

Half-year Report 2008



Ready...

Basilea in Brief

Basilea Pharmaceutica Ltd. is an integrated biopharmaceutical company headquartered in Basel, Switzerland, listed on the SWX Swiss Exchange (SWX:BSLN).

The company focuses on the discovery, development and future commercialization of innovative medicines for serious diseases and medical conditions to satisfy high medical and patient needs in the hospital and specialty pharmaceutical setting.

Basilea has a diversified product portfolio including novel treatments for resistant bacterial infections, systemic fungal infections and severe skin diseases. The highly competitive product pipeline comprises: ceftobiprole, an antibiotic that received its first approval in Canada this year; alitretinoin, a dermatological product candidate in pre-registration; and isavuconazole, an antifungal in clinical phase III; as well as substantial early-stage programs.

Basilea is currently building its sales and marketing organization in the USA, Canada and major European markets to promote alitretinoin and co-promote ceftobiprole.

www.basilea.com



“We are tremendously excited that eight years of R&D allow us to soon meet patients’ needs with our first two products. We are ready to take the road to commercial success.”

Dr. Anthony Man, Chief Executive Officer

Ready... set...

Half-year Highlights

January 10, **Ceftobiprole**

FDA Advisory Committee Meeting scheduled

Ceftobiprole, as a new chemical entity, to be reviewed by the US Food and Drug Administration (FDA) Anti-Infective Drugs Advisory Committee.

February 13, **Ceftobiprole**

FDA Advisory Committee Meeting cancelled

The FDA determined that the Anti-Infective Drugs Advisory Committee Meeting will not be held.

March 18, **Ceftobiprole**

Approvable Letter received

The FDA issued an Approvable Letter for ceftobiprole, indicating that the ceftobiprole application is approvable.

March 28, **Corporate**

Holding structure implemented

Changes of the Articles of Association approved by shareholders at the Annual General Meeting on March 19, 2008 were executed and a holding structure was implemented in order for Basilea to provide an adequate corporate group structure for the future commercialization of its products.

April 15, **Isavuconazole**

New phase III study opened

Additional phase III study opened to evaluate the efficacy and safety of isavuconazole in treating serious and life-threatening invasive fungal infections.

May 5, **Alitretinoin**

New Drug Submission accepted for review

The Therapeutic Products Directorate (TPD) of Health Canada has accepted for review the New Drug Submission (NDS) of oral alitretinoin for the treatment of severe refractory chronic hand eczema.

June 30, **Ceftobiprole**

First marketing authorization

Ceftobiprole obtained regulatory approval from Health Canada authorizing the marketing of ZEFTERA™ for the treatment of complicated skin and skin structure infections including diabetic foot infections.

Our Lead Product Candidates



Ceftobiprole (Approved in Canada under the trade name ZEFTERA™, in pre-registration in the USA and Europe) The first broad-spectrum cephalosporin antibiotic with anti-MRSA (methicillin-resistant *Staphylococcus aureus*) activity in pre-registration stage in the USA and Europe and with first approval in Canada, intended to treat patients with severe complicated skin infections and pneumonia including those involving resistant bacteria. The antibiotic is developed in collaboration with Cilag GmbH International, a Johnson & Johnson company.

Alitretinoin (Pre-registration stage) An investigational oral dermatology drug intended to treat patients with severe chronic hand eczema who do not respond to steroid creams. The relapsing illness results in significant patient disability and has profound occupational, medical and social consequences. To date, there is no approved treatment available for this severe skin disease.

Isavuconazole (Phase III) An antifungal azole with an extended activity spectrum, convenient water-soluble injection and oral dose forms intended to address the limited treatment options and high mortality associated with severe invasive fungal infections in immunocompromised cancer, transplant and HIV patients.

Balanced Late-stage Product Portfolio

With one product having received its first marketing authorization, one in pre-registration, and one in clinical phase III and substantial early-stage programs Basilea is positioned to realize long-term growth with innovative therapeutics for serious diseases.

