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September 30, 2022

*Testo del comunicato*

Vedi allegato.

Media release as at October 21, 2022

Interim report of BB Biotech AG as at September 30, 2022

## US drug pricing legislation drives biotech business to adapt for further innovation

**Financial markets remained volatile throughout the third quarter, and the healthcare sector was no exception. The US Inflation Reduction Act (IRA) signed into law in mid-August had an impact on biotech stocks. The IRA establishes a new framework for federal spending on prescription drugs but is not expected to jeopardize US leadership in medical innovation. The Nasdaq Biotech Index ended the third quarter with a slightly positive return of 0.7% in USD, thanks to positive clinical trial results from Alnylam in TTR cardiomyopathy as well as from Eisai/Biogen's trial of an Alzheimer's drug. BB Biotech shares ended the quarter with a negative return of 6.9% in CHF and 4.7% in EUR. This contrasts with the change in portfolio Net Asset Value (NAV), which increased by 8.3% in CHF, 12.1% in EUR and 4.8% in USD over the same period. Reported net profit for the third quarter of 2022 amounted to CHF 210 mn compared to a net loss of CHF 208 mn in the prior-year period. A direct consequence of the above developments is the significant reduction in the share price premium to portfolio NAV. Investor interest has focused on the continued successful market uptake of drugs launched by mid-sized biotech companies. In the eyes of BB Biotech's Investment Team, the biotech sector is attractively valued and offers attractive investment opportunities.**

Healthcare markets held up in July and August, but sold off in September, ending the third quarter with losses more or less in line with broader markets. The MSCI World Healthcare Index declined 6.7% (in USD), while the Nasdaq Biotech Index (NBI) ended with a small gain of 0.7% (in USD) consequent to acquisitions and positive clinical trial data from Alnylam for TTR and the surprising data from Eisai/Biogen's newest Alzheimer program. Within the NBI smaller and mid cap biotechnology companies (XBI S&P Biotechnology ETF +6.8%, in USD) outperformed larger cap names during the quarter. The US Inflation Reduction Act (IRA) was signed into law by President Biden in mid-August – resulting in a pause of the pharmaceutical and biotechnology sectors as investors digested the implications. Conclusions have been mixed, ranging from significant concerns about price negotiations and controls to diffidence. BB Biotech believes that the legislation, if it is maintained, will spur innovation so that winners emerge in a more competitive and price-sensitive environment.

BB Biotech's third quarter 2022 share price performance was -6.9% in CHF and -4.7% in EUR. In contrast, the Net Asset Value (NAV) gained 8.3% in CHF, 12.1% in EUR and 4.8% in USD. The net gain was CHF 210 mn compared to a net loss of CHF 208 mn for the same period in 2021. The solid third quarter numbers brought total share price return for the first nine months of 2022 – including the dividend – to -27.7% in CHF and -22.4% in EUR; in line with European markets but well behind the evolution of the NAV's depreciation of 9.9% in CHF, 3.3% in EUR and 16.7% in USD. The performance difference is an erosion of the share price premium over NAV, accentuated by exclusion from the SMIM Index on September 16, 2022, which precipitated a sell-off by ETFs. Year-to-date, the net loss was CHF 323 mn compared to a net gain of CHF 141 mn at the same time in 2021. USD/CHF exchange-rate fluctuations contributed 6.8% to performance for the first nine months and 13.4% for the USD/EUR.

### Portfolio activity – New private equity investment

Radius Health was taken private by Gurnet Point und Patient Square for USD 10 per share and one contingency value right of USD 1 per share depending on future sales targets. While at a disappointingly low price, the cash inflow of USD 87 mn increased the investment management team's flexibility to act on interesting investment opportunities. First, the capital released from Radius was invested privately into Rivus Pharmaceuticals' Series B financing. The funds will support clinical advancement of HU6, a first-in-class controlled metabolic accelerator designed to treat cardio-metabolic diseases with a focus on obesity. Second, the investment management increased its holdings in Celldex. Third BB Biotech

increased the holdings in Revolution Medicines as the company progressed two clinical studies for their promising KRAS G12C and RAS-Multi inhibitors.

### **Encouraging developments at portfolio companies**

Positive trial read outs drove our third quarter results. The RNA companies Alnylam (siRNA) and Ionis (antisense RNA) both presented positive results in TTRA amyloidosis patients.

Alnylam reported the APOLLO-B Phase III study of patisiran. Statistically significant improvements were reported among TTRA patients with cardiomyopathies, in the 6 minute walk test at 12 months. This was the first siRNA late stage trial with a clear-cut benefit for patients cardiac manifestations of TTRA.

