

Half-year report 2006



**Moving...**

## **Who We Are**

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

Our focus is on the discovery, development and commercialization of innovative medicines to satisfy high medical and patient needs in the hospital setting.

We have a diversified product portfolio including novel treatments for bacterial infections, fungal infections and skin diseases. Three of our drug candidates have successfully advanced into late stage clinical development.

**[www.basilea.com](http://www.basilea.com)**

# ...forward

## Half-year Highlights

### **March 2, Ceftobiprole**

[Positive phase III results.](#) First study results for the treatment of complicated severe skin and skin structure infections (cSSSI) revealed high clinical cure rates, good safety and tolerability.

### **May 2, BAL8557**

[Fast-track designation.](#) The U.S. Food and Drug Administration (FDA) granted fast track designation because of the potential benefit of our extended-spectrum antifungal for the treatment of severe invasive infections including patients with renal impairment.

### **May 17, Ceftobiprole**

[Start phase III CAP study.](#) Additional phase III study opened for hospitalized patients suffering from community-acquired pneumonia (CAP) to broaden potential label.

### **May 17, Alitretinoin**

[Phase III trial recruitment completed.](#) Over 1000 patients included in trial. This is the largest and first randomized placebo-controlled study ever performed in patients suffering from severe chronic hand dermatitis.

### **June 27, BAL8557**

[Promising clinical and preclinical data.](#) Basilea presentations at the International Society for Human and Animal Mycology (ISHAM) congress highlighted a promising safety and drug-drug interaction profile and confirmed broad-spectrum activity of our antifungal.

## Our Key Value Drivers



**Ceftobiprole** – developed with Cilag GmbH International, a Johnson & Johnson company - the first broad-spectrum cephalosporin antibiotic with anti-MRSA (methicillin-resistant *Staphylococcus aureus*) activity to treat the increasing number of patients with severe infections who may no longer respond to traditional antibiotic treatment.



**BAL8557** – an antifungal azole with extended spectrum and convenient water-soluble injection and oral dose forms addressing the limited treatment options and high mortality associated with severe invasive fungal infections in immunocompromised cancer, transplant and HIV patients.



**Alitretinoin** – an oral dermatology drug to treat patients with severe chronic hand dermatitis who do not respond to topical steroids. The illness results in significant patient disability and has profound occupational, medical and social consequences. To date, there is no approved treatment available for this skin disease.

### Balanced Late-stage Product Portfolio

Our Portfolio		Research	Development Phase 0	I	II	III
Antibacterials	Ceftobiprole Broad-spectrum anti-MRSA	██████████	██████████	██████████	██████████	██████████
	Macrolides	██████████	██████████			
	β-Lactams	██████████	██████████			
	Exploratory Projects	██████████				
Antifungals	BAL8557 Broad-spectrum Triazole	██████████	██████████	██████████	██████████	
Dermatology	Alitretinoin Chronic Hand Dermatitis	██████████	██████████	██████████	██████████	██████████

## Report of Independent Accountants



To the Board of Directors  
of Basilea Pharmaceutica Ltd., Basel, Switzerland

We have reviewed the accompanying condensed consolidated balance sheet of Basilea Pharmaceutica Ltd. and its subsidiaries as of June 30, 2006, the related condensed consolidated statements of operations and cash flows for each of the six-month periods ended June 30, 2006 and 2005, the condensed consolidated statement of changes in shareholders' equity for the six months ended June 30, 2006, and the related notes, included on pages 5 to 13. These interim financial statements are the responsibility of the Board of Directors.

We conducted our review in accordance with Swiss Auditing Standard 910 and standards established by the American Institute of Certified Public Accountants. A review of interim financial information consists principally of applying analytical procedures and making inquiries of persons responsible for financial and accounting matters. It is substantially less in scope than an audit conducted in accordance with generally accepted auditing standards, the objective of which is the expression of an opinion regarding the financial statements taken as a whole. Accordingly, we do not express such an opinion.

Based on our review, we are not aware of any material modifications that should be made to the accompanying condensed consolidated interim financial statements for them to be in conformity with accounting principles generally accepted in the United States of America and to comply with relevant Swiss law.

