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BB Biotech

Media release as of October 20, 2017

Interim Report of BB Biotech AG as of September 30, 2017

Product approvals and solid company results lead the biotech sector higher

BB Biotech closes the third quarter with a double-digit performance in Swiss francs

Several factors helped to make the third quarter a pleasing one for the sector and BB Biotech. Uncertainty regarding government price controls in the US subsided and biotech companies reported solid quarterly results and new product approvals. The US FDA has already approved more drugs this year than all of last year. There was another major acquisition with Gilead's purchase of Kite Pharma. If the proposed US tax reform is passed, M&A activity is likely to pick up. In the third quarter, BB Biotech's shares rose by 10.7% in CHF, 6.4% in EUR and 9.6% in USD. In the first nine months of 2017, BB Biotech achieved a total return of 24.2% in CHF, 15.7% in EUR and 30.8% in USD. Net profit amounted to CHF 365 mn for the third quarter and CHF 843 mn for the first nine months. This compares with the profit of CHF 392 mn reported for the third quarter of last year and a loss of CHF 778 mn for the first nine month of 2016.

During the third quarter US equity markets increased by around 5% (S&P Index 4.5%, Dow Jones Index 5.6% and Nasdaq Composite Index 6.1%), driven by solid corporate results and a continued favorable interest rate environment. European stocks increased by around 3% (DAX 4.1%, SMI 2.9%). Healthcare stocks traded higher – including a 7.7% increase in the Nasdaq Biotechnology Index. For the same period, BB Biotech shares gained 10.7% in CHF, 6.4% in EUR and 9.6% in USD. Gains by equities, including BB Biotech's stock, were opposed by currency fluctuations. For the third quarter, the US Dollar fell a further 3.4% versus the Euro, while gaining 1.1% versus the Swiss Franc. That brings currency headwinds for the year to -12.3% for the US Dollar against the Euro and -5.0% against the Swiss Franc.

Positive environment

BB Biotech expects continued inflows of funds into the biotech sector due to strong fundamentals. Many investors were underweight biotechnology during 2016 because of uncertainty about the US presidential election campaign and about US drug price controls. But as maintained on numerous occasions, BB Biotech expects incremental changes in the US health environment – Affordable Care Act reform has been stalled and pricing concerns are being managed carefully from all sides.

Like others, BB Biotech was encouraged by the appointment of Dr. Scott Gottlieb as Commissioner of the FDA and is not disturbed by the recent resignation of Gottlieb's superior, Tom Price, as HHS Secretary. The FDA has already approved more new drugs so far in 2017 than in all of 2016.

Several factors drove favorable biotech performance during the third quarter. High-revenue companies reported solid Q2 2017 results. A significant number of products achieved regulatory approval, and progress was reported for a range of potentially valuable clinical candidates. Perhaps more significantly for the long-term outlook, the industry announced major breakthroughs with new approaches to medicines, including advancements with RNA-based drugs, novel gene therapies, cell-based therapies, and novel formats of antibodies. There are more exciting technologies on the horizon which offer potential transformative innovations, examples of which are gene editing CRISPR/Cas technology, and novel RNA-based therapies beyond antisense and RNA-interference.

Merger and acquisition trends

Merger and acquisition activity in the biotechnology sector has been subdued so far in 2017. So Gilead's announced acquisition of Kite for USD 12 bn came as a pleasant surprise to equity markets and has encouraged the belief that there's more to come – not only from Gilead, which announced its intention to do more, perhaps encouraged by the market's response to their deal. Given the fundamental progress in the sector and US attempts at tax reform including potentially favorable terms for cash repatriation, BB Biotech anticipates a growing appetite among larger pharma firms and likely a pick-up in M&A activities going into 2018.

Third-quarter 2017 and year-to-date 2017 performance
For the third quarter BB Biotech's share return gained 10.7% in CHF, 6.4% in EUR and 9.6% in USD. Net Asset Value (NAV) performance for the third quarter was similar with gains of 11.0% in CHF, 6.2% in EUR and 9.8% in USD, ahead of the NBI's return of 7.7% in USD for the same period. This positive portfolio performance led to a net profit of CHF 365 mn for the third quarter compared to CHF 392 mn for the same period in 2016.