Portfolio Overview		Research	Development				Pre-registration ¹	Market ²
			Phase 0	I	II	III		
Antibacterials	Ceftobiprole Broad-spectrum anti-MRSA	█	█	█	█	█	█	
	Macrolides	█	█					
	Gram-negative Antibacterials	█	█					
	Exploratory Projects	█						
Dermatology	Alitretinoin Chronic Hand Eczema	█	█	█	█	█		
Antifungals	Isavuconazole Broad-spectrum Triazole	█	█	█	█			
Oncology	Cell Death Inducer	█						

¹ Ceftobiprole is currently under regulatory review in the USA, the EU, Switzerland and other countries for the treatment of severe skin infections. Alitretinoin is under regulatory review in various EU member states, Canada and Switzerland.

² Ceftobiprole is approved by the Canadian health authority Health Canada under the trade name ZEFTERA™ for the treatment of complicated skin and skin structure infections (cSSSI) including severe foot infections (diabetic foot).

Condensed Consolidated Interim Financial Statements

Basilea Pharmaceutica Ltd. and subsidiaries

Condensed Consolidated Balance Sheets as of June 30, 2008 and December 31, 2007, in CHF

	Footnote reference	Unaudited Jun 30, 2008	Dec 31, 2007
ASSETS			
Current assets			
Cash and cash equivalents		61 711 264	169 819 448
Short-term financial assets	4	295 000 000	255 000 000
Accounts receivable		540 172	349 243
Other receivables		3 919 559	2 995 976
Accrued interest		2 025 406	4 079 011
Other current assets		2 552 193	1 699 184
Total current assets		365 748 594	433 942 862
Non-current assets			
Tangible assets, net		19 631 418	19 269 451
Intangible assets, net		2 671 272	2 557 486
Other non-current assets	9	6 104 690	5 679 214
Total non-current assets		28 407 380	27 506 151
TOTAL ASSETS		394 155 974	461 449 013
LIABILITIES			
Current liabilities			
Accounts payable		1 661 964	2 829 006
Deferred revenue	3	8 218 523	8 251 787
Accrued liabilities and other current liabilities	5	22 140 229	24 870 311
Total current liabilities		32 020 716	35 951 104
Non-current liabilities			
Deferred revenue, less current portion	3	86 299 645	90 376 794
Other non-current liabilities		10 768	16 249
Total non-current liabilities		86 310 413	90 393 043
Total liabilities		118 331 129	126 344 147
Commitments and contingencies	12		
SHAREHOLDERS' EQUITY			
Share capital ¹	7	9 553 837	9 543 678
Additional paid-in capital		810 945 058	802 509 264
Accumulated other comprehensive income/loss		142 735	(43 907)
Accumulated deficit		(544 816 785)	(476 904 169)
Total shareholders' equity		275 824 845	335 104 866
TOTAL LIABILITIES AND EQUITY		394 155 974	461 449 013

¹ As of June 30, 2008, 9,553,837 shares issued and outstanding with a par value of CHF 1 per share.
As of December 31, 2007, 9,543,678 shares issued and outstanding with a par value of CHF 1 per share.

These financial statements should be read in conjunction with the accompanying notes.

Basilea Pharmaceutica Ltd. and subsidiaries

Condensed Consolidated Statements of Operations for the six months ended June 30, 2008 and 2007 (unaudited), in CHF

	Jun 30, 2008	Jun 30, 2007
Revenues	5 170 389	3 208 147
Other income	152 215	169 792
Total operating income	5 322 604	3 377 939
Research & development expenses	(49 025 399)	(60 614 044)
General & administrative expenses	(29 382 683)	(10 819 210)
Total operating expenses	(78 408 082)	(71 433 254)
Operating loss	(73 085 478)	(68 055 315)
Interest income	5 094 809	3 495 166
Other financial income/expenses, net	78 053	122 437
Loss before taxes	(67 912 616)	(64 437 712)
Income taxes	-	-
Net loss	(67 912 616)	(64 437 712)
	2008	2007
Loss per share	6 months	6 months
Basic and diluted loss per share, in CHF	(7.11)	(7.40)

These financial statements should be read in conjunction with the accompanying notes.