### PricewaterhouseCoopers AG

Ralph R. Reinertsen

Garrett C. Thompson

Basel, August 22, 2006

## Condensed Consolidated Interim Financial Statements

Basilea Pharmaceutica Ltd. and Subsidiaries

Condensed Consolidated Balance Sheets as of June 30, 2006 and December 31, 2005, in CHF

Assets	Footnote reference	Unaudited Jun 30, 2006	Dec 31, 2005
<b>Current assets</b>			
Cash and cash equivalents		15 347 260	29 635 274
Short-term investments	5	195 000 000	200 000 000
Accounts receivable		526 856	437 730
Other receivables		757 458	529 518
Accrued interest		1 000 416	949 281
Other current assets		992 055	776 966
<b>Total current assets</b>		<b>213 624 045</b>	<b>232 328 769</b>
<b>Non-current assets</b>			
Property, plant and equipment, net		18 994 728	19 792 420
Other non-current assets	11	3 628 000	3 442 000
<b>Total non-current assets</b>		<b>22 622 728</b>	<b>23 234 420</b>
<b>Total Assets</b>		<b>236 246 773</b>	<b>255 563 189</b>
<b>Liabilities</b>			
<b>Current liabilities</b>			
Accounts payable		1 857 924	854 371
Deferred revenue	4	5 515 102	5 541 207
Accruals and other current liabilities	7	14 801 634	12 626 394
<b>Total current liabilities</b>		<b>22 174 660</b>	<b>19 021 972</b>
<b>Non-current liabilities</b>			
Deferred revenue, less current portion	4	66 047 564	68 671 971
<b>Total non-current liabilities</b>		<b>66 047 564</b>	<b>68 671 971</b>
<b>Total liabilities</b>		<b>88 222 224</b>	<b>87 693 943</b>
<b>Shareholders' Equity</b>			
Share capital <sup>1</sup>	9	7 694 792	7 436 502
Additional paid-in capital		445 856 108	425 976 934
Accumulated other comprehensive loss		(797 838)	(609 252)
Accumulated deficit		(304 728 513)	(264 934 938)
<b>Total shareholders' equity</b>		<b>148 024 549</b>	<b>167 869 246</b>
<b>Total Liabilities and Equity</b>		<b>236 246 773</b>	<b>255 563 189</b>

<sup>1</sup> As of June 30, 2006, 7,694,792 shares issued and outstanding at par value of CHF 1 per share.  
As of December 31, 2005, 7,436,502 shares issued and outstanding at 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, 2006 and 2005 (unaudited), in CHF**

	Jun 30, 2006	Jun 30, 2005
<b>Revenues</b>	<b>3 890 242</b>	<b>19 562 823</b>
Research & development expenses	(39 012 094)	(36 750 821)
General & administrative expenses	(5 879 555)	(3 690 656)
<b>Total operating expenses</b>	<b>(44 891 649)</b>	<b>(40 441 477)</b>
<b>Operating loss</b>	<b>(41 001 407)</b>	<b>(20 878 654)</b>
Interest expense	–	(155 735)
Interest income	1 239 351	820 564
Other financial expenses, net	(31 519)	(322 550)
<b>Loss before taxes</b>	<b>(39 793 575)</b>	<b>(20 536 375)</b>
Income taxes	–	–
<b>Net loss</b>	<b>(39 793 575)</b>	<b>(20 536 375)</b>

	2006 6 months	2005 6 months
<b>Loss per share</b>		
Basic and diluted loss per share, in CHF	(5.24)	(2.78)

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, 2006 and 2005 (unaudited), in CHF**

	Jun 30, 2006	Jun 30, 2005
<b>Net cash used for/provided by operating activities</b>	<b>(33 755 440)</b>	<b>61 935 589</b>
<b>Cash flow from investing activities</b>		
Short-term investments, net	5 000 000	(14 250 000)
Investments in property, plant & equipment, net of disposals	(903 334)	(303 610)
<b>Net cash provided by/used for investing activities</b>	<b>4 096 666</b>	<b>(14 553 610)</b>
<b>Cash flow from financing activities</b>		
Net proceeds from exercise of stock options	15 421 766	407 912
Repayment of mortgage	–	(10 000 000)
Repayment of capital lease liabilities	–	(252 034)
<b>Net cash provided by/used for financing activities</b>	<b>15 421 766</b>	<b>(9 844 122)</b>
<b>Effect of exchange rate changes on cash and cash equivalents</b>	<b>(51 006)</b>	<b>130 417</b>
<b>Net decrease/increase in cash and cash equivalents</b>	<b>(14 288 014)</b>	<b>37 668 274</b>
<b>Cash and cash equivalents, beginning of period</b>	<b>29 635 274</b>	<b>66 918 453</b>
<b>Cash and cash equivalents, end of period</b>	<b>15 347 260</b>	<b>104 586 727</b>

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, 2006 (unaudited), in CHF**