For the first nine months of 2017, BB Biotech's share return is 24.2% in CHF, 15.7% in EUR and 30.8% in USD. The NAV performance was better, with total returns of 28.8% in CHF, 20.2% in EUR and 35.6% in USD, well ahead of the NBI's total return of 26.5% in USD. Both the share and NAV returns include the dividend payment of CHF 2.75 per share that was paid on March 22, 2017. For the year-to-date 2017 period, value appreciation of portfolio investments led to a net profit of CHF 843 mn compared to a loss of CHF 778 mn for the same period in 2016.

Pipeline highlights and product updates from portfolio companies
Multiple pipeline events were reported in the third quarter. Alnylam, with its partner Sanofi, announced that Patisiran, an investigational RNAi therapeutic being developed for patients with hereditary ATTR amyloidosis with polyneuropathy, met all the clinical endpoints in the trial. Alnylam is planning to file a new drug application (US) in late 2017 and a market authorization application (EU) in early 2018. The news lifted Alnylam shares substantially as investors saw it as substantiation of the platform as well as great news for the product.

Vertex reported positive data from Phase I and Phase II studies of three investigational triple combination regimes for cystic fibrosis patients with one F508del mutation and one minimal function mutation. The data suggest that these investigational combinations may treat the underlying cause of cystic fibrosis in severe and difficult-to-treat types. Given the significant market opportunity for these combination regimens, Vertex's shares also increased substantially.

By contrast, Sage Therapeutics reported failure of brexanolone in super refractory status epilepticus. Investors have made substantial bets on the strength of this potential indication – but BB Biotech managers were more cautious about such high expectations and had sold a substantial part of the position prior to the news. After the news, BB Biotech reacquired Sage shares at a lower price given its belief in the ultimate potential for brexanolone in post-partum depression.

Some of the portfolio holdings experienced volatility as the FDA enabled greater access to its Adverse Event Reporting System on the last day of September. The FDA move should ultimately support transparency regarding innovation, but for the short term, misinterpretation of the data may have effects on share prices. BB Biotech's investment in Intercept is an example here. The FDA disclosed all safety data in its reporting system for Intercept's product Ocaliva, which is used for severe liver disease. The newly released FDA data included previously unknown adverse events associated with higher-than-recommended dosages of the product. Investors overreacted and BB Biotech subsequently added to its Intercept position.

Product approvals from the portfolio holdings
Celgene, and partner Agios, won US market approval for enasidenib to treat adult patients with relapsed or refractory acute myeloid leukemia associated with an isocitrate dehydrogenase-2 (IDH2) gene mutation. Approval was granted based on an extended Phase I/II study which not only validated the efficacy and safety, but also demonstrates the FDA's increasing willingness to accelerate the approval of drugs for high unmet medical needs.
Gilead's Vosevi, a fixed-dose combination of sofosbuvir, velpatasvir and voxilaprevir, was approved by the FDA for treatment of adults with chronic hepatitis C. This builds further on Gilead's leading franchise.

Novo Nordisk's Fiasp (fast-acting insulin aspart) was also approved by the FDA. This is a new fast-acting mealtime insulin for adult diabetics. Novo's share price has also been spurred by the expected approval of Semaglutide, a once weekly GLP-1 analogue. If approved in 2017, Semaglutide will extend Novo Nordisk's GLP-1 franchise and allow them to compete more effectively against Eli Lilly's Trulicity. However, if approved, BB Biotech anticipates a slow uptake of Semaglutide and stiff price competition in the US market place.

Merger and acquisition activities within BB Biotech's portfolio
Gilead announced its proposed acquisition of Kite (an immuno-oncology company) for USD 180 per share (total value USD 12 bn). Kite anticipates approval of its CD19 CAR-T product in the fourth quarter of 2017. The acquisition has been approved by the boards of both companies. BB Biotech sold its entire holding in Kite into the announced transaction – generating approximately USD 124 mn in cash and an overall profit of USD 75 mn from the investment. Stocks of several other midcap oncology companies rallied on the news. Juno, the closest competitor to Kite, rose significantly, adding to BB Biotech's NAV performance in the third quarter.

License deals
Licensing deals are less impactful on BB Biotech's portfolio than in prior years as companies become more and more valuable. However, Halozyme added to NAV performance in the third quarter after announcing deals with Bristol Myers Squibb and Roche for its drug delivery technology. The deals delivered non-dilutive upfront cash that bolstered Halozyme's balance sheet so that they can invest aggressively in their promising and unencumbered oncology assets.

