

## WE TARGET RESISTANCE

“An increasing number of patients are suffering from bacterial diseases that do not respond to currently available antibacterial drugs, with serious consequences, including increased mortality.”

U.S. FDA. Draft Guidance for Industry. Antibacterial Therapies for Patients With Unmet Medical Need for the Treatment of Serious Bacterial Diseases. July 2013.



## HALF-YEAR REPORT 2013



## BASILEA IN BRIEF

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

### OUR COMPANY

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. ("Basilea"), 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.

### OUR VISION

We strive for excellence in integrated research and development in areas of infectious diseases and oncology, while retaining the option to commercialize our products. We aspire to provide innovative medications through a sustainable business, solving high unmet medical needs in patients and focusing on resistance while maximizing shareholder value.

“Basilea is tackling the growing global threat of resistance against established therapies. We continue to focus on achieving our key milestones this year, including a potential approval of our antibiotic ceftobiprole in Europe, reporting phase 3 results for our anti-fungal isavuconazole and continued improvement of our financial performance. We remain open to innovative structures and we were very pleased to announce a significant agreement with BARDA in the first half of this year allowing for non-dilutive funding of up to USD 89 million for our drug candidate BAL30072, which addresses Gram-negative bacterial resistance.”

**RONALD SCOTT**  
Chief Executive Officer

Title page lower panel: methicillin-resistant  
Staphylococcus aureus (MRSA) bacteria

## KEY EVENTS

### CORPORATE

- ▶ BARDA (Biomedical Advanced Research and Development Authority within the U.S. Department of Health and Human Services) contract of up to USD 89 million for development of novel antibiotic addressing Gram-negative bacterial resistance, BAL30072
- ▶ Distribution of CHF 5.00 per share following shareholder approval at the annual general meeting, corresponding to approximately CHF 48 million from capital contribution reserves
- ▶ Recruitment completion into isavuconazole phase 3 study VITAL for the treatment of aspergillosis in renally impaired patients and infections caused by emerging fungi
- ▶ U.S. FDA orphan drug designation granted to isavuconazole for the treatment of invasive aspergillosis
- ▶ Ongoing European regulatory procedure of ceftobiprole for the treatment of pneumonia in the hospital with regulatory decision anticipated in second half of 2013

### FINANCIALS

- ▶ Half-year cash and short-term investments of CHF 262.8 million
- ▶ Significantly improved operating results due to lower selling, general and administrative expenses
- ▶ Continued prudent cost management with improved operating loss and expense guidance
- ▶ Determination of maximum tolerated dose in second multiple ascending dose study with Gram-negative antibiotic BAL30072
- ▶ Presentation of new data on anti-infective drug candidates isavuconazole, ceftobiprole and BAL30072 at the European Congress of Clinical Microbiology and Infectious Diseases (ECCMID)
- ▶ Presentation of interim phase 1 data of novel anti-cancer drug BAL101553 at the conference of the American Society of Clinical Oncology (ASCO)

### PROGRAM UPDATES

- ▶ Isavuconazole phase 3 SECURE and VITAL study data timing confirmed for the second half of 2013
- ▶ Amendment of isavuconazole phase 3 ACTIVE study protocol for the treatment of invasive *Candida* infections

## DRUG RESISTANCE – A GLOBAL HEALTH THREAT

### ANTIBIOTIC RESISTANCE

“Without effective antibiotics, diverse fields of medicine will be severely hampered, including surgery, the care of premature infants, cancer chemotherapy, care of the critically ill, and transplantation medicine, all of which are feasible only in the context of effective antibiotic therapy.”

“Our ability to respond to national security threats (e.g., bioterrorism and pandemics) also is in serious jeopardy.”

“Ultimately, the loss of effective antibiotics will result in a great increase in morbidity and mortality from infections. Antimicrobial resistance is of such tremendous global concern that the World Health Organization has proclaimed it the central focus of World Health Day 2011.”

Infectious Diseases Society of America (IDSA). Combating Antimicrobial Resistance: Policy Recommendations to Save Lives. Clinical Infectious Diseases. 2011.

### ANTIFUNGAL RESISTANCE

“Invasive fungal infections constitute a significant burden in patients with a weakened or impaired immune system. The spectrum of fungal pathogens causing infections in such immunocompromised hosts is growing.”

Kanafani ZA, Perfect JR. Resistance to Antifungal Agents: Mechanisms and Clinical Impact. Clinical Infectious Diseases. 2008.

“Both the frequency of invasive fungal infections and resistance to antifungal therapy continue to increase despite the introduction of new antifungal agents.”

Pfaller MA, Diekema DJ. Epidemiology of invasive mycoses in North America. Critical Reviews in Microbiology. 2010.

“The resistance may be intrinsic, acquired or clinical. The understanding of the mechanism of resistance and clinical impact is important while planning treatment strategies.”

Chakrabarti A. Drug resistance in fungi – an emerging problem. Regional Health Forum 2011.

