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Ad hoc announcement pursuant to Art. 53 LR

Basilea reports strong financial results for half-year 2021 with significantly increased cash flow from marketed brands and increases 2021 full-year guidance

- **CHF 46.1 million (+26% year-on-year) non-deferred Cresemba and Zevtera revenue, including CHF 23.6 million royalty income (+27% year-on-year) reflecting continued commercial success of marketed brands**
- **Strong operational performance led to 18% improvement in net cash used in operating activities**
- **Operating result improved by 40% year-on-year, excluding the one-off profit from HQ property sale in H1 2020 and deferred revenue**
- **CHF 164.7 million cash and investments at half-year 2021**
- **2021 full-year guidance increased; higher revenue expectations leading to better operating result**

Basel, Switzerland, August 17, 2021

Basilea Pharmaceutica Ltd. (SIX: BSLN) announced today its financial results for the first six months ended June 30, 2021.

David Veitch, Chief Executive Officer, said: “The first half of 2021 reflected a strong operational performance as we significantly increased the cash flow from our two marketed brands. In addition, we are building the basis for future growth by making good progress in our oncology development programs. Particularly encouraging are the updated efficacy data for patients with FGFR2 fusion-positive iCCA, a form of bile duct cancer, who received derazantinib within our FIDES-01 study and the continued long-lasting clinical benefit reported for EB1-positive glioblastoma patients from the phase 1/2 study with lisavanbulin.”

Adesh Kaul, Chief Financial Officer, added: “As announced last year, we will have largely completed the significant change in our revenue mix in 2021. The non cash-relevant recognition of deferred revenue from upfront, development and regulatory milestone payments received in prior years, has reduced 95% year-on-year, now representing less than 3% of our total Cresemba and Zevtera related revenue. This allows a much clearer view on the significant cash contribution of our commercial business. We have reported CHF 46.1 million in total Cresemba and Zevtera non-deferred revenue, a 26% growth year-on-year. Royalty income, which most closely reflects the underlying strength of our key brand Cresemba in the major territories, grew by 27% year-on-year to CHF 23.6 million.”

He continued: “We also continue to manage our cost base. We were able to keep our total cost and operating expenses at a stable level in spite of the growth of our commercial business and the continued progress in our drug development portfolio. The strong underlying operational performance is positively reflected in our operating result, which improved 40% year-on-year, when excluding the one-off profit from the sale of our headquarters property in the first half-year 2020 and the deferred revenue recognition in both periods.”

Financial summary

Total revenue in the first half-year 2021 was CHF 54.2 million (H1 2020: CHF 69.3 million), reflecting the already anticipated decrease in the recognition of deferred revenue to CHF 1.3 million (H1 2020: CHF 25.5 million) related to upfront, development and regulatory milestone payments received in prior years from partners. Non-deferred revenue contribution from the two marketed brands Cresemba and Zevtera increased by 26.3% to CHF 46.1 million (H1 2020: CHF 36.5 million). Other revenue amounted to CHF 6.6 million (H1 2020: CHF 7.1 million). This included CHF 5.5 million BARDA reimbursements (H1 2020: CHF 6.6 million), which are offsetting a substantial portion of the ceftobiprole phase 3 development expenses.[1] The BARDA reimbursements year-on-year decreased in line with the reduced development expenses following the successful completion of the ceftobiprole phase 3 skin infection study.

In the first half of 2021, investments in the pipeline resulted in research and development expenses of CHF 41.7 million (H1 2020: CHF 43.9 million). Such expenses were mainly driven by costs for the phase 3 program for ceftobiprole, the costs related to the ongoing preclinical and clinical programs for derazantinib and lisavanbulin, as well as to the ongoing pediatric programs for ceftobiprole and isavuconazole.

Selling, general and administrative expenses amounted to CHF 14.4 million (H1 2020: CHF 14.5 million). In line with increasing sales of products to partners, cost of products sold increased to CHF 13.5 million (H1 2020: CHF 13.1 million).

