

## PRESS RELEASE

### Basilea reports 2008 financial results

**Basel, Switzerland, February 24, 2009 - Basilea Pharmaceutica Ltd. (SIX:BSLN) announces 2008 financial results reflecting focused investments to support launches of Toctino® and ZEFTERA™/Zevtera™. R&D investments were focused on phase III clinical trials of Basilea's antifungal drug, isavuconazole, and the start of the phase III program in the U.S. for alitretinoin (Toctino®). Combined cash and short-term investments amount to CHF 293.6 million as of December 31, 2008.**

Basilea Pharmaceutica Ltd. began an important transition in 2008 from an R&D organization to a fully integrated company with a strong commercial focus in order to create further shareholder value through launching Toctino® (alitretinoin) and ZEFTERA™/Zevtera™ (ceftobiprole) to generate revenues.

The Company announces its 2008 financial results reflecting focused investments to support Toctino® marketed by Basilea's marketing organization in UK, Germany and Denmark for the treatment of severe chronic hand eczema and for the support of ZEFTERA™/Zevtera™ launch in Canada to treat complicated skin and soft tissue infections including diabetic foot infections.

Key achievements in 2008 were the regulatory approvals of Toctino® in UK, Germany, Denmark, France and Finland as well as its recommendation for approval in six additional EU Member States. Furthermore the approval of the novel antibiotic, ceftobiprole, by the Canadian health authority as ZEFTERA™, by the Swiss authority as Zevtera™ and the positive recommendation for approval from the European Committee for Medicinal Products for Human Use confirming that this novel antibiotic is considered to fulfill a high medical need, is considered a major achievement.

Research and development investments were principally focused on phase III clinical trials of the late-stage antifungal drug, isavuconazole, and the start of a phase III program in the U.S. for alitretinoin. In addition investments were made to advance programs in late-stage research such as BAL30072, a novel antibiotic against some of the most difficult to treat multi-resistant Gram-negative bacteria, and BAL27862, an innovative cell death inducer, a cancer compound active against a broad panel of tumor cell lines.

#### Financial Summary

Total revenues in 2008, excluding other income, amounted to CHF 11.8 million compared to CHF 7.9 million in 2007. Revenues included CHF 8.2 million (2007: CHF 6.6 million) related primarily to the release of deferred revenue in connection with upfront and milestone payments received for ZEFTERA™/Zevtera™ and income from reimbursement of costs related to co-promotion activities. In addition, revenues included product sales in the amount of CHF 1.9 million in 2008 as a result of the launches of Toctino® in Germany, the United Kingdom and Denmark at the end of 2008.

Research and development expenses amounted to CHF 97.4 million in 2008 compared to CHF 115.7 million in 2007. The expenses in 2008 relate primarily to conducting the phase III clinical trials for isavuconazole. In addition, R&D expenses include costs in connection with the manufacturing of registration batches and process development activities for isavuconazole. Furthermore, the Company started the phase III clinical trials for alitretinoin in the U.S. in 2008.

Selling, general and administrative expenses amounted to CHF 66.8 million in 2008 and include expenses for the establishment and maintenance of an international commercialization organization to prepare and support the launch of Toctino® as well as the co-promotion activities related to ZEFTERA™/Zevtera™. Operating loss totaled CHF 152.5 million in 2008 compared to CHF 136.5 million in 2007 and net loss increased to CHF 143.5 million in 2008 (2007: CHF 126.8 million), as a consequence of the increased investments in the Company's commercial organization. Basic and diluted loss per share amounted to CHF 15.02 for 2008 as compared to CHF 13.97 in 2007.

The cash out from operating activities increased to CHF 127.2 million in 2008 compared to CHF 79.0 million. The increase resulting mainly from the milestone payments received in 2007 in the amount of CHF 36.4 million related to the filings of the new drug applications for ZEFTERA™/Zevtera™ in the U.S. and Europe. Combined cash and short-term investments amounted to CHF 293.6 million as of December 31, 2008, compared to CHF 424.8 million at year-end 2007.

## Key Figures

(in CHF million)	2008	2007
Revenues and other income	12.0	8.2
Cost of sales	(0.3)	-
Research & Development Expenses	(97.4)	(115.7)
Selling, General & Administrative Expenses	(66.8)	(29.0)
Operating Loss	(152.5)	(136.5)
Net Loss	(143.5)	(126.8)
Cash Flow from Operating Activities	(127.2)	(79.0)
Basic and Diluted Loss per Share in CHF	(15.02)	(13.97)

Notes: Consolidated figures in conformity with US GAAP

The consolidated financial statements of Basilea Pharmaceutica Ltd. for 2008 can be found on the company's website at [www.basilea.com](http://www.basilea.com).

Ron Scott, Chief Financial Officer, said: "Our expenses and results in 2008 were in line with our expectations reflecting further investments into our commercial organization to support the launches of Toctino® and ZEFTERA™/Zevtera™. We are pleased to see first product sales for Toctino® in Germany, the United Kingdom and Denmark and we look forward to launching Toctino® in additional countries in 2009. In addition to our focus on commercial activities, we invested in the phase III clinical trials for isavuconazole and on the initiation of Toctino phase III trials in the U.S."

"This last year was of major importance for Basilea with our first market launches of two key products, Toctino® to treat severe chronic hand eczema and ZEFTERA™/Zevtera™ to treat severe skin infections including resistant bacterial infections such as methicillin-resistant *Staphylococcus aureus*," stated Dr. Anthony Man, CEO. "In 2009, we aim to create shareholder value by launching Toctino in additional countries, working toward ZEFTERA™/Zevtera™ regulatory approvals and advancing our highest priority R&D programs."