### RESISTANCE TO CANCER THERAPY

“Resistance represents one of the key challenges in cancer treatment. A patient may obtain a dramatic response on a new treatment, but as the cancer finds escape routes [...], resistance to the drug is acquired and the cancer reappears.”

Sawyers CL. Overcoming Resistance to Cancer Drug Therapy. Science of Oncology Award Lecture at 2013 ASCO annual meeting.

“Despite the progress that has been made, further work is necessary to untangle the complex causes for primary and secondary resistance to [cancer] therapy to make a dramatic impact on the lives of patients we treat.”

Reckamp KL. EGFR Pathway: Enabling Patient Selection, More Research Needed Regarding Resistance. ASCO Daily News, 2nd June 2013 ASCO annual meeting.

## BASILEA – ADDRESSING RESISTANCE

- ▶ Well differentiated and competitive drug candidates for the treatment of drug-resistant bacterial infections, systemic fungal infections, and drug-resistant tumors
- ▶ Two late-stage anti-infectives: isavuconazole in phase 3 clinical testing and ceftobiprole under regulatory review by European authorities
- ▶ Promising early-stage pipeline including two drug candidates from Basilea's research in phase 1 clinical development: anti-Gram-negative antibiotic BAL30072 and the novel microtubule-destabilizing oncology compound BAL101553

PRODUCT / INDICATION		RESEARCH	DEVELOPMENT PHASE 0	PHASE 1	PHASE 2	PHASE 3	UNDER REGULATORY REVIEW	MARKET
ANTIFUNGALS	<b>Isavuconazole<sup>1</sup></b> Broad-spectrum triazole Invasive fungal infections							
ANTIBIOTICS	<b>Ceftobiprole</b> Broad-spectrum cephalosporin MRSA, <i>Pseudomonas</i>							
	<b>BAL30072</b> Sulfactam MDR * Gram-neg. bacteria							
	<b>Exploratory projects</b>							
ONCOLOGY	<b>BAL101553</b> Microtubule destabilizer Taxane-resistant tumors							
	<b>Exploratory projects</b>							
DERMATOLOGY	<b>Toctino® (alitretinoin)<sup>2</sup></b> Systemic vitamin A derivative Chronic hand eczema							

\* Multidrug-resistant

<sup>1</sup> Partnered with Astellas Pharma Inc.

<sup>2</sup> Participation with Stiefel/GSK; Basilea eligible for a milestone payment related to the launch of alitretinoin in the U.S. and participation in future U.S. product sales

## OUR PRODUCTS

### ANTI-INFECTIVES

**ISAVUCONAZOLE** is an investigational intravenous (i.v.) and oral broad-spectrum antifungal, which demonstrated *in-vitro* and *in-vivo* coverage of a broad range of yeasts (e.g. *Candida*) and molds (e.g. *Aspergillus*) as well as *in-vitro* activity against emerging and often fatal molds including those that cause mucormycosis. In clinical studies, isavuconazole achieved predictable drug levels in patients, supporting reliable once-daily dosing and a switch from i.v. to oral administration. The i.v. formulation of water-soluble isavuconazole does not contain possible kidney-damaging solubilizers and has the potential to be given also to patients with pre-existing renal impairment. Isavuconazole is partnered with Astellas Pharma Inc. It has U.S. FDA fast-track status and U.S. orphan drug designation.

Topline data from the SECURE and VITAL phase 3 studies are expected in the second half of 2013, supporting a potential initial regulatory filing for the invasive aspergillosis indication in the first part of 2014. The ACTIVE phase 3 study for the treatment of invasive *Candida* infections will continue to recruit in 2014.

**CEFTOBIPROLE** is a broad-spectrum antibiotic for the potential first-line empiric treatment of severe bacterial infections. It has demonstrated 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 is currently under regulatory review in Europe for the treatment of pneumonia in the hospital. A regulatory decision is anticipated in the second half of 2013. Regarding the U.S., the FDA indicated

that their current guidelines mandating two pivotal trials per indication are still valid. We are continuing our discussions with the agency.

**BAL30072** is an innovative bactericidal sulfactam antibiotic with *in-vitro* and *in-vivo* coverage of Gram-negative bacteria including multidrug-resistant *Acinetobacter baumannii* and *Pseudomonas aeruginosa*. It has robust activity against common strains that produce antibiotic-inactivating enzymes including carbapenemases and metallo-beta-lactamases such as the New Delhi metallo-beta-lactamase 1 (NDM-1). In addition, BAL30072 has shown additive or synergistic activity with antibiotics from the carbapenem class.

The phase 1 development of BAL30072, which will include combination studies with carbapenems and special patient population studies, is ongoing.

### ONCOLOGY

**BAL101553** is a novel synthetic small-molecule drug, directly attacking tumor cells through microtubule destabilization as well as disrupting tumor blood vessels. It has shown potent anti-proliferative activity in a panel of tumor models including many that are not responsive to conventional microtubule-targeting agents, such as taxanes, as a result of diverse resistance mechanisms. BAL101553 is a water-soluble prodrug of Basilea's BAL27862, formulated in an injectable dosage form without potentially harmful solubilizers. In addition, it is orally bioavailable.

