Ad hoc announcement pursuant to Art. 53 LR

Basilea reports strong financial half-year results and progress in the implementation of new anti-infectives strategy

- **CHF 29 million royalty income (+22.5% year-on-year) reflecting continued commercial success of Cresemba**
- **Continued improvement of operating cash flow**
- **CHF 142 million cash, restricted cash and investments at half-year 2022**
- **Full-year 2022 guidance confirmed as well as expected sustainable profitability from 2023**

Basel/Allschwil, Switzerland, August 16, 2022

Basilea Pharmaceutica Ltd (SIX: BSLN), a commercial-stage biopharmaceutical company, announced today its results for the first half-year ended June 30, 2022.

David Veitch, Chief Executive Officer, stated: “We have made significant progress in the implementation of our new strategy. We have extended our pipeline by in-licensing a potential first-in-class preclinical antifungal project. We also made good progress on the separation of our oncology assets to enable us to focus our resources exclusively on our anti-infectives business from 2023. Our antifungal, Cresemba, continues to show significant double-digit growth in in-market sales driven by both, a strong performance in established markets and initial contributions from new markets such as China, where Cresemba has recently been launched. Additionally, the positive topline results from the phase 3 study with our antibiotic ceftobiprole, are an important milestone for accessing the U.S. market. We are now preparing the New Drug Application, which we expect to submit around year-end 2022.”

Adesh Kaul, Chief Financial Officer, said: “We have shown a very solid financial performance in the first half of 2022, which is reflected by the 22.5% growth in royalty income from Cresemba and the significant improvement in our operating cash flow year-on-year. Our strong cash position combined with the positive financial prospects put us in a good position for the implementation of our growth strategy, including the in-licensing of new assets in our strategic focus area of anti-infectives and for managing our maturing convertible bond. Our focus here is on reducing our overall debt level and on minimizing potential dilution. We therefore do not intend to make use of the CHF 2 million conditional capital approved by our shareholders at the annual general meeting in 2022.”

In the second half of 2022, Basilea will focus on preparing the NDA submission for ceftobiprole in the U.S. and on completing the transactions for its oncology assets.

Financial summary

Total revenue in the first half-year (H1) 2022 increased 8.2% to CHF 58.6 million (H1 2021: CHF 54.2 million). This included royalty income from Cresemba, which increased by 22.5% to CHF 28.9 million (H1 2021: CHF 23.6 million), and milestone payments of CHF 2.2 million (H1 2021: CHF 8.9 million), reflecting progress made with the commercialized products. Other revenue amounted to CHF 7.5 million (H1 2021: CHF 6.7 million). This included CHF 5.0 million BARDA reimbursements (H1 2021: CHF 5.5 million), which are offsetting a substantial portion of the ceftobiprole phase 3 development expenses.

In H1 2022, research and development expenses decreased to CHF 37.1 million (H1 2021: CHF 41.7 million). The expenses mainly included the costs for the phase 3 program for ceftobiprole, the costs related to the preclinical and clinical program for derazantinib, the ongoing pediatric programs for ceftobiprole and isavuconazole, as well as the completion of the preclinical development for BAL0891.

Selling, general and administrative expenses amounted to CHF 15.6 million (H1 2021: CHF 14.3 million). Cost of products sold increased in line with product sales to our partners and amounted to CHF 14.9 million (H1 2021: CHF 13.5 million).

In H1 2022, an operating loss of CHF 9.0 million was recorded (H1 2021: CHF 15.4 million). The net loss was significantly reduced to CHF 12.2 million (H1 2021: CHF 19.9 million), resulting in a basic and diluted loss per share of CHF 1.03 (H1 2021: CHF 1.84).

In H1 2022, a positive net cash flow of CHF 0.15 million was provided by operating activities (H1 2021: net cash used in operating activities of CHF 27.2 million). This improvement is a result, on the one hand of the significant increase in cash inflow and on the other hand of Basilea’s continued focus on managing operating expenses by optimizing investments into the R&D portfolio and improving the cost base. Cash, restricted cash and investments amounted to CHF 141.9 million as of June 30, 2022, compared to CHF 150.0 million as of December 31, 2021. The convertible bond maturing in December 2022 (ISIN CH0305398148) was reduced by CHF 6.6 million in H1 2022.