Basilea Pharmaceutica Ltd. and subsidiaries

Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2008 and 2007 (unaudited), in CHF

	Jun 30, 2008	Jun 30, 2007
Net cash used for operating activities	(66 496 798)	(27 969 265)
Cash flow from investing activities		
Payments for financial investments	(265 000 000)	(440 000 000)
Maturities of financial investments	225 000 000	155 000 000
Investments in tangible assets, net of disposals	(1 689 992)	(866 938)
Investments in intangible assets, net of disposals	(574 895)	(568 319)
Net cash used for investing activities	(42 264 887)	(286 435 257)
Cash flow from financing activities		
Net proceeds from capital increase	-	310 097 353
Net proceeds from exercise of stock options	724 346	13 723 155
Repayments of capital lease liabilities	(3 485)	-
Net cash provided by financing activities	720 861	323 820 508
Effect of exchange rate changes on cash and cash equivalents	(67 360)	17 632
Net decrease/increase in cash and cash equivalents	(108 108 184)	9 433 618
Cash and cash equivalents, beginning of period	169 819 448	36 593 700
Cash and cash equivalents, end of period	61 711 264	46 027 318

These financial statements should be read in conjunction with the accompanying notes.

Basilea Pharmaceutica Ltd. and subsidiaries

Condensed Consolidated Statement of changes in Shareholders' Equity for the six months ended June 30, 2008 and 2007 (unaudited), in CHF, except for number of shares

	Number of shares	Share capital	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income/loss	Total
Balance at December 31, 2006	7 785 506	7 785 506	456 690 649	(350 084 627)	(2 081 997)	112 309 531
Currency translation adjustment	–	–	–	–	35 489	35 489
Net loss	–	–	–	(64 437 712)	–	(64 437 712)
Comprehensive income/loss	–	–	–	(64 437 712)	35 489	(64 402 223)
Capital increase, net	1 380 000	1 380 000	308 717 353	–	–	310 097 353
Exercise of stock options, net	215 297	215 297	13 507 858	–	–	13 723 155
Stock-based compensation, net	–	–	7 041 090	–	–	7 041 090
Balance at June 30, 2007	9 380 803	9 380 803	785 956 950	(414 522 339)	(2 046 508)	378 768 906
Balance at December 31, 2007	9 543 678	9 543 678	802 509 264	(476 904 169)	(43 907)	335 104 866
Currency translation adjustment	–	–	–	–	186 642	186 642
Net loss	–	–	–	(67 912 616)	–	(67 912 616)
Comprehensive income/loss	–	–	–	(67 912 616)	186 642	(67 725 974)
Exercise of stock options, net	10 159	10 159	714 187	–	–	724 346
Stock-based compensation, net	–	–	7 721 607	–	–	7 721 607
Balance at June 30, 2008	9 553 837	9 553 837	810 945 058	(544 816 785)	142 735	275 824 845

These financial statements should be read in conjunction with the accompanying notes.

1 Basis of Presentation

The condensed consolidated interim financial statements of Basilea Pharmaceutica Ltd. ("Basilea") and its subsidiaries (together the "Company") have been prepared in accordance with Generally Accepted Accounting Principles in the United States of America ("US GAAP") for interim financial information and accordingly do not include all information and disclosures as required by US GAAP for complete financial statements. The year-end condensed balance sheet data was derived from audited financial statements, but does not include all disclosures required by US GAAP. Please refer to the consolidated financial statements as of December 31, 2007, as included in the Annual Report 2007, for further information. The financial statements are presented in Swiss Francs (CHF).

In the opinion of management, these condensed consolidated interim financial statements reflect all adjustments necessary to present fairly the consolidated balance sheets, statements of operations, cash flows and changes in shareholders' equity for the interim periods presented.

Reclassifications of prior year amounts have been made related to intangible assets and other income within the consolidated balance sheet, statement of operations and statement of cash flows to conform to the current period presentation.

2 Significant Accounting Policies and New Accounting Pronouncements

Revenue Recognition

The Company generally recognizes revenue if the criteria of Staff Accounting Bulletin ("SAB") No. 101, as amended by SAB No. 104, are met, which is when there is evidence of an arrangement, the price is fixed or determinable, collectibility is reasonably assured and the service has been rendered or delivery has occurred. For agreements with multiple deliverables, the Company recognizes revenue separately for each deliverable in accordance with Emerging Issues Task Force ("EITF") Issue No. 00-21. The Company records revenues net of any sales and value added taxes.

Revenue from non-refundable, upfront license fees and milestone payments under licensing agreements, where the Company has continuing involvement, is recognized over the estimated performance or agreement period, depending on the terms of the agreement. Performance based milestone payments are recognized upon achievement of the respective event and if there is no continuous involvement by the Company related to this milestone payment. To the extent that the Company receives payments, including non-refundable payments, in excess of the recognized revenue, such excess is recorded as deferred revenue until the respective revenue is earned.