A phase 1 study is ongoing to determine the maximum tolerated dose. Expansion into phase 2a, investigating larger patient numbers for signals of efficacy in different tumor types is anticipated in 2013. A biomarker strategy has been implemented to support selection of the potentially most responsive tumor types.

## OUR PRODUCTS TARGET RESISTANCE

“Isavuconazole is on track for phase 3 data in the second half of 2013 and ceftobiprole continues to be under regulatory review in Europe with a decision anticipated in the second half of the year.”

PROF. DR. ACHIM KAUFHOLD  
Chief Medical Officer

### ISAVUCONAZOLE

Broad-spectrum triazole  
Invasive fungal infections

### BAL101553

Microtubule destabilizer  
Taxane-resistant tumors



### BAL30072

Sulfactam  
MDR Gram-negative bacteria

### CEFTOBIPROLE

Broad-spectrum cephalosporin  
MRSA, *Pseudomonas*

# CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

## BASILEA PHARMACEUTICA LTD. AND SUBSIDIARIES

Condensed consolidated balance  
sheets as of June 30, 2013 and  
December 31, 2012 (in CHF)

	Footnote reference	Unaudited 2013	2012
<b>ASSETS</b>			
<b>Current assets</b>			
Cash and cash equivalents		142 752 479	223 955 498
Short-term investments	4	120 000 000	120 000 000
Accounts receivable	5	5 849 768	7 554 534
Other receivables		2 977 151	3 939 242
Other current assets		4 623 869	4 725 429
<b>Total current assets</b>		<b>276 203 267</b>	<b>360 174 703</b>
<b>Non-current assets</b>			
Tangible assets, net		13 409 050	14 376 938
Intangible assets, net		491 772	600 033
Other non-current assets		165 938	193 029
<b>Total non-current assets</b>		<b>14 066 760</b>	<b>15 170 000</b>
<b>TOTAL ASSETS</b>		<b>290 270 027</b>	<b>375 344 703</b>
<b>LIABILITIES</b>			
<b>Current liabilities</b>			
Accounts payable		1 617 976	1 705 205
Deferred revenue	3	38 831 549	38 831 549
Accruals and other current liabilities	7	14 870 068	18 076 659
<b>Total current liabilities</b>		<b>55 319 593</b>	<b>58 613 413</b>
<b>Non-current liabilities</b>			
Deferred revenue, less current portion	3	181 346 612	200 762 387
Other non-current liabilities	11	10 514 091	10 466 933
<b>Total non-current liabilities</b>		<b>191 860 703</b>	<b>211 229 320</b>
<b>Total liabilities</b>		<b>247 180 296</b>	<b>269 842 733</b>
Commitments and contingencies	15		
<b>SHAREHOLDERS' EQUITY</b>			
Share capital <sup>1</sup>	9	9 597 574	9 587 621
Additional paid-in capital		810 473 083	856 299 215
Accumulated other comprehensive income/loss		(15 702 401)	(16 391 322)
Accumulated deficit		(761 278 525)	(743 993 544)
<b>Total shareholders' equity</b>		<b>43 089 731</b>	<b>105 501 970</b>
<b>TOTAL LIABILITIES AND EQUITY</b>		<b>290 270 027</b>	<b>375 344 703</b>

<sup>1</sup> As of June 30, 2013, 9,597,574 registered shares were issued and outstanding with a par value of CHF 1 per share.  
As of December 31, 2012, 9,587,621 registered shares were 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 ending  
June 30, 2013 and 2012 (unaudited, in CHF)

	Footnote reference	2013	2012
Product sales		–	17 696 119
Contract revenue	3	20 383 347	13 377 084
Revenue from R&D services		87 794	117 978
Other income		127 055	37 794
<b>Total operating income</b>		<b>20 598 196</b>	<b>31 228 975</b>
Cost of sales		–	(5 141 714)
Research & development expenses		(26 702 374)	(31 570 731)
G&A expenses / SG&A expenses		(11 256 154)	(28 740 738)
<b>Total operating expenses</b>		<b>(37 958 528)</b>	<b>(65 453 183)</b>
<b>Operating loss</b>		<b>(17 360 332)</b>	<b>(34 224 208)</b>
Interest income		197 364	233 396
Other financial income/expenses, net		(103 136)	(316 809)
<b>Loss before taxes</b>		<b>(17 266 104)</b>	<b>(34 307 621)</b>
Income taxes		(18 877)	(259 941)
<b>Net loss</b>		<b>(17 284 981)</b>	<b>(34 567 562)</b>
<b>Loss per share</b>	10	<b>2013</b>	<b>2012</b>
Basic and diluted loss per share, in CHF		(1.80)	(3.61)

# BASILEA PHARMACEUTICA LTD. AND SUBSIDIARIES

Condensed consolidated statements  
of comprehensive income/loss for the  
six months ending June 30, 2013 and 2012  
(unaudited, in CHF)

