PRESS RELEASE

Basilea reports 2012 financials with a solid cash position and significant milestones ahead

- **CFO Joachim Blatter to depart company, CEO Ronald Scott to serve as interim CFO**
- **Cash position and short-term investments increased to CHF 344.0 million**
- **Target patient recruitment reached in two isavuconazole phase 3 studies with data expected in H2 2013**
- **European regulatory review of ceftobiprole in pneumonia ongoing with first potential approval in Q4 2013**
- **Toctino® agreement with potential U.S. filing by Stiefel early 2014**

Basel, Switzerland, February 7, 2013 – Basilea Pharmaceutica Ltd. (SIX: BSLN) presented today full-year financial results for 2012 with an increased year-end cash position of CHF 344.0 million and a reduced net loss of CHF 53.0 million. CFO Joachim Blatter will be leaving the company to pursue other opportunities. Ronald Scott, CEO will serve as interim CFO effective February 7, 2013.

2012 was a transformational year. Basilea took the strategic decision to focus its activities on anti-infective and oncology drugs and entered into an agreement for its dermatology drug Toctino® (alitretinoin) with Stiefel, a GSK company, for a CHF 224.1 million initial payment and additional potential payments related to the commercialization of Toctino® in the U.S. Stiefel has assumed responsibility for the development, manufacturing and commercialization of Toctino®. Basilea is eligible for a further milestone payment related to the launch of alitretinoin in the U.S. and will participate in future U.S. product sales. Toctino® 2012 sales through completion of the Stiefel agreement were CHF 20.2 million, in line with the company's guidance.

In 2012, Basilea advanced the isavuconazole phase 3 program in collaboration with Astellas and filed a ceftobiprole Marketing Authorization Application submission for severe pneumonia in Europe. In addition, Basilea completed its U.S. phase 3 study for alitretinoin.

The isavuconazole SECURE phase 3 registration study, evaluating safety and efficacy of once-daily isavuconazole versus twice-daily voriconazole for the primary treatment of life-threatening invasive fungal disease caused by *Aspergillus* species completed patient recruitment. In addition, enrollment into the isavuconazole VITAL study, an open-label phase 3 study in the treatment of aspergillosis patients with pre-existing renal impairment or with invasive fungal disease caused by rare but often fatal molds, has achieved its initially targeted recruitment of patients. Enrollment will continue to further expand the database on the use of isavuconazole in the primary treatment of diverse rare mold infections. Topline data from these two isavuconazole phase 3 studies are expected in the second half of 2013 and could result in a first potential filing in the first quarter of 2014. Under the agreement with Astellas, Basilea is eligible for milestone payments related to filing, approval and sales, and double-digit royalty payments. Furthermore, Basilea retains co-promotion rights on the drug and will evaluate these rights as the drug comes closer to the market. The isavuconazole ACTIVE phase 3 study, evaluating the use of isavuconazole i.v. and oral versus caspofungin i.v. followed by oral voriconazole for the treatment of invasive *Candida* infections, will likely continue to recruit into 2014. Basilea and its

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partner Astellas are reviewing potential filing strategies including a first filing of the SECURE and VITAL studies.

In 2012, Basilea also focused on bringing ceftobiprole to the market, initially for patients with severe lung infections. Basilea submitted a Marketing Authorization Application in Europe for the treatment of pneumonia which was accepted for review in October 2012. Currently the company focuses on answering the questions received from the European agencies. Basilea had a consultation meeting with the FDA in 2012 and will continue its discussions with the FDA to receive the agency's final recommendation on the indications that could potentially be supported by the existing data package. The FDA requested that Basilea conduct further analyses of the existing phase 3 dataset to assist FDA in developing a final recommendation. A follow-up consultation meeting for a discussion of the data is envisaged in the second quarter of 2013. Basilea is managing the ceftobiprole supply chain to support a potential regulatory approval and launch and is engaged in discussions with potential partners.

Basilea's commitment to address the medical challenge of resistance in the areas of anti-infectives and oncology is also reflected in its phase 1 programs with innovative compounds from in-house research, addressing high medical needs in these focus areas. The novel antibiotic BAL30072 is intended for the treatment of multidrug-resistant Gram-negative bacteria where current antibiotics often fail, and the new oncology drug BAL101553 focuses on the treatment of tumors resistant to current cancer therapies. Basilea made substantial progress during 2012 in advancing these compounds in clinical phase 1 development. BAL30072 moved into its next stage of phase 1 testing and BAL101553 is anticipated to move into phase 2a studies in 2013.

