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Oggetto : Interim report of BB Biotech AG as at
September 30, 2018

Testo del comunicato

Vedi allegato.

Media release as of October 19, 2018

Interim report of BB Biotech AG as at September 30, 2018

Investors showed renewed interest in biotech stocks during the third quarter

After a lackluster first half, biotech stocks displayed more vitality in the third quarter. BB Biotech's share price advanced 7.8% in CHF. It gained 9.4% in EUR and 8.8% in USD. Net Asset Value (NAV) increased by nearly the same amount, up 7.3% in CHF, 8.9% in EUR and 8.3% in USD. Net profit for the period amounted to CHF 242 million (Q3 2017: CHF 365 million). BB Biotech's inclusion in the SMIM index of stocks bolstered investor demand for its shares and widened the gap (premium) between the stock's NAV and its market price. Further action was taken to realign the portfolio. Smaller and mid-sized firms represent a growing percentage of the portfolio, while the weighting of large cap stocks is declining. The latter segment made an outstanding contribution to portfolio performance in past years, but it is likely to relinquish its status as the sector's preeminent growth driver going forward. Through its active investment style, BB Biotech is increasing its exposure to novel treatment methods and thereby gradually shifting away from small molecule and recombinant protein treatment avenues. Challenging monoclonal antibodies, RNA-based therapeutic agents, and gene and cell-based therapies offer greater potential.

Third quarter developments extended 2018 equity market trends. The US and China ratcheted up rhetoric and trade tariffs, yet the US markets traded higher – the S&P500 gained 7.7% in USD, reaching new highs. European equity markets again lagged the US as Brexit and Italian political uncertainty filled the economic news. So the DAX Index (-0.5% in EUR) and the Euro Stoxx 600 (1.3% in EUR) went sideways. Meanwhile, SMI gains (5.7% in CHF) were driven by investors rotating into defensive stocks.

Currencies did move around consequent to trade tariffs. Weak in the early third quarter, the US dollar recovered once the US Federal Reserve raised interest rates in September.

Healthcare markets performed well in the third quarter after a disappointing first half year. The MSCI World Health Care Index moved up 11.6% in USD. Biotech equities were similar – with the NBI up 11.2% in USD for the same period. Among other healthcare subsectors, life science tools, medtech and service companies were notably strong.

The innovation elements of the drug sector benefited from US policy statements. Both the FDA and its parent HHS took aim at intermediaries in supply chain. Wall Street was relieved (at least for biotech stocks) and capital flowed into the biotech sector in the third quarter for the first time in at least a year. Renewed investor appetite encouraged IPOs and secondary placements. These trends are helpful, but not particularly informative with respect to BB Biotech's strategy. There were no new major M&A activities involving biotech firms during the third quarter.

The sector continued to see short-term investing strategies to the fore. Positive news events precipitated brisk upward trading, whereas arguably minor setbacks led to even more brisk downward trading. Meantime, BB Biotech remains consistently committed to long-term value and the constant rebalancing of its portfolio. Next-generation investment opportunities are remarkable and so its managers have rebalanced large caps into mid and smaller cap companies and moved positively towards new drug modalities and approaches. This rebalance is part of the perpetual active management of portfolio assets and it marks a move away from small molecules and recombinant human proteins to sophisticated monoclonal antibodies, RNA-based therapeutics, gene therapies and cell therapies. Some of these provide long-lasting effects which can improve product performance and economic value relative to older modalities.

BB Biotech Q3 2018 and 9M 2018 performance

The third quarter 2018 total share return for BB Biotech was 7.8% in CHF, 9.4% in EUR and 8.8% in USD. The Net Asset Value gained 7.3% in CHF, 8.9% in EUR and 8.3% in USD. Consequently, third quarter net gain was CHF 242 mn, compared to CHF 365 mn for the same period in 2017.

The 9-month performance redressed the first half year 2018 performance. The total share price return (16.8% in CHF, 18.4% in EUR and 15.9% in USD) was higher than the portfolio's Net Asset Value return (4.6% in CHF, 7.5% in EUR and 3.9% in USD). The 9-month net gain of CHF 172 mn compares to a gain of CHF 843 mn for the same period in 2017.