	2013	2012
<b>Net loss</b>	<b>(17 284 981)</b>	<b>(34 567 562)</b>
Currency translation adjustments <sup>1</sup>	223 921	318 933
Amortization of unrecognized pension costs	465 000	427 500
<b>Other comprehensive income, net of tax</b>	<b>688 921</b>	<b>746 433</b>
<b>Comprehensive loss</b>	<b>(16 596 060)</b>	<b>(33 821 129)</b>

<sup>1</sup> For the six months ending June 30, 2013 net gain of CHF 0.0 million (for the six months ending June 30, 2012 net losses of CHF 0.1 million) related to the close-down of organisations and the liquidation of subsidiaries were transferred from accumulated other comprehensive income/loss to the condensed consolidated statements of operations. For further details please refer to footnote 9.

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

Condensed consolidated statements  
of cash flows for the six months ending  
June 30, 2013 and 2012 (unaudited, in CHF)

	2013	2012
<b>Net cash used for operating activities</b>	<b>(33 677 588)</b>	<b>(47 642 296)</b>
<b>Cash flow from investing activities</b>		
Payments for financial investments	(50 000 000)	(80 000 000)
Maturities of financial investments	50 000 000	25 000 000
Investments in tangible assets, net of disposals	(176 190)	(317 405)
Investments in intangible assets, net of disposals	(30 553)	(160 112)
<b>Net cash used for investing activities</b>	<b>(206 743)</b>	<b>(55 477 517)</b>
<b>Cash flow from financing activities</b>		
Net proceeds from exercise of stock options	465 240	(104)
Distribution of capital to shareholders	(47 955 180)	–
<b>Net cash used for financing activities</b>	<b>(47 489 940)</b>	<b>(104)</b>
<b>Effect of exchange rate changes on cash and cash equivalents</b>	<b>171 252</b>	<b>5 647</b>
<b>Net change in cash and cash equivalents</b>	<b>(81 203 019)</b>	<b>(103 114 270)</b>
<b>Cash and cash equivalents, beginning of period</b>	<b>223 955 498</b>	<b>172 146 002</b>
<b>Cash and cash equivalents, end of period</b>	<b>142 752 479</b>	<b>69 031 732</b>

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

# BASILEA PHARMACEUTICA LTD. AND SUBSIDIARIES

Condensed consolidated  
statement of changes in share-  
holders' equity for the six  
months ending June 30, 2013  
and 2012 (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
<b>Balance at December 31, 2011</b>	<b>9 587 571</b>	<b>9 587 571</b>	<b>851 207 674</b>	<b>(690 960 439)</b>	<b>(16 565 534)</b>	<b>153 269 272</b>
Net loss	–	–	–	(34 567 562)	–	(34 567 562)
Other comprehensive loss	–	–	–	–	746 433	746 433
Exercise of stock options, net	–	–	(104)	–	–	(104)
Stock-based compensation, net	–	–	1 838 060	–	–	1 838 060
<b>Balance at June 30, 2012</b>	<b>9 587 571</b>	<b>9 587 571</b>	<b>853 045 630</b>	<b>(725 528 001)</b>	<b>(15 819 101)</b>	<b>121 286 099</b>
<b>Balance at December 31, 2012</b>	<b>9 587 621</b>	<b>9 587 621</b>	<b>856 299 215</b>	<b>(743 993 544)</b>	<b>(16 391 322)</b>	<b>105 501 970</b>
Net loss	–	–	–	(17 284 981)	–	(17 284 981)
Other comprehensive income	–	–	–	–	688 921	688 921
Exercise of stock options, net	9 953	9 953	455 287	–	–	465 240
Distribution of capital to shareholders	–	–	(47 955 180)	–	–	(47 955 180)
Stock-based compensation, net	–	–	1 673 761	–	–	1 673 761
<b>Balance at June 30, 2013</b>	<b>9 597 574</b>	<b>9 597 574</b>	<b>810 473 083</b>	<b>(761 278 525)</b>	<b>(15 702 401)</b>	<b>43 089 731</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, all amounts in CHF)****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 accounting principles generally accepted 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, 2012, as included in the Annual Report 2012, 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, which are of a normal recurring nature, to present fairly the consolidated balance sheets, statements of operations, statements of comprehensive income/loss, cash flows and changes in shareholders' equity for the interim periods presented.

**2 Significant accounting policies and new accounting pronouncements****Cash and cash equivalents**

The Company considers cash equivalents to be highly liquid investments which are readily convertible to cash with original maturities of not more than 3 months.

**Short-term investments**

Short-term investments include time deposits with banks with original maturities of more than 3 months and remaining maturities of up to 12 months. These investments are carried at cost which approximates fair value. Gains and losses resulting from such investments are included as a component of other financial income/expenses in the statement of operations.

