Informazione Regolamentata n. 0472-44-2016	Data/Ora Ricezione 21 Ottobre 2016 09:35:46	MTA - Star

Societa'	:	BB BIOTECH
Identificativo Informazione Regolamentata	:	80434
Nome utilizzatore	:	BIOTECHNSS01 - Alderuccio
Tipologia	:	IRAG 03
Data/Ora Ricezione	:	21 Ottobre 2016 09:35:46
Data/Ora Inizio Diffusione presunta	:	21 Ottobre 2016 09:50:47
Oggetto	:	Interim Report of BB Biotech AG as of September 30, 2016

Testo del comunicato

Vedi allegato.

Media release as of October 21, 2016

Interim Report of BB Biotech AG as of September 30, 2016

Biotech stocks continue to advance

Good operational progress and renewed M&A activity lead to a positive third quarter for biotech stocks

BB Biotech shares continued to recover lost ground, gaining +11.9% in CHF and +11.7% in EUR during the past quarter. Net Asset Value (NAV) also rose and resulted in a quarterly profit of CHF 392.1 mn. A pickup in M&A activity contributed to the positive sector performance. Investor interest centered on Pfizer's acquisition of Medivation and Allergan's bid for Tobira. Many biotech firms also reported good progress in their clinical trials. Highlights here included Ionis, Agios, Kite, Sage, Radius and Alder. Meanwhile the US elections on November 8, 2016 are looming large and the possibility of more government price controls is commanding the attention of investors. That said, BB Biotech believes that any changes enacted by the next administration and Congress will be incremental rather than dramatic. BB Biotech AG made careful adjustments to its portfolio during the third quarter to capture opportunities presented by the ongoing market volatility and possible overreactions to news flow. Positions in Novo Nordisk and Regeneron were increased, for example, and profits were taken in Celgene, Actelion, Tesaro, Swedish Orphan Biovitrum and Puma Biotechnology.

Global equity markets generally traded higher in Q3 2016, as the US Federal Reserve Bank once more deferred raising interest rates and other reserve banks continued expansive policies. The third quarter of 2016 saw positive USD returns of 3.9% for the S&P Index, 2.8% for the Dow Jones Index, 10.7% for the Nasdaq 100 and 12.5% for the Nasdaq Biotech Index. In Europe, a recovery of sorts continued after the Brexit vote with the DAX gaining 8.6% in EUR but the SMI gaining a mere 1.7% in CHF. In the same time period, BB Biotech reported a gain of 11.9% in CHF, and 11.7% in EUR.

Biotech valuations saw modest upward progress despite improving fundamentals and this disconnect reinvigorated the M&A market in the third quarter. Large pharmaceutical companies took advantage of the disconnect to acquire small and midcap companies – eschewing mega-mergers and generating cash from their own restructuring-related divestment activity – which included the sale by entire pharmaceutical divisions in some cases. Pharma's entry into M&A once more led the recovery of BB Biotech's Net Asset Value (NAV), which increased 15.5% in USD, 14.9% in CHF and 14.3% in EUR.

Key events and readouts which impacted BB Biotech's portfolio holdings in the third quarter of 2016 included M&A transactions:

- Medivation – acquired by Pfizer for USD 81.50 per share, valuing the company at USD 14.5 bn.
- Tobira – received a takeover offer from Allergan for USD 28.35 per share in cash and up to USD 49.84 per share in contingency value rights, representing USD 600 mn in upfront cash payment and an additional USD 1.1 bn in milestone payments.

In addition, valuable progress with drug development programs was announced:

- Ionis, with its development partner Biogen, announced that the nusinersen Phase III ENDEAR study treating spinal muscular atrophy (SMA 1) patients was stopped early due to a positive interim data for motor milestone achievements.
- Agios announced, with its development partner Celgene, it would accelerate the filing of AG-221 for treating AML patients with IDH mutations.
- Kite reported positive initial results for KTE-019 for treating DLBCL patients.
- Sage announced positive Phase II data for severe post-partum depression for SAGE-547. The FDA granted SAGE-547 breakthrough designation status.
- Radius' abaloparatide patch demonstrated positive PK/PD data for the treatment of osteoporosis.
- Alder reported positive Phase II data for ALD403 for the treatment of chronic migraine.