Ronald Scott, CEO stated: "We made significant achievements in 2012. Through the Toctino transaction we improved our cash position and we will continue to prudently invest our resources to achieve our key value-driving events. Now we are focused on our important milestones for 2013, including the potential approval of ceftobiprole in Europe and first anticipated isavuconazole phase 3 topline data." He added: "Basilea is uniquely positioned through our innovative drug portfolio to address the increasing threat posed by multi-drug resistant infections and drug resistant cancers for which there are currently limited treatments available. The critical need to address drug resistance is gaining increasing awareness. Recent measures taken by several countries further encourage the development of novel antibiotics and antifungals for the treatment of drug-resistant life-threatening infections by providing potential benefits that could result in shorter development and regulatory timelines and longer market exclusivity." Related to the departure of Joachim Blatter he said: "We want to thank Joachim for his contributions, and wish him all the best for his new endeavors."

Key figures

(In CHF million, except per share data)	**2012**	**2011**
Product sales*	20.2	31.0
Contract revenue	37.4	35.2
Revenue from R&D services	0.2	0.6
Other income	0.5	0.2
Total operating income	58.3	66.8
Cost of sales	(4.4)	(2.4)
Research & development expenses	(58.9)	(70.0)
Selling*, general & administrative expenses	(45.9)	(51.7)

Total operating expenses	(109.2)	(124.1)
Operating loss	(50.8)	(57.3)
Net loss	(53.0)	(57.6)
Net cash provided by/used for operating activities	148.2	(82.4)
Cash and short-term investments	344.0	197.1
Basic and diluted loss per share, in CHF	(5.53)	(6.01)

Notes: Consolidated figures in conformity with US GAAP; rounding was consistently applied.

*2012 numbers: Through July.

The consolidated financial statements of Basilea Pharmaceutica Ltd. for 2012 can be found on the company's website at http://annualreport.basilea.com.

Financial summary

Product sales in 2012 for Toctino® were within guidance amounting to CHF 20.2 million, through July 2012, when the Stiefel transaction closed (full-year 2011: CHF 31.0 million).

Contract revenue in 2012 amounted to CHF 37.4 million (2011: CHF 35.2 million), including CHF 16.1 million related to the agreement with Stiefel on Toctino®, CHF 12.8 million related to Toctino® distribution agreements and CHF 8.2 million related to the license agreement with Astellas for isavuconazole. Total operating income decreased to CHF 58.3 million in 2012 (2011: CHF 66.8 million) primarily due to the shorter product sales period as a result of the agreement with Stiefel on Toctino® in July 2012.

Research and development expenses amounted to CHF 58.9 million in 2012, compared to CHF 70.0 million in 2011. This decrease is mainly due to the completion of the alitretinoin phase 3 U.S. study in the first half of 2012 and Basilea fulfilling its financial participation commitment in the development of isavuconazole under the license agreement with Astellas. Selling, general and administrative expenses decreased to CHF 45.9 million in 2012 (2011: CHF 51.7 million) primarily due to closing Basilea's commercial organizations following its Toctino® agreement with Stiefel in the second half of 2012.

In 2012, the operating loss decreased to CHF 50.8 million from CHF 57.3 million in 2011, mainly due to lower research and development costs as well as lower selling, general and administrative expenses. As a result of this, the average monthly operating loss for 2012 was CHF 4.2 million. The net loss 2012 amounted to CHF 53.0 million, compared to CHF 57.6 million in 2011.

2012 basic and diluted loss per share amounted to CHF 5.53 compared to basic and diluted loss per share of CHF 6.01 in 2011.

In 2012, the net cash provided by operating activities was CHF 148.2 million as compared to net cash used by operating activities of CHF 82.4 million in 2011, mainly due to the upfront payment of CHF 224.1 million received from Stiefel for the Toctino® agreement. Combined cash and short-term investments increased to CHF 344.0 million as of December 31, 2012, compared to CHF 197.1 million at year-end 2011.

Financial outlook

Total operating expenses for 2013 are estimated to decrease to around CHF 7 to 8 million per month primarily due to the Toctino® transaction and Basilea having fulfilled in 2012 its financial participation commitment related to the development of isavuconazole. Basilea's average operating loss in 2013 is estimated at around CHF 4 to 5 million per month.