**Revenue recognition**

The Company generally recognizes revenue, when it is realized or realizable and earned in accordance with Accounting Standard Codification ("ASC") 605 "Revenue Recognition". For agreements with multiple deliverables, the Company recognizes revenue separately for each deliverable in accordance with ASC 605. A deliverable is separable if it is deemed to have standalone value to the customer, delivery and performance is considered probable, within a company's

control and the best estimate of selling price is determined in a way that is consistent with the price at which the Company would sell the deliverable if the item were to be sold separately.

#### *Product sales*

The Company recognizes revenue from the sale of its products when the following conditions are met: delivery has occurred; the price is fixed or determinable; the collectability is reasonably assured and persuasive evidence of an arrangement exists. Product sales are recognized net of any sales and value added taxes and sales deductions. Allowances are recorded for estimated rebates, discounts, returns and charge backs. When the Company grants rights of return to its customers, revenue is recognized if all of the conditions of ASC 605 are met.

#### *Contract revenue*

Contract revenue includes realized amounts from upfront and milestone payments in connection with licensing and distribution agreements, royalties as well as income from reimbursement of costs related to the co-promotion activities of the Company. The costs related to the co-promotion activities are included in selling, general and administrative expenses. Contract revenue also includes payments received from a licensee for services provided by the Company in accordance with the respective license agreement. Furthermore, the Company recognizes contract revenue for sale of semi-finished products and clinical material to licensees.

For license agreements with multiple deliverables, the Company allocates the arrangement consideration, including upfront and milestone payments, to the separate deliverables based on the relative fair values of all deliverables under the agreements. The Company recognizes revenue for each separately identified deliverable, as the revenue recognition criteria for each deliverable are fulfilled.

The amount of upfront and milestone payments under a license agreement allocated to the grant of the license is recognized over the estimated remaining agreement period, depending on the terms of the agreement. Milestone payments under license agreements are recognized in its entirety as revenue when the respective milestone is achieved, if such milestone meets the following criteria: milestone is substantive; milestone is commensurate with the Company's performance to achieve the milestone; the milestone relates solely to past

performance; and the milestone amount is reasonable relative to all deliverables and payment terms in the arrangement. Milestone payments under license agreements, for which these criteria are not met, are recognized as revenue over the estimated remaining agreement period.

Upfront and milestone payments under distribution agreements, which are allocated to the grant of the distribution right, are generally recognized over the estimated remaining agreement period, depending on the terms of the agreement.

Revenue related to royalties received from licensees is recognized as earned; that is, when the royalties can be reasonably estimated based on the sales of the underlying products and when collectability is reasonably assured. The Company considers sales-based milestone payments under license and distribution agreements as contingent considerations, which are recognized based on achievement.

To the extent 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 from R&D services*

Revenue for research and development services provided by the Company is recorded as earned based on the performance requirements of the underlying contracts. The costs related to these services are primarily included in research and development expenses.

#### *Research and development expenses*

Research and development costs are expensed as incurred. Costs of research and development equipment with alternative future uses are capitalized and depreciated over its respective useful life.

Research and development expenses primarily include costs for third-party services in connection with clinical trials and research projects, costs for producing substance to be used in such trials and projects, personnel expenses for the Company's research and development groups and depreciation of equipment used for research and development activities. In addition, research and development expenses contain expenses for producing pharmaceutical material which may be used for commercialization, subject to regulatory approval, and

which was produced prior to obtaining regulatory approval or evidence being available that regulatory approval can reasonably be expected.

Payments that the Company makes or receives related to its co-development arrangement for isavuconazole, and the payments the Company makes or receives related to the contract with the Biomedical Advanced Research and Development Authority ("BARDA"), a division within the U.S. Department of Health and Human Services, for development of Basilea's antibiotic BAL30072, are recorded in research and development expenses.

#### Inventories

Costs related to the manufacturing of inventories are expensed as research and development expenses when incurred prior to obtaining regulatory approval or evidence being available that regulatory approval can reasonably be expected. If regulatory approval is subsequently obtained, the recorded expenses are not reversed.

Costs related to the manufacturing of inventories which occurred after the receipt of regulatory approval or evidence being available that regulatory approval can reasonably be expected, are capitalized. Inventories are valued at the lower of cost or market. Cost is determined based on the first-in first-out principle. If inventory costs exceed market, a provision is recorded. In addition, provisions are recorded due to obsolescence or lack of demand.

#### Income taxes

The Company applies the asset and liability method for the determination of provisions for income taxes. The income taxes for the reporting period consist of the current taxes (taxes paid and taxes payable) plus the change in the deferred taxes for the respective period. Deferred taxes represent the estimated future tax consequences of temporary differences between the amounts of assets and liabilities recognized for financial reporting purposes and such amounts recognized for tax purposes. Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized. Interest and penalties in connection with income taxes are recorded as income taxes.

#### Fair value measurements

The Company applies the ASC 820 "Fair Value Measurements and Disclosures". ASC 820 defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. Fair value is defined as the

price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

The book values of the short-term financial assets and liabilities, including cash and cash equivalents, short-term investments, accounts receivable, accrued interests, accounts payable and accruals and other current liabilities, approximate the fair values due to the short-term nature of these positions. The discounted cash flow method was applied to determine the fair values of the short-term investments.