Key financial figures

(in CHF million, except per share data)	H1 2022	H1 2021
Product revenue	19.4	13.6
Contract revenue	31.8	33.8
Revenue from R&D services	-	0.2
Other revenue	7.5	6.7
Total revenue	**58.6**	**54.2**
Cost of products sold	(14.9)	(13.5)
Research & development expenses, net	(37.1)	(41.7)
Selling, general & administrative expenses	(15.6)	(14.3)
Total cost and operating expenses	**(67.7)**	**(69.6)**
Operating loss	**(9.0)**	**(15.4)**
Net loss	**(12.2)**	**(19.9)**
Net cash provided by / used in operating activities	0.1	(27.2)
Basic loss per share, in CHF	(1.03)	(1.84)
Diluted loss per share, in CHF	(1.03)	(1.84)

(in CHF million)	June 30, 2022	Dec 31, 2021
Cash, restricted cash and investments	141.9	150.0

Note: Consolidated figures in conformity with U.S. GAAP; rounding was applied consistently.

The unaudited, condensed consolidated interim financial statements of Basilea Pharmaceutica Ltd for the first half-year 2022 can be found on the Company's website at https://www.basilea.com/financial-reports.

Full-year 2022 financial guidance

The company confirms its financial guidance, which does not take into consideration the potential effect of any transactions related to its oncology assets:

– In line with the expected continued strong growth of Cresemba in-market sales, royalty income is expected to increase double-digit to approximately CHF 59 million, reflecting the underlying health of the commercial business.
– Cresemba & Zevtera related revenue is expected to amount to CHF 98 – 104 million. The decrease versus 2021 is solely due to lower expected milestone payments from partners. 2022 milestone payments are expected to be more in line with previous years.
– Compared to 2021, net cash used in operating activities is expected to improve to CHF 10 – 15 million for full-year (FY) 2022.

(in CHF million)	FY 2022e	FY 2021a
Cresemba & Zevtera related revenue	98 to 104	131.4
Royalty income	~59	53.2
Total revenue	106 to 112	148.1
Cost of products sold	21 to 24	24.1
Operating expenses	~110	122.9
Operating loss/profit	-20 to -25	1.2
Net cash used in operating activities	10 to 15	32.0

Basilea expects to reach sustainable profitability and generate positive cash flow from operating activities in 2023, based on further increasing revenue from Cresemba and Zevtera and an expected reduction of approximately 30% in operating expenses in 2023 versus 2022, mainly due to the fact that the company does not expect to incur any material expenses related to oncology activities beyond 2022.

Portfolio progress 2022

Cresemba (isavuconazole): global in-market sales continue to show double-digit growth

Cresemba has reached USD 344 million global in-market sales for the 12 months to the end of March 2022. This is an increase of 31% year-on-year and makes Cresemba the market leader in value terms of the best-in-class antifungals for the treatment of invasive fungal infections in the U.S.[1]

Zevtera (ceftobiprole): positive topline results from ERADICATE phase 3 study pave the way for a U.S. NDA submission

Zevtera is marketed in 20 countries. However, Basilea expects the largest commercial potential in the U.S. and has conducted a phase 3 program in order to support a marketing authorization.[2] In June 2022, positive topline results from the phase 3 ERADICATE study[3], evaluating ceftobiprole in the treatment of adult patients with bacterial bloodstream infections caused by *Staphylococcus aureus* (SAB), were reported. Basilea is planning to submit a New Drug Application (NDA) for ceftobiprole to the U.S. Food and Drug Administration (FDA) around year-end 2022. In accordance with the agreed Special Protocol Assessment (SPA), Basilea will seek approval for SAB and acute bacterial skin and skin structure infection (ABSSSI) indications based on the successfully completed ERADICATE study and the TARGET phase 3 study[4], which was successfully completed in patients with ABSSSI in 2019. In addition, the company will explore the possibility for gaining approval for a third indication, based on a previously performed phase 3 study in community-acquired bacterial pneumonia (CABP).[5]

Conference call and webcast

Basilea Pharmaceutica Ltd will host a conference call and webcast today, Tuesday, August 16, 2022, at 4 p.m. (CEST), to discuss the Company's financial and operating results and to provide an outlook.