Revenue for research and development services provided by the Company is recorded as earned based on the performance requirements of the underlying contracts.

Inventories

Costs related to the manufacturing of inventories are expensed as research and development expenses when incurred prior to obtaining regulatory approval or evidence is available that regulatory approval can reasonably be expected. As of June 30, 2008, the Company had not capitalized any inventories. The Company recognized CHF 0.3 million as research and development expenses in the first six months of 2008 related to the manufacturing of pharmaceutical material which may be used for commercialization of one of its compounds, subject to regulatory approval. The corresponding amount that was included in research and development expenses in the first six months of 2007 amounted to CHF 10.6 million.

New Accounting Pronouncements

As new accounting pronouncements are released, the Company reviews such pronouncements for the potential impact on the Company's financial statements.

In September 2006, the Financial Accounting Standards Board ("FASB") issued SFAS No. 157 related to fair value measurements. This statement defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. The Company adopted SFAS No. 157 as of January 1, 2008. The adoption did not have a significant impact on its financial position or results of operations.

In September 2006, the FASB issued SFAS No. 158 related to accounting for defined benefit and other postretirement plans. This statement requires that the funded status of defined benefit plans is recognized on the balance sheet. In addition, this statement requires that the measurement of plan assets and obligations is performed as of the fiscal year-end. Furthermore, SFAS No. 158 establishes certain additional disclosure provisions. The Company adopted the recognition provisions of SFAS No. 158 in 2006 and recognized the funded status of its defined benefit pension plan in its consolidated balance sheet as of December 31, 2006. In addition, the Company will in fiscal year 2008, for the first time, adopt December 31, as the measurement date. The Company does not expect that the change in measurement date will have a significant impact on its financial position or results of operations.

3 Licensing Agreement

In February 2005, the Company entered into a licensing, development and co-promotion agreement with Cilag GmbH International, Zug, Switzerland ("Licensee"), a subsidiary of Johnson & Johnson, under which the Company grants the Licensee an exclusive worldwide license to develop and commercialize the Company's antibiotic compound ceftobiprole (BAL5788). In 2007, the Company exercised its option to co-promote ceftobiprole in certain major market countries.

Under this agreement, the Company is eligible for a non-refundable upfront payment and non-refundable milestone payments based on the achievement of milestones related to development, regulatory filing, regulatory approval and commercialization of ceftobiprole. In addition, the Company is also eligible for royalty payments in the event of commercialization of ceftobiprole.

The Company recognized CHF 4.1 million as revenue in the first six months of 2008 related to these payments (CHF 2.6 million in the first six months of 2007). In the first six months of 2007, the Company received a further milestone payment in the amount of CHF 24.5 million related to filing of the new drug application in the United States. The non-refundable upfront and milestone payments received under this agreement were recognized as deferred revenue and are subsequently being recognized as revenue on a straight-line basis over the estimated term of the agreement.

4 Short-Term Financial Assets

The short-term financial assets as of June 30, 2008 contain short-term time deposits with banks, all denominated in Swiss Francs, in the amount of CHF 295.0 million (CHF 255.0 million as of December 31, 2007).

5 Accrued Liabilities and Other Current Liabilities

Accrued liabilities and other current liabilities as of June 30, 2008 and December 31, 2007 consisted of the following:

In CHF million	Jun 30, 2008	Dec 31, 2007
Accrued R&D expenses	11.7	15.3
Accrued personnel and compensation costs	6.5	6.6
Other	3.9	3.0
Total accruals and other current liabilities	22.1	24.9

6 Stock-Based Compensation

The Company has established a stock option plan effective on December 13, 2000, to provide incentives to directors, executives and employees with an opportunity to obtain stock options on registered shares of Basilea. The shareholders approved conditional capital necessary for the issuance of shares upon the exercise of stock options, of which CHF 2.2 million remains available as of June 30, 2008. CHF 1.4 million of this remaining available conditional capital is reserved for stock options, which are issued and outstanding as of June 30, 2008.

Each option entitles the participant to the purchase of one registered share at the strike price pursuant to the rules of the stock option plan. At the end of the option term, all unexercised options expire without value.

