 2019 performance

Despite maintaining the medium-long term strategy, BB Biotech was disappointed with second-quarter share returns for BB Biotech. Management is in the midst of portfolio reconstruction for long-term growth and some of the small and mid cap holdings underperformed relative to large cap firms.

Second-quarter 2019 share returns were -4.8% in CHF, and -4.8% in EUR. The NAV pulled back -9.4% in CHF, -8.8% in EUR and -7.6% in USD. Consequently, our second quarter net loss was CHF 336 mn compared to a loss of CHF 98 mn for the same period in 2018. Currency volatility also affected Q2 2019 results by about -1.9% due to the USD weakening against the CHF.

For the half year 2019, the total return for the share price including the dividend (18.2% in CHF, 19.4% in EUR) was in line with the Net Asset Value return (18.8% in CHF, 20.6% in EUR and 19.5% in USD), which led to a half-year gain of CHF 554 mn compared to a net loss of 70 mn for H1 2018. Exchange-rate fluctuations in the USD/CHF currency pair lowered performance by approximately -0.5%.

BB Biotech's share price proved more resilient in the second quarter, slightly extending the share price premium over the NAV to 12% at the end of the second quarter. The average premium throughout the first six months of 2019 was approximately 11%.

Performance of shares in BB Biotech's portfolio companies ranged from large gains to large declines. Voyager Therapeutics shares gained after deals with Neurocrine and Abbvie; Incyte gained after cancer drug development updates and their foray into dermatology. On the other hand, Myovant, Sangamo, Macrogenics and Scholar Rock each undertook capital increases – and these business-appropriate financings were interpreted by some as lack of M&A exit opportunity – driving down share prices by an amount disproportionate to the magnitude of the actual share dilution. Two other small firms in the portfolio, Kezar and Wave, announced ambiguous data, disappointing investors.

Second quarter 2019 developments in portfolio positions
The forward-looking portfolio strategic reshaping initiated in 2018 and designed to drive long-term growth is largely complete. Two remaining long-term large cap positions in Celgene (sale to Bristol Myers) and Gilead (stepwise divestment) will soon be closed. The substantial long-term gains from these and other successful investments will reduce leverage and generate cash investments in next-generation biotechnology companies at earlier stages of the growth cycle.

In the second quarter, Homology, Scholar Rock, Sangamo and Myovant undertook secondary offerings to raise capital for product development projects. BB Biotech participated in the Homology, Scholar Rock, and Sangamo offerings on favorable terms. Intercept placed a combination of equity and convertible debt in the same period. BB Biotech sold off its holding in Novavax following their failed Phase III trial of maternal respiratory syncytial virus vaccination and request by FDA for the company to undertake additional trials – a demand that precludes further investment in the company at this time.

Second quarter 2019 milestones
Akcea with Ionis announced European approval of the antisense drug Waylivra (volanesorsen). The drug is indicated for adults with genetically confirmed familial chylomicronemia syndrome (FCS) – a rare genetic disease characterized by the buildup of chylomicrons, the largest lipoprotein particles that transport a proportion of dietary fat and cholesterol in the bloodstream – in patients at high risk for pancreatitis after failing diet restrictions and triglyceride lowering therapy. BB Biotech anticipates Waylivra's launch in Germany this summer, followed by other European countries during 2020. Akcea and Ionis will continue their dialogue with the FDA after the agency's negative decision back in 2018.

Incyte received FDA approval of Jakafi (ruxolitinib, an oral Janus kinase 1/2 inhibitor), to treat adults and children 12 years of age and older with acute graft-versus-host disease after organ transplants who have taken corticosteroids that had not worked sufficiently enough. This new indication expands the market opportunity for Jakafi – so far approved for myelofibrosis and polycythemia vera. Incyte guided to expected long-term total annual US net product sales of USD 2.5-3.0 bn.