BB Biotech provides fresh capital for companies
Improved equity markets led to significant fundraising by biotech companies in the third quarter. Five of BB Biotech's small and midcap companies, Esperion, Incyte, Alder, Intracellular and Juno, sold new shares, and Radius Health issued a convertible bond. BB Biotech participated in the Alder and Esperion deals and took the opportunity of share price pressure associated with Radius' debt offering to increase its holding in the company.

Few portfolio changes in the third quarter
During 2017, BB Biotech's investment portfolio has included 6.8% borrowing at the beginning of the year to a peak of 10.2% in May and to holding 0.3% in cash in August 2017. Fluctuations in leverage/deleverage resulted from major M&A transactions such as the sale of Actelion in the second quarter and Kite in the third quarter. Year-to-date cash outflow was mostly attributable to the CHF 2.75 per share dividend (total outflow CHF 152 mn).

During the third quarter, minor changes were made to the portfolio. Holdings in Incyte, Ionis and Regeneron were modestly increased. BB Biotech added to its holdings in Alder, Cidara, Esperion, Halozyme, Intercept and Tesaro, took further profits from Novo Nordisk, Celgene, and Swedish Orphan and sold its entire position in Kite.
No new investments were added to the portfolio. BB Biotech continues to look for new investment candidates and will add new positions if valuations are compelling.

Outlook for the sector and the portfolio
Looking ahead BB Biotech maintains its view of future incremental changes in drug pricing policies and practices in the US. Management continues to believe that excellent new drugs, priced appropriately, will flourish and continues to incorporate value-for-money and pricing considerations in its financial models and valuation assumptions for new products of the biotechnology industry in order to deliver superior returns to BB Biotech shareholders.

Significant potential milestones for the remainder of 2017 include:
- FDA approval for Semaglutide for treating type 2 diabetes patients (Novo Nordisk)
- FDA approval for Axicabtagene Ciloleucel for lymphoma patients (Gilead/Kite)
- Phase III data for Brexanolone for treating postpartum depression (Sage Therapeutics)
- Phase III data for Revlimid in lymphoma patients (Celgene)
- Phase I/II data Ivosidenib for relapse refractory AML patients (Agios)

In addition, investors are focused on important, ongoing commercial launches including Spinraza for spinal muscular atrophy (Biogen and Ionis), Ocaliva for primary biliary cholangitis (Intercept), Zejula for maintenance treatment of recurrent epithelial ovarian cancer (Tesaro), and Ingrezza for tardive dyskinesia (Neurocrine). Revenue growth of these drugs will drive profit forecasts and share price valuations for these companies. Overall, BB Biotech believes that the encouraging progress in biotechnology during the first nine months of 2017 will continue for the rest of 2017 and into 2018. Management anticipates more progress with exciting drug development programs, new approvals and commercial progress of marketed products.

The complete interim report as at September 30, 2017 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 September 30, 2017

(in % of securities, rounded values)

Celgene	12.2%
Incyte	11.2%
Ionis Pharmaceuticals	10.4%
Gilead	5.9%
Vertex Pharmaceuticals	5.9%
Neurocrine Biosciences	5.6%
Radius Health	5.6%
Alexion Pharmaceuticals	5.0%
Agios Pharmaceuticals	4.8%
Novo Nordisk	4.0%
Halozyme Therapeutics	3.9%
Alnylam Pharmaceuticals	3.4%
Tesaro	3.4%
Esperion Therapeutics	2.8%
Juno Therapeutics	2.4%
Regeneron Pharmaceuticals	2.4%
Sage Therapeutics	1.8%
Myovant Sciences	1.4%
Macrogenics	1.2%
AveXis	1.0%
Intra-Cellular Therapies	0.9%
Five Prime Therapeutics	0.8%
Intercept Pharmaceuticals	0.7%
Alder Biopharmaceuticals	0.7%
Prothena Corp.	0.6%
Swedish Orphan Biovitrum	0.5%
Probiodrug	0.5%
Cidara Therapeutics	0.3%
Idorsia	0.3%
Novavax	0.2%
Achillion Pharmaceuticals	0.2%
Radius Health warrants, 04/23/2018	0.1%
Radius Health warrants, 02/19/2019	< 0.1%
Total securities	**CHF 3 695.5 mn**
Other assets	CHF 15.3 mn
Other payables	CHF (19.2) mn
Total shareholders' equity	**CHF 3 691.6 mn**

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