

PRESS RELEASE

Basilea reports 2009 financial results

Basel, Switzerland, February 1, 2010 - Basilea Pharmaceutica Ltd. (SIX:BSLN) announces 2009 financial results reflecting first full year of Toctino® sales in its initial launch countries, and focused investments to support phase III development of isavuconazole globally and U.S. alitretinoin (Toctino®) trials. Combined cash and short-term investments amount to CHF 178.4 million as of December 31, 2009.

Business review 2009

In 2009, Basilea reached a new milestone in its history reporting its first full year of Toctino® sales. Product sales of Toctino®, for the treatment of severe chronic hand eczema, amounted to CHF 17.3 million in the first launch countries. By year-end, Toctino® had been launched in Denmark, France, Germany and the United Kingdom.

Further regulatory approvals of Toctino® were obtained in five additional European Union countries plus Canada and Switzerland, as well as a recommendation for approval in another 15 European countries. Furthermore, the endorsement of Toctino® by pricing and reimbursement bodies in the UK and France marked important milestones confirming that Toctino® is an innovative cost-effective therapy that fills a high medical need. In addition, a phase III clinical trial program is ongoing in the U.S.

As communicated at the end of 2009, the U.S. approval of ceftobiprole, an anti-MRSA broad-spectrum antibiotic, was delayed as the Food and Drug Administration (FDA) requested new phase III studies for complicated skin and skin structure infections (cSSSI) from the sponsor Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (Johnson & Johnson PRD).

After a positive opinion from the European Committee for Medicinal Products for Human Use (CHMP) in November 2008, the European Medicines Agency (EMA) halted the European Commission decision process on ceftobiprole for complicated skin and soft tissue infections (cSSTI) early 2009 pending completion and assessment of Good Clinical Practice (GCP) inspections at investigator sites.

Early 2009 Basilea submitted a Request for Arbitration relating to substantial damages suffered by Basilea as consequence of the delayed approval of ceftobiprole as well as delay in milestone payments.

In 2009, patient recruitment in the international phase III program of Basilea's antifungal drug isavuconazole was interrupted due to manufacturing issues, which have been addressed to allow recruitment re-initiation.

Basilea's research and development investments were focused on the phase III clinical trials of isavuconazole and the phase III program in the U.S. for alitretinoin during 2009. In addition, Basilea focused on advancing early-stage programs such as BAL30072, a novel antibiotic against the most difficult-to-treat multidrug-resistant Gram-negative bacteria, and BAL27862, a novel anti-cancer compound with the potential to treat drug-resistant cancers.

Ron Scott, Chief Financial Officer, said: "We are pleased to see first full year product sales for Toctino with major contributions from the German market and additional sales from Denmark and the UK. We also achieved first sales in France, a major European market, where the product was launched recently. During 2010 we expect enhanced sales uptake of Toctino following

further national approvals and launches. We are committed going forward to take advantage of the strategic flexibility that our rich and competitive product portfolio provides."

"Basilea experienced successes as well as setbacks in 2009. We are very proud of the successful commercialization of Toctino in first key markets in the past year reflecting the innovation and pharmacoeconomic value of Toctino. We are, however, clearly disappointed with the delays following the review of the market applications for ceftobiprole," stated Dr. Anthony Man, Chief Executive Officer. "We expect to resume the phase III recruitment of our second anti-infective, isavuconazole, in the first half of the year and anticipate to see first clinical results from the phase III study of alitretinoin in the U.S. at year-end. We will continue with high priority to seek solutions to make ceftobiprole available as quickly as possible to patients in need of new treatment options to fight potentially deadly resistant bacterial infections."

Management changes

Basilea announces the appointment of Professor Achim Kaufhold, M.D., as Chief Medical Officer and member of the Executive Committee. Prof. Kaufhold, a specialist in Medical Microbiology and Infectious Diseases, has a long and successful track record in the biotech and pharmaceutical industry. Prior to joining Basilea he held executive positions at Pharmexa, Chiron, Berna Biotech, GlaxoSmithKline and was most recently President & CEO of Affitech A/S Denmark. Prof. Kaufhold will succeed Dr. Dieter Götte who will leave the company.