In the first half-year of 2021, the operating loss amounted to CHF 15.4 million (H1 2020: operating profit of CHF 12.8 million). The operating result H1 2020 was positively impacted by CHF 15.0 million in an one-off profit from the sale of Basilea’s headquarters property and CHF 24.2 million higher deferred revenue related to upfront and milestone payments from Astellas, Pfizer and Gosun, which were all fully recognized in FY 2020. The net loss amounted to CHF 19.9 million (H1 2020: net profit of CHF 9.9 million), resulting in a basic and diluted loss per share of CHF 1.84 (H1 2020: basic earnings and diluted earnings per share of CHF 0.92 and CHF 0.91, respectively).

Net cash used in operating activities in H1 2021 was reduced by 18.1% to CHF 27.2 million as compared to CHF 33.2 million in H1 2020. This improvement is a result, on the one hand of the

significant increase in cash inflow, based on the growth of Cresemba and Zevtera non-deferred revenue contributions and on the other hand, of Basilea's continued focus on managing operating expenses, by continuously optimizing investments into the preclinical and clinical portfolio and improving the cost base through strategic transactions. Cash and investments amounted to CHF 164.7 million as of June 30, 2021, compared to CHF 167.3 million as of December 31, 2020. The convertible bond maturing in December 2022 (ISIN CH0305398148) was reduced by CHF 12.4 million in H1 2021.

Key financial figures

(in CHF million, except per share data)	**H1 2021**	**H1 2020**
Product revenue	13.6	30.5
Contract revenue	33.8	31.5
Revenue from R&D services	0.2	0.2
Other revenue	6.6	7.1
Total revenue	**54.2**	**69.3**
Cost of products sold	(13.5)	(13.1)
Research & development expenses, net	(41.7)	(43.9)
Selling, general & administrative expenses	(14.4)	(14.5)
Total cost and operating expenses	**(69.6)**	**(71.5)**
Profit from sale of assets	-	15.0
Operating loss/profit	**(15.4)**	**12.8**
Net loss/profit	**(19.9)**	**9.9**
Net cash used in operating activities	(27.2)	(33.2)
Basic loss/earnings per share, in CHF	(1.84)	0.92
Diluted loss/earnings per share, in CHF	(1.84)	0.91

(In CHF million)	**June 30, 2021**	**Dec. 31, 2020**
Cash and investments	164.7	167.3

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 2021 can be found on the Company's website at https://www.basilea.com/financial-reports.

FY 2021 financial guidance

Basilea increases its revenue guidance and expects a better operating result for full-year 2021:

– Non-deferred revenue contributions from Cresemba and Zevtera are expected to grow to CHF 115 - 125 million (+47% to +60% y-o-y), reflecting the continued significant growth of in-market sales by its partners and several potential milestone events in the second half of 2021.
– Total R&D and SG&A expenses are expected to remain approximately stable. Cost of products sold is expected to increase in line with higher product deliveries to partners.

– The anticipated operating loss amounts to CHF 7 - 17 million, which is below the operating loss reported for FY 2020, excluding the one-off positive impact from the sale of the headquarters property.
– Cash and investments are expected to be approximately CHF 165 - 170 million at year-end 2021, excluding any impact from a reduction of the outstanding convertible bonds (H1 2021: CHF 13 million), and assuming that the cash-inflow from certain milestone events expected in H2 2021 will only occur in early 2022.

(in CHF million)	FY 2021e (updated)	FY 2021e (previous)	FY 2020a
Cresemba & Zevtera revenue (non-deferred)	115 - 125	108 - 118	78.2
Cresemba & Zevtera revenue (deferred)	2.5	2.5	33.8
Total revenue	134 - 144	128 - 138	127.6
Total cost and operating expenses	149 - 154	149 - 154	150.9
Profit from sale of assets	0	0	15.0
Operating loss	7 - 17	13 - 23	8.2
Cash and investments (year-end)	165 - 170*	155 - 160*	167.3

* Excluding any impact from a reduction of the outstanding convertible bonds

Corporate events: divestment of Chinese R&D subsidiary – private placement with institutional investors

Divestment of Basilea Pharmaceutica China: increases flexibility in the procurement of external research and development services and helps to better adapt the cost structure to the respective project portfolio.