Alexion received FDA approval of Soliris (eculizumab, an injectable complement inhibitor) to treat adults with neuromyelitis optica spectrum disorder (NMOSD) who are anti-aquaporin-4 antibody positive. NMSOD is a rare autoimmune disorder of the brain and spinal cord dominated by inflammation of the optic nerve and spinal cord. Most patients experience repeated attacks of blindness and severe pain inside the eye together with loss of motor, sensory and autonomic functions, plus pain in the spine or limbs. Permanent loss of vision and mobility is frequent among recurring cases. Alexion also received both European and Japanese health agency approval of Ultomiris (ravulizumab, a long acting injectable complement-5 inhibitor) for paroxysmal nocturnal hemoglobinuria (PNH) – adding to its US approval. Given every 8 weeks, Ultomiris offers potential advantages over Soliris given every 1-2 weeks – and is an important extension for Alexion's highly successful complement franchise.

Other clinical events announced by portfolio companies were less clear. Myovant reported mixed top line results for Relugolix (an oral small molecule gonadotropin-releasing hormone antagonist) in combination therapy in women with uterine fibroids. Data met the primary endpoint (reduction in menstrual blood loss) and several secondary endpoints including improvements in pain and quality of life. However, the treatment effects were less than Wall Street had hoped for based on prior data and as Myovant tapped markets for capital, investors sold off the stock, fearing diminished likelihood of an acquisition by big pharma.

Wave Life Sciences and Kezar shares also declined following release of clinical data. Wave reported Phase I safety and tolerability data and a Phase II-III clinical trial design for suvodirsen, their stereoselective oligonucleotide that induces skipping of exon 51 of dystrophin pre-mRNA, in boys with Duchenne muscular dystrophy. The data showed liver-related adverse events at the highest doses. The upcoming Phase II-III trial will not test these highest doses – and some investors are concerned this may limit suvodirsen effectiveness. Kezar reported Phase I safety and tolerability data for KZR-616, an immune proteasome inhibitor. The highest doses of KZR-616 caused gastrointestinal adverse events. Like Wave, Kezar will only test the lower doses in their ongoing Phase II lupus nephritis trial.

Better news came from Macrogenics, which reported Phase III data for margetuximab (a monoclonal antibody that targets HER2-expressing tumors) in women with HER2-positive metastatic breast cancer previously treated with anti-HER2-targeted therapies. In combination with chemotherapy margetuximab fared better for progression-free and overall survival than Herceptin plus chemotherapy. Macrogenics plans to file a biologics license application with the FDA for margetuximab in the second half of 2019. Macrogenics is also testing margetuximab in combination with checkpoint inhibitors in the first line treatment of gastric cancer.

Halozyme shares gained after Johnson & Johnson reported that subcutaneous, five-minute delivery of Darzalez (daratumumab, a monoclonal antibody to treat adult patients with multiple myeloma) is similarly effective and safe when formulated with Halozyme's Enhanze technology as the current several hours intravenous infusion. Johnson & Johnson expects to file for approval of the dramatically improved formulation in the second half of 2019. Halozyme believes this will accelerate royalty revenues substantially from 2020 onwards.

Some of the portfolio firms announced strategic moves. Alnylam announced a partnership with Regeneron to discover, develop and commercialize RNAi therapeutics for ocular and central nervous system disorders. Alnylam received USD 400 mn upfront cash and Regeneron will invest an additional USD 400 mn in newly issued Alnylam shares and milestone payments. Crispr Therapeutics expanded its collaboration with Vertex to develop novel treatments for Duchenne muscular dystrophy and myotonic dystrophy type 1. Crispr received USD 175 mn in upfront cash and will receive milestone and royalty payments on achievement of certain development milestones.

Outlook for the second half 2019

BB Biotech anticipates further pipeline progress, including key product approvals and Phase III data read-outs, in the second half of 2019:

- Halozyme expects data from their trials of PEGPH20 in combination with therapeutic agents in pancreatic cancer patients in September and would announce the results by December.
- Sage expects to report the Mountain study of Zuranolone in a short-course episodic treatment trial in major depression disorder patients in Q4 2019 or Q1 2020.
- Agios expects to present Tibsovo data from studies in previously treated isocitrate dehydrogenase-1 (IDH-1) mutant cholangiocarcinoma patients at the European Society of Medical Oncology in Barcelona (27 September – 1 October) and is planning to submit a supplemental new drug application for Tibsovo by the end of 2019 – potentially expanding indications into solid tumors by late 2020. Tibsovo (ivosidenib) is an oral drug that inhibits mutations of the IDH-1 enzyme which are known to increase leukemia cell proliferation. Tibsovo is currently indicated for the treatment of acute myeloid leukemia with a susceptible IDH-1 mutation.
- Intra-Cellular announced that the FDA plans to hold a psychopharmacologic drug advisory panel for lumateperone for the treatment of schizophrenia in adults. The FDA is expected to make a decision on approvability by September 27, 2019.
- Nektar expects an FDA decision on the approvability of NKTR-181, a novel mu-opioid agonist offering potentially reduced abuse potential and other central nervous system side effects for chronic pain by August 29, 2019. Nektar has announced the launch of Inheris Biopharma, a wholly owned subsidiary responsible for commercialization of NKTR-181.

