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Publication of BB Biotech AG's Annual Report 2015

Outlook for the biotech sector remains positive despite sell-off

Further significant increase in dividend of 25% to CHF 14.50 per share, five-for-one share split proposed

Amid last year's volatile market environment, the Nasdaq Biotech Index (NBI) advanced 11.8% in USD while BB Biotech's share price gained 28.2% in CHF, 41.2% in EUR and 27.1% in USD over the year. The outperformance of the benchmark index is attributable to BB Biotech's successful stock-picking. Major performance drivers were new product launches, regulatory approvals, positive clinical data and M&A activity. In line with the distribution policy established in 2013, the Board of Directors will propose a dividend of CHF 14.50 per share at the Annual General Meeting, which represents a significant increase of 25% compared to the previous year. BB Biotech will also propose a five-for-one share split. In its outlook for 2016, the Investment Management Team expects stock markets to remain highly volatile. In view of the growing number of biotech products reaching the market and the expected clinical data from late-stage drug candidates, the fundamentals for the biotech sector remain positive. Moreover, the stock-market valuations of many companies have subsided to attractive levels in the wake of the recent sell-off, which has made them even more attractive takeover candidates for prospective buyers in the pharmaceutical and biotech industries.

The Nasdaq Biotech Index (NBI) advanced 11.8% in USD in 2015, while the S&P 500 Index treaded water and ended the year with a gain of 1.4% in USD. European stock markets, the Euro Stoxx 600 or the DAX, for example, gained approximately 10% in EUR, buoyed by the significantly weaker currency. The SMI's total return in 2015 was a slim +1.2% in CHF.

BB Biotech AG's shares clearly outperformed the benchmark index, rising by 28.2% in CHF, 41.2% in EUR and 27.1% in USD. BB Biotech's Net Asset Value (NAV) rose by 19.0% in CHF, 31.6% in EUR and 18.0% in USD over the year. This good performance was driven by several factors: the positive sector developments, strong stock selection and ongoing high M&A activity. BB Biotech AG closed 2015 with an after-tax profit of CHF 653 mn (previous year: profit of CHF 1470 mn).

Dividend of CHF 14.50 per share proposed for 2015 fiscal year

In line with the distribution policy established in 2013, the Board of Directors will propose a distribution of CHF 14.50 per share at the Annual General Meeting on March 17, 2016, which corresponds to a 5% yield based on the volume-weighted average price of BB Biotech shares in December 2015. This marks another significant increase of 25% compared to the previous year. The remaining paid-in capital reserves of around CHF 136 mn will be distributed with the difference to be paid out as a regular dividend from retained earnings.

Five-for-one share split proposed

A five-for-one share split is being proposed in the light of BB Biotech's strong performance of +461.4% (in CHF) over the past five years and the positive prospects for its investment portfolio. The number of fully diluted outstanding shares will increase from 11.85 million to 59.25 million, excluding shares repurchased on the second trading line.

Portfolio changes in the fourth quarter and throughout 2015

Trading activity in the fourth quarter was significantly below prior quarters. Three takeovers alone, Pharmacyclics, Synageva and Receptos, had a significant impact on BB Biotech's portfolio and generated CHF 541 mn in cash in the first nine months of 2015. The small holdings in Immunogen, Theravance and Theravance Biopharma were also sold during the course of 2015. Meanwhile BB Biotech added eight new small and mid-cap positions over the year and increased many of its existing shareholdings.

The level of investment fluctuated in relation to the underlying sector performance. At the beginning of 2015 BB Biotech's cash position was zero whereas in the summer, when the biotech sector was trading at its high, the cash position was about 5%. Afterwards, during the ensuing correction, BB Biotech built up new investments and traded back into existing positions, which led to an investment level of 104% by the end of the year.

At the end of 2015, BB Biotech's portfolio consisted of six core holdings, each accounting for more than 5% of portfolio assets, namely Celgene, Incyte, Ionis Pharmaceuticals (formerly Isis), Actelion, Gilead and Radius Health. BB Biotech's investment portfolio comprises 34 positions in all.