#### New accounting pronouncements

As new accounting pronouncements are released, the Company reviews such pronouncements for the potential impact on the Company's financial statements. The new accounting pronouncement below may have an impact on the financial statements of the Company.

In February 2013, the Financial Accounting Standard Board ("FASB") issued Accounting Standards Update ("ASU") 2013-02, "Other Comprehensive Income (Topic 220: Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income)" to improve the transparency of reporting reclassifications out of accumulated other comprehensive income. The amendments require an entity to report the effect of significant reclassifications out of accumulated other comprehensive income on the respective line items in net income if the amount being reclassified is required under US GAAP to be reclassified in its entirety to net income. For other amounts that are not required under US GAAP to be reclassified in their entirety to net income in the same reporting period, an entity is required to cross-reference other disclosures required under US GAAP that provide additional detail about those amounts. The Company adopted this accounting standard as of January 1, 2013.

### 3 Agreements

#### Contract with BARDA for the development of the antibiotic BAL30072

The Company entered into a contract with the Biomedical Advanced Research and Development Authority ("BARDA") for the development of Basilea's antibiotic BAL30072 on June 24, 2013. Under this contract, BARDA will provide funding of up to USD 17 million over the initial agreement period of twenty-two months in the form of reimbursement of agreed development costs. The funding will be recognized in research & development expenses.

#### Global agreement with Stiefel related to Toctino®

In June 2012, the Company signed with Stiefel, a GSK company, a global agreement for Toctino® (alitretinoin), including a license to know-how and transfer of Toctino® assets and the business. The transaction was completed in July 2012. Under this agreement, Stiefel gained exclusive worldwide rights to Toctino®. The Company is eligible for additional payments related to a regulatory milestone of alitretinoin and participation in U.S. sales. Existing Toctino® distribution agreements were assigned to Stiefel.

The agreement consists of two significant deliverables: grant of the worldwide, exclusive, irrevocable, sub-licensable, paid-up license to the know-how and the transfer of the business.

Both, the grant of the license to know-how and the transfer of the business do not have stand-alone value as the license to know-how includes obligations to the Company, and therefore have to be considered together as a single unit of accounting.

The Company received a net non-refundable upfront payment of CHF 224.1 million (GBP 145.6 million). The upfront payment was deferred and is recognized on a straight-line basis as contract revenue over the estimated contractual term of the agreement.

For the six months ending June 2013, the Company recognized CHF 18.5 million as contract revenue related to this upfront payment. For the six months ending June 2012 no contract revenue related to this upfront payment was recognized.

For the six months ending June 2012, assets and liabilities were reassessed related to the signed agreement with Stiefel and recognition or release, accelerated amortization or depreciation as per June 30, 2012 was considered. Based on this reassessment, there was an accelerated recognition of CHF 5.4 million upfront and milestone payments from Toctino® distribution partners as contract revenue, CHF 4.2 million were recognized as cost of sales as a result of the depreciation of inventory and CHF 2.6 million were recognized as selling, general and administrative expenses (contract termination costs, legal costs, depreciation and amortization of tangible and intangible costs, and other costs). This reassessment of assets and liabilities was completed in the second six months of 2012.

#### License agreement with Astellas related to isavuconazole

In February 2010, the Company entered into a license, co-development and co-promotion agreement with Astellas Pharma Inc. ("Astellas") for isavuconazole.

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 regulatory filing, regulatory approval and commercialization of isavuconazole. In addition, the Company is also eligible for royalty payments.

The Company and Astellas jointly participate in the development of isavuconazole. Development costs for isavuconazole are shared between Astellas and the Company with Astellas bearing the majority of the costs. The Company is initially responsible to manage manufacturing while Astellas has the right to take over the management of manufacturing. Astellas bears manufacturing costs for commercial supply.

In 2010, the Company received a non-refundable net upfront payment of CHF 67.5 million (gross payment of CHF 75.0 million less withholding tax of CHF 7.5 million, which is non-refundable for the Company). This net upfront payment was recognized as deferred revenue. A portion of this upfront payment was allocated to the grant of the license to Astellas and the respective amount is accordingly recognized as revenue on a straight line basis over the remaining estimated term of the agreement. The remaining portion of the upfront payment represents compensation for the Company's co-payment of the development costs as well as other services which the Company provides in connection with the development of isavuconazole and accordingly, is recognized as co-development payments are made by the Company or the respective services are provided by the Company. The Company recognized CHF 1.0 million as contract revenue for the six months ending June 2013 (six months ending June 2012: CHF 5.5 million) related to this upfront payment. For the six months ending June 2013, the Company recognized additional contract revenue in the total amount of CHF 1.0 million (six months ending June 2012: CHF 1.2 million) related to the sale of semi-finished products and clinical material to Astellas and services provided by the Company for isavuconazole.