Portfolio

Isavuconazole – *a novel intravenous and oral broad-spectrum antifungal, partnered with Astellas Pharma Inc., for the potential treatment of severe invasive and life-threatening fungal infections*

Isavuconazole demonstrated excellent *in-vitro* and *in-vivo* coverage of a broad range of yeasts (such as *Candida* species) and molds (such as *Aspergillus* species) as well as *in-vitro* activity against less prevalent but often fatal molds such as *Mucorales* spp. It has U.S. FDA fast-track status. In clinical studies to date it achieved predictable drug levels and high oral bioavailability suggesting the potential for predictable dosing and a switch from i.v. administration to convenient once-daily oral dosing.

Ceftobiprole – *a novel broad-spectrum antibiotic for the potential first-line empiric treatment of severe multidrug-resistant bacterial infections*

Ceftobiprole has unique broad-spectrum activity against Gram-positive bacteria, including methicillin-resistant and vancomycin-resistant *Staphylococcus aureus* (MRSA, VRSA) and penicillin-resistant *Streptococcus pneumoniae* (PRSP) as well as Gram-negative pathogens, including *Enterobacteriaceae* and *Pseudomonas aeruginosa*. Ceftobiprole has met the study endpoints in several phase III studies and has shown a typical cephalosporin safety profile.

BAL30072 – *a novel innovative sulfactam antibiotic with bactericidal activity against multidrug-resistant Gram-negative bacteria*

The investigational drug has demonstrated broad *in-vitro* and *in-vivo* coverage of Gram-negative pathogens including multidrug-resistant *Pseudomonas aeruginosa* and *Acinetobacter baumannii*. It has robust activity against common strains of bacteria that produce antibiotic-inactivating enzymes including extended-spectrum beta-lactamases (ESBL) and metallo-beta-lactamases such as the New Delhi metallo-beta-lactamase 1 (NDM-1). In addition, BAL30072 has been shown to enhance the activity of antibiotics from the penem class.

BAL101553 – *a novel small-molecule anti-cancer drug with a dual mode of action directly attacking tumor cells as well as disrupting tumor blood vessels*

BAL101553 disrupts the intracellular microtubule network that is essential for cell division and has shown potent activity in many tumor cell lines that are insensitive or resistant to taxanes or other microtubule-targeting agents. In contrast to currently available microtubule-targeting agents that are derived from complex natural products, BAL101553 is a simpler synthetic molecule that bypasses some of the resistance mechanisms associated with existing drugs. BAL101553 was developed as a highly water-soluble prodrug of Basilea's BAL27862 with anticipated good oral bioavailability and an injectable formulation without potentially harmful solubilizers.

Toctino® (oral alitretinoin) – *the only licensed drug for systemic use in adults with severe chronic hand eczema unresponsive to potent topical corticosteroids*

Toctino® was developed and successfully brought to market by Basilea. In the U.S., oral alitretinoin is an investigational drug in phase III and not yet approved by the FDA. In July 2012, Basilea completed an agreement for Toctino® with Stiefel, a GSK company.

Conference call

Basilea Pharmaceutica Ltd. invites you to participate in a conference call on Thursday, February 7, 2013, 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) 203 059 5862 (UK)

A playback will be available 1 hour after the conference call until Monday, February 11, 2013, 6 p.m. (CET). Participants requesting a digital playback may dial:
+41 (0) 91 612 4330 (Europe and ROW)
+1 (1) 866 416 2558 (USA)
+44 (0) 207 108 6233 (UK)
and will be asked to enter the ID 18060 followed by the # sign.

Note to shareholders

The shareholders of Basilea Pharmaceutica Ltd. are informed that the Ordinary General Meeting of Shareholders of Basilea Pharmaceutica Ltd. will take place on **Tuesday, April 9, 2013 at 2 p.m. at the Hilton Hotel in Basel, Switzerland.** The invitation will be published in the Swiss Official Gazette of Commerce (Schweizerisches Handelsamtsblatt, SHAB). Shareholders who are recorded in the share register with voting rights on March 28, 2013 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). Through the fully integrated research and development operations of its Swiss subsidiary Basilea Pharmaceutica International Ltd., the company focuses on innovative pharmaceutical products in the therapeutic areas of bacterial infections, fungal infections and oncology, targeting the medical challenge of rising resistance and non-response to current treatment options.

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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