### **Key events for the twelve-month period in 2008 include:**

#### **Toctino® (alitretinoin) – Treatment of severe refractory chronic hand eczema**

- May: Canadian regulatory authority accepted New Drug Submission for alitretinoin for review.
- July: Regulatory approval of Toctino® recommended by the concerned EU Member States.
- September: Toctino® receives first national marketing authorization in the United Kingdom.
- September: Toctino® receives marketing authorization in Denmark.
- October: Toctino® receives marketing authorization in Germany, Finland and France.
- December: Start of U.S. phase III study on alitretinoin for the treatment of severe chronic hand eczema.

#### **ZEFTERA™/Zevtera™ (ceftobiprole) – Anti-MRSA, broad-spectrum antibiotic**

- March: FDA issues Approvable Letter for ceftobiprole for the treatment of complicated skin and skin structure infections (cSSSI) including diabetic foot infections, indicating that the ceftobiprole application is approvable.
- May: Presentation of detailed positive phase III results on ceftobiprole in the treatment of community-acquired pneumonia requiring hospitalization at the International Conference of the American Thoracic Society.
- June: ZEFTERA™ receives its first marketing authorization by Health Canada for the treatment of complicated skin and soft tissue infections (cSSTI) including diabetic foot infections.
- September: FDA accepts for review the Complete Response to ceftobiprole NDA Approvable Letter.
- October: Detailed positive phase III results on hospital-acquired pneumonia including a sub-group analysis of patients with ventilator-associated pneumonia presented at the joint meeting of the Annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) and the Infectious Diseases Society of America (IDSA).
- November: Zevtera™ receives approval by Swissmedic for the treatment of cSSTI including diabetic foot infections.
- November: Zevtera™ receives a positive opinion from the EU Committee for Medicinal Products for Human Use for the treatment of cSSTI including diabetic foot infections.
- November: FDA issues Complete Response Letter for ceftobiprole for the treatment of cSSSI including diabetic foot infections.

#### **Isavuconazole – Broad-spectrum antifungal agent**

- April: Start of an additional phase III study to evaluate the efficacy and safety of isavuconazole in special patient populations.
- April: New pre-clinical data presented at European Congress of Clinical Microbiology and Infectious Diseases confirm that isavuconazole's broad activity spectrum *in vitro* translates into effective treatment in animal models.

- October: New clinical data displayed at ICAAC/IDSA showing that isavuconazole was well tolerated and had predictable pharmacokinetics at doses twice as high as investigated in phase III clinical trials.

#### **BAL30072 - Novel early-stage antibiotic against multi-resistant Gram-negative bacteria**

- September: New pre-clinical data on BAL30072's potent *in vitro* activity against resistant Gram-negative "superbugs" such as *Acinetobacter* and *Pseudomonas aeruginosa* were presented at ICAAC/IDSA.

## Conference Calls

Basilea Pharmaceutica Ltd. will hold two conference calls on **February 24, 2009**, one at **10 a.m.** (CET) and one at **4 p.m.** (CET) to discuss today's press release.

The Company invites you to participate in the conference call **February 24, 2009**, at **10 a.m.** (CET)

Dial-in numbers are:

+41 (0) 91 610 56 00 (Europe and ROW)  
 +44 (0) 207 107 0611 (UK)  
 +1 (1) 866 291 4166 (USA)

A second conference call is scheduled on **February 24, 2009**, at **4 p.m.** (CET).

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## Note to Shareholders

The shareholders of Basilea Pharmaceutica Ltd. are kindly reminded that the Ordinary General Meeting of Shareholders of Basilea Pharmaceutica Ltd. will take place on **Wednesday, April 29 at 2 pm at the Hilton Hotel in Basel, Switzerland**. The invitation will be published in the Swiss Official Gazette of Commerce (Schweizerisches Handelsamtsblatt). Shareholders who are recorded in the share register with voting rights on April 16, 2009 will be entitled to participate and exercise their voting rights.

## About Basilea

Basilea Pharmaceutica Ltd. is headquartered in Basel, Switzerland, and listed on the SIX Swiss Exchange (SIX:BSLN). Basilea's integrated research and development operations are currently focused on new antibacterial, antifungal and oncology agents to fight drug resistance and on the development of dermatology drugs. Basilea's products are targeted to satisfy high medical and patient needs in the hospital and specialty care setting. The company owns a diversified portfolio including two commercialized drugs (alitretinoin, ceftobiprole) and one investigational drug in phase III (isavuconazole). Toctino® (alitretinoin) is marketed in the United Kingdom, Denmark and Germany and is approved in Finland and France. Alitretinoin has been recommended for approval in six additional EU Member States and is under regulatory review in Canada and Switzerland. Furthermore a phase III clinical trial on alitretinoin for the treatment of severe chronic hand eczema is ongoing in the U.S. Marketing applications for ceftobiprole (ZEFTERA™/Zevtera™) were submitted in the U.S., the EU and several other countries. The company has set up commercial organizations in UK, Denmark, Germany and Canada, while it is building sales and marketing organizations in other countries to commercialize alitretinoin and to co-promote ceftobiprole, subject to approval.

## Disclaimer

This communication expressly or implicitly contains certain forward-looking statements concerning Basilea Pharmaceutica Ltd. and its business. 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.

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