Relay Therapeutics presented promising results for RLY-4008, a selective FGFR2 inhibitor for treating cholangiocarcinoma patients with FGFR2-driven disease.

Several products from portfolio companies were approved during the third quarter. Incyte won US approval for topical agent Opzelura for forms of vitiligo. Myovant and Pfizer won US approval of Myfembree for pain associated with endometriosis.

### **The Inflation Reduction Act (IRA)**

On August 16, 2022, the Inflation Reduction Act (IRA) was signed into law by President Biden. Key provisions include:

#### Medicare's right to negotiate

Certain high-cost, older drugs that lack competition will be subject to repricing 9 years post launch for small molecules and 13 years post launch for biological drugs. The first cohort of Part D drugs will be eligible for negotiation in 2026, followed by a larger number of candidates each year. Part B drug repricing negotiations will start in 2028. Orphan drugs for a single rare disease and drugs from small biotechnology companies that represent >80% of total revenues will be excluded.

#### Rebates for price increases that exceed inflation

Drug price growth will be tied to inflation. Rebates, or penalty taxes, will be applied for price increases that exceed inflation.

#### Redesign of Medicare Part D

As soon as 2025, Medicare Part D (which covers mostly oral outpatient products) will be redesigned to limit annual out of pocket spending to USD 2000. A so-called «coverage gap» will be eliminated and out of pocket contribution in catastrophic situations will be shifted entirely to insurance plans and manufacturers, while annual insurance premium growth will be limited to 6% until 2030.

Overall, BB Biotech foresees these changes will affect companies differentially, with a handful of winners and losers. Nevertheless, the US will remain the largest and most attractive market for innovative prescription drugs.

### **Outlook for the final quarter of 2022**

US midterm elections will be on November 8. Healthcare investors will watch for results which suggest strict implementation, or possible revisions of the IRA.

Some of BB Biotech's small and mid cap portfolio companies will need capital. The investment management team will continue to look out for investment opportunities into novel, fairly valued companies, such as our recent additions Celldex and Rivus Pharmaceuticals.

Although the pandemic phase has transitioned to an endemic model, the spread of SARS-CoV-2 variants of concern will be carefully monitored this fall and winter in the Northern hemisphere. The biotechnology sector will continue to solve problems associated with COVID-19 and continue to bring forward other valuable products for severe and chronic diseases.

The quarterly report of BB Biotech AG as at September 30, 2022 can be downloaded at [report.bbbiotech.ch/Q322](https://report.bbbiotech.ch/Q322) or [www.bbbiotech.com](http://www.bbbiotech.com).

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##### **Company profile**

BB Biotech AG is an investment company with its registered office in Schaffhausen/Switzerland and listed on the Swiss, German and Italian stock exchanges. It has invested in innovative drug developers headquartered primarily in the US and Western Europe. BB Biotech is one of the world's largest investors in this sector. The competent Board of Directors with its long-standing experience set the investment strategy and guidelines. Investment decisions are taken by the experienced investment management team of Bellevue Asset Management AG based on their extensive investment research.

##### **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, 2022

(in % of securities, rounded values)

Ionis Pharmaceuticals	13.3%
Argenx SE	10.3%
Neurocrine Biosciences	9.7%
Vertex Pharmaceuticals	9.0%
Alnylam Pharmaceuticals	6.0%
Incyte	5.9%
Moderna	5.8%
Intra-Cellular Therapies	5.0%
Sage Therapeutics	3.8%
Agios Pharmaceuticals	3.7%
Myovant Sciences	3.4%
Arvinas	3.1%
Relay Therapeutics	3.0%
Revolution Medicines	3.0%
Fate Therapeutics	2.7%
Crispr Therapeutics	1.9%
Celldex Therapeutics	1.6%
Exelixis	1.4%
Esperion Therapeutics	0.9%
Beam Therapeutics	0.9%
Mersana Therapeutics	0.9%
Kezar Life Sciences	0.8%
Macrogenics	0.8%
Generation Bio Co.	0.6%
Rivus Pharmaceuticals <sup>1)</sup>	0.6%
Wave Life Sciences	0.5%
Scholar Rock Holding	0.5%
Essa Pharma	0.4%
Molecular Templates	0.3%
Black Diamond Therapeutics	0.3%
Homology Medicines	0.1%
Radius Health – CVR	0.0%
<b>Total securities</b>	<b>CHF 3 025.0 mn</b>
Other assets	CHF 3.1 mn
Other payables	CHF (306.9) mn
<b>Net Asset Value</b>	<b>CHF 2 721.3 mn</b>

<sup>1)</sup> Unlisted company

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