	Number of shares	Share capital	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income/loss	Total
<b>Balance at December 31, 2005</b>	<b>7 436 502</b>	<b>7 436 502</b>	<b>425 976 934</b>	<b>(264 934 938)</b>	<b>(609 252)</b>	<b>167 869 246</b>
Currency translation adjustment	–	–	–	–	(188 586)	(188 586)
Net loss	–	–	–	(39 793 575)	–	(39 793 575)
Comprehensive income/loss	–	–	–	(39 793 575)	(188 586)	(39 982 161)
Exercise of stock options, net	258 290	258 290	15 163 476	–	–	15 421 766
Stock-based compensation, net	–	–	4 715 698	–	–	4 715 698
<b>Balance at June 30, 2006</b>	<b>7 694 792</b>	<b>7 694 792</b>	<b>445 856 108</b>	<b>(304 728 513)</b>	<b>(797 838)</b>	<b>148 024 549</b>

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

## Basilea Pharmaceutica Ltd. and Subsidiaries

### Notes to the Condensed Consolidated Interim Financial Statements (unaudited)

## 1 Basis of Presentation

The condensed consolidated interim financial statements of Basilea Pharmaceutica Ltd. and its subsidiaries ("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. Please refer to the consolidated financial statements as of December 31, 2005, as included in the Annual Report 2005, 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.

## 2 Significant Accounting Policies

### 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.

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.

Payments received as reimbursement of expenses incurred by the Company, for which the Company was the primary obligor at the time the expenses incurred, are recognized as revenue in accordance with EITF Issue No. 01-14.

## Stock-Based Compensation

As of July 1, 2005, the Company adopted the Statement of Financial Accounting Standards ("SFAS") No. 123R related to Accounting for Stock-Based Compensation. According to SFAS No. 123R, the Company measures the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. Under the modified prospective application method of SFAS No. 123R, the Company applies this accounting treatment to awards issued, modified, repurchased or cancelled after June 30, 2005 as well as to portions of awards, to the extent they have not vested by June 30, 2005. The amounts recorded for stock-based compensation in periods prior to July 1, 2005, the adoption date of SFAS No. 123R, have not been restated and do not reflect the effects of this change in accounting policy.

For periods prior to July 1, 2005, the Company applied Accounting Principles Board ("APB") Opinion No. 25. Under APB Opinion No. 25, the Company recorded compensation expenses in connection with stock-based compensation awards based on the difference between the exercise price of the award and the market value of the underlying shares at the measurement date of such award.

The stock-based compensation expenses are allocated over the vesting period of the award. For awards, which consist of portions with different vesting periods, the compensation expense is recognized pro rata for each portion of the award over the respective vesting period of such portion.

### Pro forma disclosure

The following pro forma net loss and net loss per share for the first half of 2005 were determined as if the Company had used the fair value method of accounting for its stock option grants for that period in accordance with the provisions of SFAS No. 123 and No. 148.

The following table illustrates the effect on net loss and loss per share for the six months ended June 30, 2005 if the fair value based method had been applied in that period:

In CHF million, except per share data	6 months 2005
Net loss, as reported	(20.5)
+ Stock-based compensation included in reported net loss, net of tax	0.7
- Stock-based compensation determined under fair value based method, net of tax	(2.9)
Pro forma net loss (fair value method)	(22.7)
Per share data:	
Basic and diluted loss per share, as reported, in CHF	(2.78)
Basic and diluted loss per share, pro forma, in CHF	(3.08)

## Certain Risks and Uncertainties

The Company is subject to risks common to companies in its industry, including, but not limited to, uncertainty of results of clinical trials for its compounds; ability to achieve regulatory approval for its compounds; acceptance of Company's products by the market, once they are marketed; ability to market its products; ability to manufacture its products at reasonable costs; protection of proprietary technology; development of new technological innovations by its competitors; dependence on key personnel; dependence on key suppliers and compliance with governmental and other regulations.

## 3 Exchange Rates of Principal Currencies

The exchange rates used for the consolidation in 2006 and 2005 were the following:

	Statement of Operations Average rate 6 months 2006	Statement of Operations Average rate 6 months 2005	Jun 30, 2006	Balance Sheet Period-end rate Dec 31, 2005
US Dollar	1.27	1.20	1.25	1.32

## 4 Licensing Agreement

In February 2005, Basilea Pharmaceutica Ltd. ("Basilea") entered into a royalty-bearing 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). Under this agreement, the Company maintains the option to co-promote ceftobiprole in 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.