#### Distribution agreement with Almirall

In June 2010, the Company entered into an exclusive distribution agreement with Almirall, S.A. ("Almirall") for Basilea's Toctino® in Austria, Belgium, the Czech Republic, Italy, Luxembourg, Mexico, the Netherlands, Poland, Portugal, Slovakia

and Spain. The Company retained the future right to co-promote Tocrino® in selected markets covered under this agreement.

In July 2012, the agreement was assigned to Stiefel, a GSK company, for further details please refer to "Global agreement with Stiefel related to Tocrino®".

Under this distribution agreement, the Company was eligible for non-refundable upfront and milestone payments related to the launch of Tocrino® in the two key markets of the territory and the commercialization of Tocrino® in the territory. In addition, the Company sold Tocrino® to Almirall for the distribution in the respective countries in the territory, and recognized the related revenue in product sales.

In 2010, the Company received non-refundable upfront and milestone payments of CHF 14.3 million in connection with this distribution agreement, which were recorded as deferred revenue.

For the six months ending June 2013, no contract revenue related to this payment has been recognized due to the assignment of the agreement to Stiefel in July 2012. For the six months ending June 2012, the Company recognized CHF 5.9 million as contract revenue related to these payments.

#### 4 Short-term investments

The short-term investments as of June 30, 2013 and December 31, 2012 contain short-term time deposits with banks, all denominated in Swiss Francs, in the amount of CHF 120.0 million.

#### 5 Accounts receivable

The accounts receivable primarily consist of receivables related to co-development activities for isavuconazole. The Company did not record a valuation allowance as of June 30, 2013 and December 31, 2012 respectively.

#### 6 Inventories

The following table shows the components of inventories as of June 30, 2013 and December 31, 2012:

In CHF million	2013	2012
Semi-finished products	4.8	5.0
Finished products	0.0	0.1
Inventory provisions	(4.8)	(5.1)
<b>Total</b>	<b>0.0</b>	<b>0.0</b>

Due to the agreement with Stiefel, inventory was written-off. For further details please refer to footnote 3, agreements.

The Company incurred manufacturing costs in 2008 and 2007 related to pharmaceutical material, which was produced prior to obtaining regulatory approval for the respective product. As a consequence, an inventory provision for the full amount of such inventories was recognized and the related expenses were recorded as research and development expenses in the respective periods. The Company used such material for commercialization as regulatory approval was obtained in 2008.

#### 7 Accruals and other current liabilities

Accruals and other current liabilities as of June 30, 2013 and December 31, 2012 consisted of the following:

In CHF million	2013	2012
Accrued R&D expenses	3.1	3.1
Accrued personnel and compensation costs	6.8	8.7
Accrued sales and marketing costs	0.2	0.4
Other	4.8	5.9
<b>Total accruals and other current liabilities</b>	<b>14.9</b>	<b>18.1</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 necessary for the issuance of shares upon the exercise of stock options, of which CHF 2.7 million remain available as of June 30, 2013. CHF 1.9 million of this remaining available conditional capital are reserved for stock options, which were issued and outstanding as of June 30, 2013.

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

For the six months ending June 30, 2013, the Company recognized stock-based compensation expenses of CHF 1.7 million (six months ending June 30, 2012: CHF 1.8 million) related to this stock option plan.

## 9 Shareholders' equity

As of June 30, 2013, Basilea had 9,597,574 registered shares (*Namenaktien*) issued and outstanding with a par value of CHF 1 per share. As of December 31, 2012, Basilea had 9,587,621 registered shares (*Namenaktien*) issued and outstanding with a par value of CHF 1 per share.

For the six months ending June 30, 2013, 9,953 stock options were exercised, using conditional capital, which resulted in the issuance of 9,953 registered shares with a par value of CHF 1 per share. For the six months ending June 30, 2012, no stock options were exercised.

Basilea had a total approved conditional capital of CHF 3,302,567 as of June 30, 2013 for the issuance of a maximum of 3,302,567 registered shares with a nominal value of CHF 1 per share. This conditional capital contained CHF 2,662,567 (2,662,567 registered shares with a nominal 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 nominal value of CHF 1 each, available for the exercise of option or conversion rights granted with new option or convertible bonds.

Changes of the accumulated other comprehensive income/loss for the periods ending June 30, 2013 and 2012:

In CHF million	Currency translation adjustment	Unrecognized pension cost	Total
<b>December 31, 2011</b>	<b>(2.3)</b>	<b>(14.3)</b>	<b>(16.6)</b>
Change during the period	0.5	–	0.5
Reclassification adjustment, included in the condensed consolidated statements of operations	(0.1) <sup>1</sup>	0.4	0.3
<b>Total change during the period</b>	<b>0.4</b>	<b>0.4</b>	<b>0.8</b>
<b>June 30, 2012</b>	<b>(1.9)</b>	<b>(13.9)</b>	<b>(15.8)</b>
<b>December 31, 2012</b>	<b>(0.6)</b>	<b>(15.8)</b>	<b>(16.4)</b>
Change during the period	0.2	–	0.2
Reclassification adjustment, included in the condensed consolidated statements of operations	0.0 <sup>2</sup>	0.5	0.5
<b>Total change during the period</b>	<b>0.2</b>	<b>0.5</b>	<b>0.7</b>
<b>June 30, 2013</b>	<b>(0.4)</b>	<b>(15.3)</b>	<b>(15.7)</b>

<sup>1</sup> Currency translation adjustment related to the close-down of the Spanish organisation and the Italian subsidiary in liquidation.