Two new positions were added during the fourth quarter of 2015 – Sage Therapeutics and Cidara Therapeutics. Sage is focused on central nervous system (CNS) disorders with its lead pipeline candidate SAGE-547 under development to treat super-refractory status epilepticus. Cidara is developing novel anti-infectives, including their lead product CD101, a novel molecule from the echinocandin class, for the treatment of systemic Candida infections.

Progress for the portfolio companies continues

In the final quarter of 2015, three of BB Biotech's portfolio companies announced product approvals in key markets. Gilead announced the US FDA approval of Genvoya for the treatment of HIV-1 infected patients. Genvoya is the first single tablet regimen containing tenofovir alafenamide (TAF) in combination with elvitegravir, cobicistat and emtricitabine. As a next generation tenofovir, TAF has been proven to match tenofovir's activity against HIV-1 with significantly less side effects. Elocta reached approval status by the European Commission and can be launched in all 28 member states of the EU for treating patients with hemophilia A, both as prophylaxis and on-demand treatment/application. Swedish Orphan Biovitrum will market Elocta in Europe while its development partner Biogen will market the drug in the US. Actelion received US regulatory nod to launch Uptravi, its novel orally available prostacyclin receptor agonist. Uptravi (Selexipag) will complement Actelion's market leading PAH product offering and allow the company to sustain long-term top and bottom line growth.

Disappointingly, Clovis announced following its mid-cycle communication meeting with the US FDA that the previously published and presented 60% response rate for rociletinib, the company's mutant selective EGFR inhibitor for the treatment of non-small cell lung cancer patients, did not hold up and was confirmed to be about half that. Investors questioned both the approvability as well the competitiveness of the drug in the case of approval, leading to a significant correction in the company's market capitalization.

As a significant positive, Neurocrine announced positive Phase III data for NBI-98854 in tardive dyskinesia patients. The VMAT2 inhibitor showed a statistically significant reduction in tardive dyskinesia during six weeks of placebo-controlled treatment. The company has applied for a regulatory review and is expecting product approval in late 2016.

Besides the approvals and clinical data read-outs, there were other headlines on the biotech sector. Celgene, for example, announced the settlement of the Revlimid patent litigation with Natco Pharma and Allergan. The settlement terms give Natco unrestricted access to the US market from January 31, 2026 and "volume-limited" marketing rights as of March 2022. The settlement is positive for Celgene because it effectively protects its patent estate for Revlimid and allows Celgene to continue its diversification and growth strategy for many years to come.

Outlook

In its outlook for 2016, BB Biotech expects more announcements of regulatory approvals as well as strong pipeline newsflow from its portfolio companies. Merger and acquisition activity was an important performance driver in 2015 and BB Biotech's Investment Management Team expects more large deals to come. As for the macroeconomic environment, management expects volatility to climb higher over the next few quarters, triggered by diverging central bank monetary policy and election news in the US.

Major product approvals likely to be announced by BB Biotech's portfolio companies in 2016 are:

- Uptravi for treating pulmonary arterial hypertension patients (Actelion) by EMA
- OCA for the treatment of primary biliary cirrhosis (Intercept)
- TAF containing HIV medications (Gilead)
- Sovaldi/Velpatasvir combo for HCV (Gilead)
- Ataluren for Duchenne muscular dystrophy patients (PTC Therapeutics)
- Valbenazine for the treatment of tardive dyskinesia patients (Neurocrine)
- EU decision on Abaloparatide for treating osteoporosis (Radius)

Furthermore, updates in key clinical programs are expected for literally all portfolio holdings. BB Biotech's portfolio consists of established, profitable firms with attractive valuations and on highly innovative small and mid-caps. Thanks to this diversity, the Investment Management Team believes it is well positioned to capture many of the important value-creating sector milestones in 2016.

BB Biotech's annual report as of December 31, 2015, is available at 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.

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