Some news events were negative or mixed, including:

- Novavax announced that the Phase III RSV vaccine trial for elderly patients did not meet the primary endpoint of prevention of moderate to severe RSV-associated lower respiratory tract disease.
- Intra-Cellular reported that the second Phase III trial for ITI-007 did not reach the primary endpoint in schizophrenia patients.
- Celgene's Phase III trial for Revlimid to treat diffuse large B cell lymphoma reported a positive progression-free survival effect but failed to show an overall survival benefit.

Life-science investors also remained focused on the US presidential election (November 8) – looking for signals of policy change from either candidate. The debate was fueled as a consequence of inquiries into aggressive price increases for Mylan's EpiPen – a long-established product. EpiPen is not a product of modern biotechnology. Nevertheless these controversies fuel investor concerns about future price control mechanisms in the US – which BB Biotech believes will be modest and will not impede investment and value in innovative medicines.

Innovation continues to be recognized as the strongest foundation for attractive pricing – and firms that deliver biotech progress and smart health economics will continue to win. In the meantime, pharmacy benefit managers (PBMs) in the US continue to come under scrutiny. PBMs act as middle-market negotiators between payers, pharmacies, providers and biopharmaceutical companies. They have been widely criticized for taking too big a slice of the cost of medicines in the US – but continue to exert influence on drug adoption, prices and payment terms. Recently, Novo Nordisk reduced its revenue growth outlook for 2017 consequent to PBM pressure, leading to a sharp correction in its share price over the last few weeks.

BB Biotech will continue to monitor the US political, pricing and reimbursement landscape for healthcare reforms, and believes that any modifications introduced by the next president and Congress will be incremental rather than dramatic.

Third quarter 2016 and year to date 2016 performance

For the third quarter 2016, BB Biotech's positive share return was 11.9% in CHF and 11.7% in EUR. For the same period the NAV gained 14.9% in CHF and 14.3% in EUR. The resulting profit for Q3 2016 is CHF 392.1 mn.

For the first nine months of 2016, BB Biotech's share price return was –9.1% in CHF and –9.6%% in EUR. The total return for the NAV for the same period was –18.5% in CHF and –18.7% in EUR, corresponding to a net loss of CHF 777.8 mn.

BB Biotech reduced its investment leverage most significantly by selling its Medivation position into the Pfizer offer and by selling its Tobira position in the takeover offer by Allergan. The fund's investment grade of 112.3% at the end of June 2016 was reduced to 107.6% by the end of the third quarter 2016.

Throughout the third quarter, BB Biotech increased the number of its own shares through the first trading line by 11 000, representing a total of around 0.5% of the 55.4 mn outstanding shares of BB Biotech.

BB Biotech's portfolio news in the third quarter

The NAV performance moved up in the third quarter – outperforming the benchmark by 3% in USD, and moving closer to the benchmark on a year-to-date basis. Most of the clinical trial results reported by portfolio companies were positive, but the (few) negative outcomes limited growth reported for the quarter. As described earlier, M&A activity contributed positively to overall performance.

During the quarter BB Biotech portfolio companies reported several important clinical milestones. Ionis, and its partner Biogen, surprisingly announced the early stopping of the ENDEAR Phase III study (SMA 1 patients), which met one of the co-primary endpoints in an interim analysis – showing impressive improvements in motor milestone achievements compared to untreated babies. Biogen has already completed the filing process and the product is expected to be launched in 2017 in the US and Europe.

Capitalizing further on BB Biotech's experience in SMA, Avexis was added to the portfolio based on early, but highly promising improvements seen in SMA type 1 babies after a single administration of Avexis' gene therapy

product AVXS-101. Early results indicate strong improvements in motor milestones, in contrast to the devastating deterioration seen in untreated SMA 1 babies.

Radius Health announced further progress on the abaloparatide program. The subcutaneous injection formulation – abaloparatide SC – is expected to receive the CHMP opinion by the end of 2016 and has been accepted for filing in the US. The FDA decision on approvability is expected in 2017. Improvements in the transdermal patch have significantly enhanced the delivery profile, making it closer in release performance than the subcutaneous formulation, potentially allowing for approval based on bioequivalence and without running another long term fracture study. The abaloparatide patch has the potential to address a significant group of patients who do not want to receive regular injections.