Dr. Anthony Man commented, "We thank Dr. Götte for his contributions he made as Chief Medical Officer to help advance our development programs. It is part of our strategic intent to further enhance our R&D efforts in hospital based therapies. We welcome in particular the extensive anti-infectives and R&D experience that Professor Kaufhold brings to Basilea."

Financial summary

Revenues and other income in 2009 amounted to CHF 26.8 million compared to CHF 12.0 million in 2008. Revenues included CHF 17.3 million (2008: CHF 1.9 million) related primarily to product sales as a result of the commercialization of Toctino® in Germany, the United Kingdom, France and Denmark in 2009. In addition, revenues included CHF 8.4 million (2008: CHF 8.2 million) related to our licensing agreement for ZEFTERA™/Zevtera™, mainly comprising the release of deferred revenue in connection with upfront and milestone payments received.

Research and development expenses decreased to CHF 77.2 million in 2009 compared to CHF 97.4 million in 2008, largely as a result of a reduction in expenses due to cost control measures, the temporary interruption of the isavuconazole phase III recruitment and a decrease in costs for clinical supply, which was largely established in 2008 for the isavuconazole phase III program. The R&D expenses in 2009 relate primarily to conducting the phase III clinical program for isavuconazole. In addition, they include costs for the phase III clinical trials for alitretinoin in the U.S. and costs for the advancement of our early-stage antibacterial and anti-cancer compounds.

Selling, general and administrative expenses amounted to CHF 69.2 million in 2009 (2008: CHF 66.8 million) 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 121.2 million in 2009 compared to CHF 152.5 million in 2008 and net loss decreased to CHF 120.7 million in 2009 (2008: CHF 143.5 million), as a consequence of the increased product sales for Toctino® and reduced operating expenses. Basic and diluted loss per share amounted to CHF 12.61 for 2009 as compared to CHF 15.02 in 2008.

The cash out from operating activities decreased to CHF 114.5 million in 2009 as compared to CHF 127.2 million. Combined cash and short-term investments amounted to CHF 178.4 million as of December 31, 2009, compared to CHF 293.6 million at year-end 2008.

Key Figures

(in CHF million)	2009	2008
Revenues and Other Income	26.8	12.0
Cost of Sales	(1.6)	(0.3)
Research & Development Expenses	(77.2)	(97.4)
Selling, General & Administrative Expenses	(69.2)	(66.8)
Operating Loss	(121.2)	(152.5)
Net Loss	(120.7)	(143.5)
Cash Flow from Operating Activities	(114.5)	(127.2)
Basic and Diluted Loss per Share in CHF	(12.61)	(15.02)

Notes: Consolidated figures in conformity with US GAAP

The consolidated financial statements of Basilea Pharmaceutica Ltd. for 2009 can be found on the company's website at <http://annualreport.basilea.com>.

Financial outlook

Anticipating further launches and increasing market penetration, Toctino® sales for 2010 are estimated at CHF 35-45 million. Average monthly net operating losses in 2010 are estimated at approximately CHF 9 million.

Product and pipeline update

Toctino® (alitretinoin) - By year-end 2009, Toctino® had been introduced in Denmark, France, Germany and the United Kingdom. Initial regulatory approvals for Toctino® in ten European countries were complemented by national approvals in Canada and Switzerland and recommendations for approval in an additional 15 European countries. Following the issuance of national marketing authorizations as well as pricing and reimbursement approvals, further launches are anticipated throughout 2010. Regulatory applications for further territories, e.g., Middle East, South America, are scheduled for early 2010 to expand Toctino®'s commercial availability. In the U.S., the first multi-centered, controlled clinical phase III study on alitretinoin for patients with severe refractory chronic hand eczema is ongoing and first results are anticipated at year-end 2010.