The disconnect between share price and NAV growth reflected a continued share price premium throughout the first nine months of the year. The index inclusion of BB Biotech into the SMIM Index (at around 2.6% weight) and the SPI Index (at around 0.3%) on September 24, 2018 increased demand for BB Biotech shares.

Several of the portfolio companies continued to experience a challenging third quarter. Key holdings such as Radius Health, Alnylam and Tesaro failed to keep pace with the biotech indices. The market was disappointed with Alnylam's Onpattro label – and drug launches at Tesaro and Radius Health failed to excite anyone.

New cycle of portfolio re-positioning initiated

Since mid cap companies take up more of BB Biotech's top portfolio spots, management remains quite committed to the large caps Gilead and Celgene, and performance relative to the NBI has therefore been affected negatively.

Portfolio restructuring planned in the summer is progressing well. The long-term holdings such as Celgene, Gilead and Novo Nordisk, have been historically superb performers for the portfolio. But these bellwethers may no longer lead growth trends. Portfolio re-adjustment therefore began with careful profit-taking throughout the third quarter. Some shares of Regeneron and Neurocrine were also sold for tactical reasons.

Profits were invested in Scholar Rock, a new holding initiated in this reporting period, and added to existing recent positions taken in Argenx, Exelixis and Nektar Therapeutics. Existing positions in Alnylam, MacroGenics, Voyager Therapeutics, Wave Life Sciences and Radius Health were also increased since their market valuations are substantially below intrinsic value. During the third quarter, the remaining positions in Probiobrug and Five Prime Therapeutics were sold off.

The top portfolio positions reflect expectations of significant growth for RNA-based medicines which will transform drug markets. Supporting this view, a post-quarter note should highlight Janssen's enormous investment in RNAi technology at Arrowhead Pharmaceuticals. BB Biotech is also interested in neurology companies which address broad patient populations and companies such as Vertex, which is well established now with winning technologies and products for cystic fibrosis.

Scholar Rock is focused on extracellular activation of growth factors, such as the TGFbeta superfamily. Their lead compound, SRK-015, is a monoclonal antibody targeting proMyostatin and latent myostatin - designed to inhibit myostatin activation and thereby promote muscle growth and function. The initial indication is late onset spinal muscular atrophy (Type 2 and 3) in combination with Spinraza and other therapeutics. Scholar Rock is also focused on (1) TGFβ and (2) BMP6. For the former, the company could disclose a target and lead indication in this area sometime in 2019. For the latter (bone morphogenic peptide-6) which regulates iron, a lead indication in anemia could be announced in 2019.

BB Biotech was 109% invested at the end of the third quarter – a stable level in absolute and relative terms compared to H1 2018, but well above the 102.5% at the beginning of the year.

Milestones for the third quarter

Important clinical trial results were reported by portfolio companies in the third quarter:

- Alexion reported a successful study for Soliris (eculizumab) in patients with Neuromyelitis Optica Spectrum Disorder (NMOSD). Treatment with Soliris led to a 92% reduced risk of NMOSD relapse.
- Esperion announced that bempedoic acid was successful as a fix dose combination with Zetia (Ezetimibe), adding 35% LDL-C lowering in patients on maximally tolerated statin background therapy. The combination proved safe and well tolerated.
- Alnylam announced positive topline results for givosiran for the treatment of patients with acute hepatic porphyria. Results of the interim analysis showed that givosiran led to reduced urinary ALA levels, in acute intermittent porphyria compared to placebo.
- Akcea and Ionis reported positive topline data for AKCEA-Apo(a)-LRx in patients with established cardiovascular disease and elevated lipoproteins(a) reporting Lp(a) reductions. The program is part of a strategic collaboration with Novartis – which has an option on the program.

In the third quarter, three new products from portfolio companies received approval and one product application was declined.