Sage continued to make progress with its neurology pipeline. Although its Phase III seizure study data read-out was delayed to 2017, the company reported positive Phase II results for SAGE-547, which is being tested in severe postpartum depression (PPD). Remission from depression was seen in 7 of 10 patients treated with SAGE-547 compared with 1 of 11 patients given placebo ($p = 0.008$). The FDA breakthrough designation, which offers the potential for expedited development and review, underscores the significant unmet medical need in women with severe PPD.

Agios, and partner Celgene, disclosed that Celgene has filed AG-221, a first in class, oral inhibitor of mutant isocitrate dehydrogenase-2 (IDH2) in relapsed and/or refractory acute myeloid leukemia (AML). The NDA is based on the broad Phase II/III study, with a Phase III program expected to generate data in 2018. Agios' fully owned AG-120 molecule to treat mutant IDH1 patients with AML is also being developed with a similar clinical trial strategy, potentially leading to an NDA filing as early as 2017.

The quarter saw a handful of unexpected setbacks in the portfolio as well. Celgene provided an update on the Phase III REMARC study of Revlimid maintenance treatment in patients with diffuse large b-cell lymphoma (DLBCL) responding to the current standard or care (R-CHOP therapy). The primary endpoint of progression free survival was statistically significant but the overall survival at the interim analysis showed no benefit. Celgene will not seek approval for the DLBCL indication but has further trials treating lymphoma patients that are expected to report data in the coming year or so. The disappointment modestly impacts the growth trajectory for Revlimid, and therefore the effect on Celgene's share price was limited.

Two smaller companies in the portfolio experienced share price declines following negative outcomes for Phase III trials. Novavax unexpectedly announced negative topline RSV F vaccine data from its Phase III RESOLVE in older adults. As a consequence Novavax lost 80% of its value and announced restructuring plans to conserve cash for ongoing RSV programs.

Intra-Cellular, a new portfolio investment company, also unexpectedly reported negative top line results from its second Phase III trial of ITI-007 in patients with schizophrenia. This means Intra-Cellular now has positive Phase II data, one positive Phase III trial, one negative Phase III trial and a superior safety profile versus the standard of care. The company is evaluating next steps with the FDA regarding the schizophrenia indication and continues to test ITI-007 in other indications such as bipolar disorder, depression and other psychiatry indications.

As summarized earlier, M&A transactions played a substantial role in BB Biotech's performance in the third quarter. Although many large pharmaceutical and biotechnology companies expressed an appetite for acquisitions, few have yet consummated a transaction. Pfizer's contested takeover offer for Medivation in August at USD 81.50 per share beat the USD 52 offer made by Sanofi in late April 2016. Tobira – themselves under pressure due to Phase II study failures – accepted a strong takeover offer from Allergan of USD 28.50 per share in cash, and a CVR of up to USD 49 per share. After the offer, Tobira's share price rose to around USD 39 per share, substantially higher than the last share price pre-offer of USD 4.70 per share, and reflecting confidence in the terms, which are attractive for shareholders.

Portfolio changes

With an eye to opportunities presented by volatile markets and potential over-reaction to news flow, careful adjustments were made to the portfolio during the third quarter of 2016. Two existing larger cap positions in Novo Nordisk and Regeneron were increased, which reflects BB Biotech's confidence in the growth potential these two

well-established firms offer. The position in Sage was also increased on the strength of the Phase II data for severe PPD. Shareholdings of Macrogenics and in Intra-Cellular Therapeutics were likewise increased.

Positions in Celgene, Actelion, Tesaro, Swedish Orphan Biovitrum and Puma Biotechnology were trimmed to take profits. As stated earlier, the positions in Medivation and Tobira were closed, generating both significant profits and cash inflows.

Avexis was added to the portfolio. Avexis is developing AVXS-101, a recombinant adeno-associated virus 9 (AAV9) therapy that delivers a fully functional human 'survival of motor neuron 1' (SMN 1) gene into target motor neurons. The compound is being tested in an ongoing Phase I study in SMA type 1 patients with initial promising data showing improved motor functions. The product has been granted orphan drug status and breakthrough designation by the FDA.