For the six months ended June 30, 2008, the Company recognized compensation expenses of CHF 7.7 million related to this stock option plan, while CHF 7.0 million of compensation expenses were recognized in the respective period in 2007.

7 Shareholders' Equity

As of June 30, 2008, Basilea had 9,553,837 registered shares (Namenaktien) issued and outstanding with a par value of CHF 1 per share. As of December 31, 2007, Basilea had 9,543,678 registered shares with a par value of CHF 1 per share issued and outstanding.

In the six months ended June 30, 2008 and 2007, 10,159 and 215,297 stock options were exercised, respectively, using conditional capital, which resulted in the issuance of 10,159 and 215,297 registered shares with a par value of CHF 1 per share in the respective periods.

In March 2007, Basilea increased its share capital by an amount of CHF 1,380,000 through issuance of 1,380,000 registered shares with a nominal value of CHF 1 per share through a secondary offering. Basilea realized net proceeds of approximately CHF 310.1 million through this capital increase.

Basilea had a total approved conditional capital of CHF 2,846,304 as of June 30, 2008 for the issuance of a maximum of 2,846,304 registered shares with a nominal value of CHF 1 per share. This conditional capital contained CHF 2,206,304 (2,206,304 registered shares with a par value of CHF 1 per share) reserved for the issuance of shares under the stock option plan available to directors, executives and employees. In addition, the shareholders approved conditional capital of CHF 640,000, consisting of 640,000 registered shares with a par value of CHF 1 per share, available for the exercise of option or conversion rights granted with new option or convertible bonds.

In addition, the Company is authorized, through March 2009, to increase its share capital by a maximum of CHF 660,000 by issuing a maximum of 660,000 registered shares with a nominal value of CHF 1 per share.

In the ordinary shareholders' meeting on March 19, 2008, the shareholders of the Company approved the release of reserves in the amount of CHF 119.6 million to offset the loss carried forward for Swiss statutory purposes.

8 Loss per Share

For the six months ended June 30, 2008 and 2007, there was no difference between basic and diluted loss per share. The weighted average number of shares outstanding and the loss per share for the six months ended June 30, 2008 and 2007 are as follows:

	2008	2007
Net loss in CHF million	(67.9)	(64.4)
Weighted average number of shares outstanding, basic and diluted	9 550 986	8 702 050
Basic and diluted loss per share in CHF	(7.11)	(7.40)

The computation of the dilutive loss per share for the six months ended June 30, 2008 excludes 196,388 incremental shares (2007: 665,654 incremental shares) related to potential exercises of stock options, as the effect would have been anti-dilutive.

9 Pension Plan

The following table provides information on the pension expenses related to the Company's defined benefit pension plan for the six months periods ended June 30, 2008 and 2007:

In CHF million	Jan 1 to Jun 30, 2008	Jan 1 to Jun 30, 2007
Service cost	1.0	1.1
Interest cost	0.5	0.4
Expected return on plan assets	(0.7)	(0.6)
Gross benefit expense	0.8	0.9
Participant contributions	(0.4)	(0.4)
Net periodic pension cost	0.4	0.5
Employer contributions	(0.8)	(0.8)
(Increase) of prepaid pension asset	(0.4)	(0.3)

As of June 30, 2008, the Company recognized a prepaid pension asset of CHF 5.9 million in other non-current assets (December 31, 2007: CHF 5.5 million).

10 Segment Information

The Company operates in one segment, which is the discovery, development and commercialization of pharmaceutical products. The CEO of the Company reviews the profit and loss of the Company on an aggregated basis and manages the operations of the Company as a single operating segment.

11 Related Party Transactions

For the six months ended June 30, 2008, there were no significant related party transactions. For the six months ended June 30, 2007, the Company purchased materials and services from F. Hoffmann-La Roche Ltd. ("Roche"), in the amount of CHF 9.0 million, of which CHF 9.0 million related to the purchase of pharmaceutical material which may be used for commercialization of one of its compounds, subject to regulatory approval.

Furthermore, as of June 30, 2008 and December 31, 2007, there were no significant positions due to or from related parties.

12 Commitments and Contingencies

The Company entered into various purchase commitments for services and materials as well as for equipment as part of the ordinary business. These commitments are not in excess of current market prices in all material respects and reflect normal business operations.

As of June 30, 2008, there were no significant contingencies.

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Photography

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