In the six months ended June 30, 2005, the Company received non-refundable upfront and milestone payments totalling CHF 78.0 million. These payments are being recognized as revenue on a straight-line basis over the term of the agreement. The Company has recognized CHF 2.6 million as revenue in the first six months of 2006 related to these payments (CHF 1.5 million in the first six months of 2005). Furthermore, the Company realized revenue under this licensing agreement in the first six months ended June 30, 2005 in the amount of CHF 17.9 million related to the reimbursement of expenses incurred by the Company for ceftobiprole as well as from services provided by the Company to the Licensee.

## 5 Short-Term Investments

The short-term financial investments as of June 30, 2006 contain short-term deposits with banks, all denominated in Swiss Francs, in the amount of CHF 195.0 million (CHF 200.0 million as of December 31, 2005).

## 6 Short-Term Debt

As of June 30, 2006, no short-term debt is outstanding. The Company repaid a mortgage in the amount of CHF 10.0 million in the first six months of 2005.

## 7 Accruals and Other Current Liabilities

Accruals and other current liabilities consisted of the following:

In CHF million	Jun 30, 2006	Dec 31, 2005
Accrued R&D expenses	10.6	8.5
Accrued personnel and compensation costs	3.2	3.2
Other	1.0	0.9
<b>Total accruals and other current liabilities</b>	<b>14.8</b>	<b>12.6</b>

## 8 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 of up to CHF 2.0 million comprising two million registered shares at a par value of CHF 1 per share, necessary for the issuance of shares upon the exercise of the options, of which CHF 1.7 million remains available as of June 30, 2006.

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, 2006, the Company recognized compensation expenses of CHF 4.7 million related to stock-based compensation, while CHF 0.7 million of compensation expenses were recognized in the respective period in 2005.

## 9 Shareholders' Equity

As of June 30, 2006, Basilea had 7,694,792 registered shares (Namenaktien) issued and outstanding with a par value of CHF 1 per share. As of December 31, 2005, Basilea had 7,436,502 registered shares with a par value of CHF 1 per share issued and outstanding, respectively.

In the six months ended June 30, 2006 and 2005, 258,290 and 6,875 stock options were exercised, respectively, using conditional capital, which resulted in the issuance of 258,290 and 6,875 registered shares with a par value of CHF 1 per share in the respective periods.

Basilea had a total approved conditional capital of CHF 2,325,349 as of June 30, 2006 for the issuance of a maximum of 2,325,349 registered shares with a nominal value of CHF 1 per share. This conditional capital contained CHF 1,685,349 (1,685,349 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 at a par value of CHF 1 each, available for the exercise of option or conversion rights granted with new option or convertible bonds.

In addition, the Company is authorized, through April 2007, to increase its share capital by a maximum of CHF 540,000 by issuing a maximum of 540,000 registered shares with a nominal value of CHF 1 per share.

In the ordinary shareholders' meeting on March 28, 2006, the shareholders of the Company approved the release of reserves in the amount of CHF 259,305,276 to offset the loss carried forward for Swiss statutory purposes.

## 10 Earnings per Share

For the six months ended June 30, 2006 and 2005, 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, 2006 and 2005 are as follows:

	2006	2005
Net loss in CHF million	(39.8)	(20.5)
Weighted average number of shares outstanding, basic and diluted	7 596 095	7 385 436
Basic and diluted loss per share, in CHF	(5.24)	(2.78)

The computation of the dilutive loss per share for the six months ended June 30, 2006 excludes 617,084 incremental shares (2005: 340,128 incremental shares) related to potential exercises of 1,280,157 stock options (2005: 1,251,794 stock options), as the effect would have been anti-dilutive.

## 11 Pension Plan

The measurement date for the Company's pension plan is September 30 of each year.

The following table provides information on the estimated pension expenses for the six months periods ended June 30, 2006 and 2005:

In CHF million	Jan 1 to Jun 30, 2006	Jan 1 to Jun 30, 2005
Service cost	1.0	0.9
Interest cost	0.4	0.4
Expected return on plan assets	(0.5)	(0.4)
Gross benefit expense	0.9	0.9
Participant contributions	(0.3)	(0.3)
Net periodic pension cost	0.6	0.6
Employer contributions	(0.8)	(0.6)
<b>(Increase) of prepaid pension asset</b>	<b>(0.2)</b>	<b>0.0</b>

## 12 Related Party Transactions

The Company has an agreement with its shareholder, F. Hoffmann-La Roche Ltd. ("Roche"), with respect to certain of its research molecules, that allows Roche to opt-in on such compounds in exchange for milestone payments and potential future royalties. The Company is currently not pursuing those research molecules for which Roche has opt-in rights.

In December 2005, Roche decided not to exercise its option to license the Company's antifungal compound, BAL8557.

## 13 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.

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