Outlook for the sector and the portfolio
BB Biotech anticipates continued volatility for the remainder of 2016. The US election and a large range of company milestones will play out. Potential product approvals and a high rate of data read-outs from clinical trials are expected to bring the curtain down on a very active 2016. The news flow offers the potential for significant appreciation in firm valuations.

Regulatory milestones to watch out for in the BB Biotech portfolio include:

- Regeneron – Sarilumab for rheumatoid arthritis
- Radius Health – Abaloparatide sc with a CHMP opinion for osteoporosis
- Cempra – Solithromycin for community acquired bacterial pneumonia

Clinical trial results of potential importance include:

- Celgene – detailed GED301 endoscopy data in Crohn's disease
- Gilead – triple combination data in HCV to test an 8 week regimen
- Halozyme – Phase II data in pancreatic cancer for pegPH20
- Actelion – third generation ERA with hemodynamic data and safety data

These events are expected to draw attention to the fundamental strength of BB Biotech's portfolio in particular and the biotechnology sector in general. Results for the third and fourth quarter should also be strong and confirm the solid operating performance. And in view of the obvious M&A opportunities that pharmaceutical companies can take advantage of, there may be increased consolidation following several quarters of significantly reduced takeover activity in the sector.

Above all, BB Biotech will continue to focus on investing in biotechnology innovation that can deliver effective treatment options, and potentially create enormous value for patients, healthcare systems and shareholders alike.

The complete interim report as of September 30, 2016 is available on **www.bbbiotech.com**

For further information:

Investor Relations
Bellevue Asset Management AG, Seestrasse 16, 8700 Küsnacht, Switzerland, tel. +41 44 267 67 00
Dr. Silvia Schanz, ssc@bellevue.ch
Maria-Grazia Iten-Alderuccio, mga@bellevue.ch
Claude Mikkelsen, cmi@bellevue.ch

Media Relations
Bellevue Asset Management AG, Seestrasse 16, 8700 Küsnacht, Switzerland, tel. +41 44 267 67 00
Tanja Chicherio, tch@bellevue.ch

b-public AG, Pfingstweidstrasse 6, 8005 Zürich, Switzerland, tel. +41 79 423 22 28
Thomas Egger, teg@b-public.ch

www.bbbiotech.com

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 of September 30, 2016

(in % of securities, rounded values)

Incyte	11.0%
Celgene	10.8%
Actelion	8.3%
Ionis Pharmaceuticals	7.9%
Radius Health	7.1%
Gilead	6.6%
Neurocrine Biosciences	4.7%
Alexion Pharmaceuticals	4.3%
Agios Pharmaceuticals	4.2%
Novo Nordisk	3.7%
Vertex Pharmaceuticals	3.7%
Regeneron Pharmaceuticals	3.0%
Tesaro	2.9%
Halozyme Therapeutics	2.7%
Alnylam Pharmaceuticals	2.4%
Swedish Orphan Biovitrum	1.7%
Alder Biopharmaceuticals	1.7%
Cempra	1.5%
Sage Therapeutics	1.4%
Kite Pharma	1.3%
Macrogenics	1.3%
Juno Therapeutics	1.3%
Intercept Pharmaceuticals	1.3%
Probiodrug	0.8%
Prothena	0.6%
Intra-Cellular Therapies	0.6%
Esperion Therapeutics	0.5%
Novavax	0.5%
PTC Therapeutics	0.5%
Puma Biotechnology	0.5%
Avexis Inc.	0.4%
Achillion Pharmaceuticals	0.3%
Cidara Therapeutics	0.3%
Radius Health Warrants 23.04.2018	0.1%
Radius Health Warrants 19.02.2019	0.1%
Merck & Co Inc Contingent Value Rights – ex Trius/Cubist	0.0%
Total securities	**CHF 3 241.8 mn**
Other assets	CHF 14.6 mn
Other payables	CHF (243.2) mn
Total shareholders' equity	**CHF 3 027.3 mn**
Treasury shares (in % of company) [1)]	0.5%

1) Corresponds to the total of all own shares held including the second trading line

BB Biotech AG Schwertstrasse 6 T +41 52 624 08 45
www.bbbiotech.com CH-8200 Schaffhausen

Fine Comunicato n.0472-44	Numero di Pagine: 8