In April 2021, Basilea announced that it has completed the divestment of its Chinese research and development subsidiary to the U.S.-based custom manufacturing organization PHT International Inc. for an initial payment of USD 2.5 million (CHF 2.3 million). In addition, Basilea is entitled to receive additional payments of USD 3.8 million (CHF 3.6 million) over the next three years.

Private placement: provides further financial flexibility and opens up a number of strategic opportunities for the further development of oncology drug candidates

In February 2021, Basilea carried out a strategic capital increase in the form of a private placement with institutional investors, which generated gross proceeds of around CHF 46 million.

Continued reduction of 2022 convertible bond further improves debt ratio

Since the beginning of the year, Basilea reduced the convertible bond maturing in December 2022 (ISIN CH0305398148) by CHF 12.4 million.

Portfolio progress: three clinical studies expected to report topline results until mid-2022 – clinical pipeline expansion expected – significant progress made in commercialization of marketed brands

FGFR inhibitor derazantinib[1]: further strengthened differentiated efficacy and safety profile

Encouraging topline results have been reported for cohort 1 (FGFR2 fusion-positive iCCA) of the FIDES-01 phase 2 study in February 2021.[2] These data further matured during patient follow-up and with data cut-off in April 2021 showed a median progression-free survival (PFS) of 7.8 months, which is in the upper range reported for this endpoint with FGFR inhibitors in this patient population.[2] This further supports the clinically relevant efficacy for derazantinib monotherapy in this indication. For cohort 2 of FIDES-01 (iCCA with FGFR2 mutations/amplifications), positive interim results were published in March and topline results for this cohort are expected in the first half of 2022. In the FIDES-02 urothelial cancer study, interim results for the cohort with patients who failed to respond to other FGFR inhibitors are expected in the second half of 2021, both for monotherapy with derazantinib and in combination with Roche's atezolizumab.[3] In May 2021, Basilea decided to also explore higher daily doses for mono- as well as combination therapy in the FIDES-02 and FIDES-03 studies (FGFR-driven urothelial and gastric cancer, respectively).[4] Initial results from cohorts receiving this intensified dose regimen are expected in the first half of 2022.

Lisavanbulin: potential expansion of lisavanbulin into other tumors based on biomarker signature – orphan drug designation granted

Basilea is currently investigating its tumor checkpoint controller lisavanbulin in patients with glioblastoma.[5] Glioblastoma is the most common type of primary brain cancer and one of the most lethal types of cancer.[6] Two patients from the phase 1 part of the ongoing clinical study, whose tumors tested positive on the potential response-predictive biomarker EB1, are showing a long-lasting clinical benefit and have been successfully treated for more than two years. One of these patients even experienced a reduction of tumor size of more than 80%. In the phase 2 part of the study, only EB1-positive glioblastoma patients are being enrolled and Basilea expects interim results at the end of 2021 and topline results in the first half of 2022. If these results provide a clinical proof-of-concept in glioblastoma, this would support exploring the selection of patients based on EB1-positivity in other tumor types as well, such as melanoma, breast, colorectal and lung cancers, or rare cancer types such as medulloblastomas or neuroblastomas. Approximately 5% of glioblastoma tissue samples were found to be EB1-positive.

In July 2021, the U.S. Food and Drug Administration (FDA) granted lisavanbulin Orphan Drug Designation for the treatment of malignant glioma, which includes glioblastoma. This is positive news as the designation qualifies for various incentives, including longer regulatory market exclusivity.

Pipeline expansion: new oncology drug candidate expected to enter clinical studies early 2022

Basilea is making encouraging progress in final preclinical studies with a potential first-in-class small-molecule kinase inhibitor, which was in-licensed in 2018. If successfully completed, Basilea plans to file an IND (Investigational New Drug) application later this year. If the IND is granted, first-in-human clinical studies could be initiated in early 2022.