ZEFTERA™/Zevtera™ (ceftobiprole) – At year-end 2009, ceftobiprole was marketed in Canada under the brand name ZEFTERA™ and in Switzerland under Zevtera™. In the U.S., the FDA issued a Complete Response Letter indicating that it cannot approve the application on ceftobiprole for cSSSI in its present form. The Agency recommended that two new, adequate, and well-controlled studies should be conducted and that the sponsor Johnson & Johnson PRD meets with the Agency to discuss the design of these trials. The regulatory review of ceftobiprole for the treatment of cSSTI in the EU is on-going. An opinion by the CHMP on the EU application is anticipated in Q1 2010.

Isavuconazole – There are three phase III trials currently open investigating isavuconazole, one targeting yeast infections, one targeting mold infections and a third trial targeting rare molds and renally impaired patients with aspergillosis.

In 2009, over three quarters of the projected number of patients had been enrolled in the aspergillosis study while the candidiasis study had recruited 40% of patients when patient recruitment was temporarily interrupted due to the need to produce new clinical trial material. The recruitment of new patients is expected to resume in H1 2010 and data from the phase III

clinical program is anticipated to be available in 2011. In Q1 2010, the Independent Data Safety Monitoring Board (IDSMB) recommended the continuation of the phase III clinical trial of isavuconazole for the treatment of invasive *Aspergillus* infections based on a futility analysis of 180 patients.

Early-stage programs - BAL30072, a novel antibiotic against the most difficult-to-treat multi-drug-resistant Gram-negative bacteria, and **BAL27862**, a novel anti-cancer compound with activity against a broad range of tumor types, including those unresponsive to standard therapeutics, are currently undergoing pre-IND (Investigational New Drug) studies. Subject to successful completion of pre-IND studies, the initiation of phase I clinical trials is planned for the second half of 2010. Both programs represent potential significant future business opportunities.

Key events for the twelve-month period in 2009 included:

Toctino® (alitretinoin) – The only therapy approved for severe chronic hand eczema unresponsive to topical corticosteroids

- December 14: Toctino® is recommended for regulatory approval in 13 additional European Union Member States as well as in Norway and Iceland.
- October - November: Health Canada and the Swiss regulatory authority Swissmedic grant marketing authorization for Toctino®.
- August 26: The UK National Institute for Health and Clinical Excellence (NICE) issues its final guidance on Toctino®, recommending its use within the licensed indication.
- March 31: Basilea submits Marketing Authorization Applications for Toctino® in 13 additional European Union Member States as well as in Norway and Iceland.
- March 26: The German Society of Dermatology incorporates Toctino® in the new treatment guidelines for the management of hand eczema.
- March 9: The Scottish Medicines Consortium (SMC) accepts Toctino® for use within the National Health Service.
- March to May: Toctino® receives approval in Austria, Belgium, Luxemburg, the Netherlands and Spain.

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

- December 30: FDA issues a Complete Response Letter on ceftobiprole for the treatment of cSSSI and recommends that new phase III clinical studies should be conducted.
- September 1: FDA accepts for review the complete response submitted by Johnson & Johnson PRD.
- February 24: Basilea files arbitration claims against Johnson & Johnson over its handling of ceftobiprole clinical studies and related to delays in approval of ceftobiprole.
- February 24 and 26: The EMEA halts the European Commission decision process on ceftobiprole pending completion of GCP inspections.

Conference call

Basilea Pharmaceutica Ltd. invites you to participate in a conference call on Monday, February 1, 2010, 4 p.m. (CET), during which the company will discuss today's press release.

Dial-in numbers are:

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

A playback will be available 1 hour after the conference call until Wednesday, February 3, 2010, 6 p.m. (CET). Participants requesting a digital playback may dial:

+41 (0) 91 612 4330 (Europe)
+1 (1) 866 416 2558 (USA)
+44 (0) 207 108 6233 (UK)

and will be asked to enter the ID 17906 followed by the # sign.

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 **Tuesday, March 30 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 March 18, 2010 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 (Toctino®, ZEFTERA™/ Zevtera™) and one investigational drug (isavuconazole) in phase III clinical development. Basilea has set up commercial organizations in Canada, France, Germany, the Nordics and the United Kingdom, 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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