Agios reported the FDA approval of Tibsovo (ivosidenib) for the treatment of relapsed or refractory acute myeloid leukemia (AML). Tibsovo is the second IDH mutant inhibitor to be approved and potentially addresses (together with IDHIFA) approximately 20% of all AML patients. In addition to these two approved agents, Agios is advancing a range of pipeline compounds in its three major focus areas: cancer metabolism; rare genetic disorders; and metabolic immune-oncology.

Anylam achieved approval of Onpattro (patisiran), the world's first commercially available RNAi product. Onpattro is indicated for the treatment of hereditary transthyretin-mediated amyloidosis in adults with polyneuropathy.

Neurocrine, together with its marketing partner AbbVie announced the approval of Orilissa (elagolix) for the management of moderate to severe pain associated with endometriosis. Orilissa is the first and only oral gonadotropin-releasing hormone (GnRH) antagonist approved for endometriosis, a large market opportunity.

Akcea and Ionis received a complete response letter from the FDA for their new drug application for Waylivra (volanesorsen). This rejection was unexpected following a positive FDA advisory panel vote in May 2018. The company is expected to update investors in the coming months on their plans to proceed with Waylivra, once the FDA clarifies their needs. Volanesorsen is also under regulatory review in Europe and Canada.

Outlook for the remaining three months of 2018

BB Biotech expects further pipeline progress including Phase III data reports and new product approvals in US and Europe during the remaining three months of 2018. News flow should come from:

- Ionis and Akcea (Tegsedi), at the time of publication, have received US FDA approval for treating transthyretin amyloidosis
- Sage Therapeutics is expected to gain FDA approval for Zulresso (brexanolone) to treat post-partum depression
- Esperion is expected to report its final Phase III safety data for bempedoic acid to treat patients with high levels of LDL-C
- Neurocrine is expected to report Phase II data for Tourette's, a potential important new indication for Ingrezza

The momentum for BB Biotech's portfolio is expected to remain high for the last quarter of 2018 and well into 2019. Multiple late stage clinical trial results and product approvals are expected. As large pharma market capitalizations increase, M&A activity may pick up.

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

For further information:

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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.

Disclaimer

This release contains forward-looking statements and expectations as well as assessments, beliefs and assumptions. Such statements are based on the current expectations of BB Biotech, its directors and officers, and are, therefore, subject to risks and uncertainties that may change over time. As actual developments may significantly differ, BB Biotech and its directors and officers accept no responsibility in that regard. All forward-looking statements included in this release are made only as of the date of this release and BB Biotech and its directors and officers assume no obligation to update any forward-looking statements as a result of new information, future events or other factors.

Composition of BB Biotech's portfolio as at September 30, 2018

(in % of securities, rounded values)

Ionis Pharmaceuticals	11.4%
Neurocrine Biosciences	9.9%
Celgene	6.8%
Vertex Pharmaceuticals	6.7%
Incyte	6.7%
Alexion Pharmaceuticals	4.7%
Agios Pharmaceuticals	4.3%
Sage Therapeutics	3.9%
Gilead	3.9%
Halozyne Therapeutics	3.8%
Esperion Therapeutics	3.7%
Alnylam Pharmaceuticals	3.1%
Radius Health	3.0%
Tesaro	2.9%
Myovant Sciences	2.4%
Akcea Therapeutics	2.1%
Regeneron Pharmaceuticals	2.1%
Moderna Therapeutics ¹⁾	1.8%
Wave Life Sciences	1.8%
Intercept Pharmaceuticals	1.8%
Novo Nordisk	1.7%
Macrogenics	1.6%
Argenx SE	1.4%
Voyager Therapeutics	1.4%
Nektar Therapeutics	1.3%
Exelixis	1.3%
Intra-Cellular Therapies	1.2%
Alder Biopharmaceuticals	1.0%
Myokardia	0.8%
G1 Therapeutics	0.6%
Novavax	0.4%
Cidara Therapeutics	0.3%
Scholar Rock Holding	0.1%
Achillion Pharmaceuticals	0.1%
Radius Health warrants, 02/19/2019	<0.1%
Total securities	CHF 3 844.5 mn
Other assets	CHF 15.2 mn
Other payables	CHF (332.3) mn
Net Asset Value	CHF 3 527.4 mn

1) Unlisted company

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