- Alnylam finalized a rolling submission for givosiran for the treatment of acute hepatic porphyria in early June. Givosiran has received breakthrough therapy designation from the FDA and there is potential for FDA approval by year-end.
- Vertex selected the triple combination regimen of VX-445, tezacaftor and ivacaftor for global regulatory approval in cystic fibrosis. Vertex plans to submit a New Drug Application to the FDA in the third quarter of 2019 to treat cystic fibrosis patients aged 12 years and older who have (1) one F508del mutation and one minimal function mutation and (2) two F508del mutations. Vertex anticipate expedited review and approval for the triple therapy by early 2020.

BB Biotech remains focused on M&A developments in biopharmaceuticals. In its view, recent deals combining Takeda with Shire, BMS with Celgene and Abbvie with Allergan reflect financial arbitrage efforts rather than technology or capability expansion – but do not address the low internal R&D productivity of these companies. BB Biotech managers expect most innovation in the biopharmaceutical industry will continue to come from biotechnology firms – such as those in their portfolio. Recognizing the potential reduction in competition, the US Federal Trade Commission has thrown cold water on such financially motivated M&A activities. Equity investors and arbitrage funds reacted negatively when Bristol-Myers Squibb announced they must divest Otezla, an important Celgene product, due to FTC concerns. The demand also delays closure of the transaction by up to six months. In BB Biotech's view, larger firms might better go after deals involving cutting-edge capabilities, novel technologies and late stage breakthrough products – the principle sources of sustainable growth in biopharmaceuticals.

As always, BB Biotech will continue to pursue such an innovation-driven investment strategy because it is effective. It remains committed to fundamental analysis to find capabilities, technologies and treatments in our core disease areas including oncology, neurology and rare, severe disorders. The portfolio management team seeks leading, vibrant companies taking on unmet medical needs, cost-effectively – thereby producing superior returns for BB Biotech shareholders.

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Company profile
BB Biotech AG invests in companies in the fast growing market of biotechnology and is one of the world's largest investors in this sector. BB Biotech AG 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 AG'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 AG's portfolio as at June 30, 2019
(in % of securities, rounded values)

Ionis Pharmaceuticals	13.2%
Incyte	8.2%
Neurocrine Biosciences	7.9%
Sage Therapeutics	6.4%
Vertex Pharmaceuticals	6.3%
Alexion Pharmaceuticals	4.6%
Celgene	4.6%
Radius Health	4.4%
Esperion Therapeutics	4.4%
Agios Pharmaceuticals	4.2%
Halozyme Therapeutics	3.8%
Argenx SE	3.5%
Alnylam Pharmaceuticals	3.3%
Nektar Therapeutics	2.0%
Voyager Therapeutics	2.0%
Moderna	1.9%
Gilead	1.7%
Myokardia	1.7%
Exelixis	1.6%
Macrogenics	1.6%
Akcea Therapeutics	1.5%
Intercept Pharmaceuticals	1.5%
Audentes Therapeutics	1.4%
Wave Life Sciences	1.1%
Sangamo Therapeutics	1.1%
Crispr Therapeutics	1.0%
Myovant Sciences	0.9%
Alder Biopharmaceuticals	0.9%
Scholar Rock Holding	0.8%
Intra-Cellular Therapies	0.8%
Homology Medicines	0.7%
G1 Therapeutics	0.6%
Kezar Life Sciences	0.3%
Cidara Therapeutics	0.1%
Total securities	**CHF 3 634.3 mn**
Other assets	CHF 10.3 mn
Other payables	CHF (375.1) mn
Net Asset Value	**CHF 3 269.5 mn**

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Fine Comunicato n.0472-27	Numero di Pagine: 7