Via audio webcast with presentation

The live audio webcast of the results presentation can be followed here: https://event.choruscall.com/mediaframe/webcast.html?webcastid=GIcE70VU. Please note that there is no function to ask questions via webcast. For questions, please additionally dial-in via phone (see below).

Via phone

To listen by phone and ask questions, please use the dial-in details below. To ensure prompt access, please call approximately five minutes prior to the scheduled start of the call.

+41 (0) 58 310 5000 (Europe and RoW)
+1 (1) 866 291 4166 (USA)
+44 (0) 207 107 0613 (U.K.)

Replay

The webcast, along with the presentation will be available online shortly after the event and accessible for three months.

About Basilea

Basilea is a commercial-stage biopharmaceutical company founded in 2000 and headquartered in Switzerland. We are committed to discovering, developing and commercializing innovative drugs to meet the needs of patients with bacterial and fungal infections. We have successfully launched two hospital brands, Cresemba for the treatment of invasive fungal infections and Zevtera for the treatment of severe bacterial infections. In addition, we have several preclinical anti-infective assets in our portfolio. Basilea is listed on the SIX Swiss Exchange (SIX: BSLN). Please visit basilea.com.

Disclaimer

This communication expressly or implicitly contains certain forward-looking statements, such as "believe", "assume", "expect", "forecast", "project", "may", "could", "might", "will" or similar expressions concerning Basilea Pharmaceutica Ltd and its business, including with respect to the progress, timing and completion of research, development and clinical studies for product candidates. Such statements involve certain known and unknown risks, uncertainties and other factors, which could cause the actual results, financial condition, performance or achievements of Basilea Pharmaceutica Ltd to be materially different from any future results, performance or

achievements expressed or implied by such forward-looking statements. Basilea Pharmaceutica Ltd is providing this communication as of this date and does not undertake to update any forward-looking statements contained herein as a result of new information, future events or otherwise.

For further information, please contact:

Peer Nils Schröder, PhD

Head of Corporate Communications & Investor Relations
Basilea Pharmaceutica International Ltd, Allschwil
Hegenheimermattweg 167b
4123 Allschwil
Switzerland

Phone +41 61 606 1102

E-mail media_relations@basilea.com
investor_relations@basilea.com

This ad hoc announcement can be downloaded from www.basilea.com.

References

1. IQVIA Analytics Link, March 2022. In-market sales reported as moving annual total (MAT) in U.S. dollar.
Best-in-class antifungals: isavuconazole, posaconazole, voriconazole, AmBisome, anidulafungin, caspofungin, micafungin
2. Basilea's ceftobiprole phase 3 program is funded in part (up to USD 134.2 million, which is approximately 70% of the total potential program costs) with federal funds from the U.S. Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under contract number HHSO100201600002C.
3. ERADICATE: ClinicalTrials.gov identifier NCT03138733
K. Hamed, M. Engelhardt, M. E. Jones et al. Ceftobiprole versus daptomycin in *Staphylococcus aureus* bacteremia: a novel protocol for a double-blind, Phase III trial. Future Microbiology. 2020 (1), 35-48
4. TARGET: ClinicalTrials.gov identifier NCT03137173
J. S. Overcash, C. Kim, R. Keech R et al. Ceftobiprole Compared With Vancomycin Plus Aztreonam in the Treatment of Acute Bacterial Skin and Skin Structure Infections: Results of a Phase 3, Randomized, Double-blind Trial (TARGET). Clinical Infectious Diseases 2021 (73), e1507-e1517
5. S. C. Nicholson, T. Welte, T. M. File Jr. et al. A randomised, double-blind trial comparing ceftobiprole medocaril with ceftriaxone with or without linezolid for the treatment of patients with community-acquired pneumonia requiring hospitalization, International Journal of Antimicrobial Agents 2012 (39), 240-246