Cresemba (isavuconazole): global "in-market" sales continue to increase – progress in Japan and China

Cresemba has reached USD 266 million global "in-market" sales for the 12 months to the end of March 2021.[7] This is an increase of 18% year-on-year. Cresemba is currently approved in almost 60 countries and has been launched in 53 countries. Thus, Basilea is well on track to achieve the target of 60 launched countries by the end of this year and is targeting to increase this to approximately 70 countries by the end of 2022.

In January 2021, the last patient was enrolled in a phase 3 study in deep-seated mycoses, conducted by Basilea's partner Asahi Kasei Pharma.[8] At the end of July, Asahi Kasei Pharma announced that the study was successfully completed and that they are planning to file a New Drug Application (NDA) for the marketing authorization of Cresemba in Japan. In China, the review of the marketing authorization applications which were accepted for review in May and October 2020 (for mucormycosis and for invasive aspergillosis respectively), is ongoing.

Zevtera (ceftobiprole): expanding commercial partnerships and making progress in key study for potential U.S. approval

In July, Basilea announced another distribution agreement, with Moscow-based JSC Lancet for Russia and the other countries of the Eurasian Economic Union. In order to gain market access to the commercially most important U.S. market, Basilea is conducting a phase 3 program of two cross-supportive studies.[9] The program was agreed with the FDA in a Special Protocol Assessment. The first of the two studies, the TARGET study that explored ceftobiprole for the treatment of complicated skin infections, was successfully completed in 2019.[10] The second study, the ERADICATE study in *Staphylococcus aureus* bacteremia (SAB), is on track to complete patient enrolment around the end of 2021, with topline results in the first half of 2022.[11]

Innovative anti-infectives: received CARB-X grant for development of novel antibiotic

In May, Basilea was awarded an up to USD 2.7 million research grant from CARB-X (Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator), a global partnership dedicated to supporting the early development of antibacterial products, for the development of DXR inhibitors, a novel class of antibiotics targeting drug-resistant Gram-negative bacteria such as carbapenem-resistant Enterobacterales, *Acinetobacter baumannii* and multidrug-resistant *Pseudomonas aeruginosa.*

Conference call and webcast

Basilea Pharmaceutica Ltd. will host a conference call and webcast today, Tuesday, August 17, 2021, at 4 p.m. (CEST), to discuss the Company's financial and operating results.

Via audio webcast with presentation

The live audio webcast of the results presentation can be followed here. 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 50 00 (Europe and RoW)
+1 (1) 866 291 41 66 (USA)
+44 (0) 207 107 06 13 (U.K.)

Replay

The webcast, along with 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 medical needs of patients with cancer and infectious diseases. We have successfully launched two hospital brands, Cresemba for the treatment of invasive fungal infections and Zevtera for the treatment of severe bacterial infections. We are conducting clinical studies with two targeted drug candidates for the treatment of a range of cancers and have a number of preclinical assets in both cancer and infectious diseases 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. Derazantinib and lisavanbulin and their uses are investigational and have not been approved by a regulatory authority for any use. Efficacy and safety have not been established. The information presented should not be construed as a recommendation for use. The relevance of findings in nonclinical/preclinical studies to humans is currently being evaluated.

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

References

1. Basilea has in-licensed derazantinib from ArQule Inc., a wholly-owned subsidiary of Merck & Co., Inc., Kenilworth, N.J., U.S.A.
2. FIDES-01 study: ClinicalTrials.gov identifier NCT03230318
3. FIDES-02 study: ClinicalTrials.gov identifier NCT04045613
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6. B. M. Alexander, T. F. Cloughesy. Adult Glioblastoma. Journal of Clinical Oncology 2017 (35), 2402-2409
7. IQVIA, March 2021. In-market sales reported as moving annual total (MAT) in U.S. Dollar corrected for currency fluctuations.
8. Clinicaltrials.gov identifier NCT03471988
9. 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.
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