<sup>2</sup> Currency translation adjustment related to the closed down organisations in Denmark, France, Germany and UK.

## 10 Loss per share

For the six months ending June 30, 2013 and 2012, 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 ending June 30, 2013 and 2012 were as follows:

	2013	2012
Net loss in CHF million	(17.3)	(34.6)
Weighted average number of shares outstanding, basic and diluted	9 591 072	9 587 571
Basic and diluted loss per share in CHF	(1.80)	(3.61)

For the six months ending June 30, 2013, 148,345 incremental shares relating to potential exercises of stock options (six months ending June 30, 2012: 71,208 incremental shares) were excluded, as the effect would have been anti-dilutive.

### 11 Pension plan

As of June 30, 2013 and December 31, 2012, the Company recorded an accrued pension liability of CHF 10.4 million in other non-current liabilities. The following table provides information on the pension expenses related to the Company's defined benefit pension plan for the six months ending June 30, 2013 and 2012:

In CHF million	2013	2012
Service cost	1.3	2.4
Interest cost	0.5	0.5
Expected return on plan assets	(0.6)	(0.7)
Amortization of pension related net loss	0.5	0.4
<b>Gross benefit expense</b>	<b>1.7</b>	<b>2.6</b>
Participant contributions	(0.6)	(0.6)
<b>Net periodic pension cost</b>	<b>1.1</b>	<b>2.0</b>

### 12 Segment information

The Company operates in one segment which is the discovery, development and commercialization of innovative pharmaceutical products. The Board of Directors and the CEO of the Company review the statement of operations of the Company on an aggregated basis and manage the operations of the Company as a single operating segment.

### 13 Concentration of risk

The Company is generally subject to credit risk related to financial investments. The Company mitigates such credit risk by investing the funds only with counterparties which are rated as high quality investment grade by a major rating agency or are fully guaranteed by Swiss cantons at the time of the company's investment. As of June 30, 2013 and December 31, 2012, the short-term investments were invested with two different banks and amounted to CHF 120.0 million.

The cash and cash equivalents as of June 30, 2013 amounted to CHF 142.7 million, of which CHF 130.4 million was held with four different banks. The cash and cash equivalents as of December 31, 2012 amounted to CHF 224.0 million, of which CHF 187.2 million was held with five different banks. As of June 30, 2013, the highest total amount of cash and cash equivalents and short-term investments held at one bank amounted to CHF 70.0 million. As of December 31, 2012, the highest total amount of cash and cash equivalents and short-term investments held at one bank amounted to CHF 110.0 million.

The Company is also subject to credit risk related to accounts receivable. The highest total amount of accounts receivable with an individual counterparty as of June 30, 2013 is from Astellas in the amount of CHF 4.5 million in connection with the license agreement related to isavuconazole (December 31, 2012: CHF 5.7 million).

### 14 Related party transactions

For the six months ending June 30, 2013 and June 30, 2012, the Company purchased services from Roche and Roche's subsidiaries in the amount of CHF 0.0 million.

The accounts receivable, accounts payable and accruals and other current liabilities do not include significant positions due to or from related parties as of June 30, 2013 and December 31, 2012.

For the six months ending June 30, 2013 the Company paid fees to one of its board members in the amount of CHF 0.0 million (six months ending June 30, 2012: CHF 0.1 million) for consulting services.

### 15 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. In the opinion of management, these commitments are not in excess of current market prices in all material respects, reflect normal business operations and will not have a material adverse effect on the Company's financial position, results of operations or cash flows.

Civil proceedings were initiated by Losan Pharma GmbH, Neuenburg/Germany against Basilea and Basilea Pharmaceutica International Ltd. in a claim related to use of know-how filed in 2012 in Basel-Stadt court (*Appellationsgericht Basel-Stadt*) to which Basilea has filed its response. The proceedings are at a preliminary stage and potential damages, if any, cannot be concretely estimated.

As of June 30, 2013, there were no significant contingencies.

#### 16 Subsequent events

The Company has evaluated subsequent events through August 19, 2013, the date on which the financial statements were available to be issued.

The Basilea Pharmaceutica Ltd. Half-year Report 2013 is published in English and German. In case of discrepancies the English version prevails.

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## CONTACT INFORMATION

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

### **BASILEA PHARMACEUTICA LTD.**

Grenzacherstrasse 487  
4058 Basel  
Switzerland

Phone +41 61 606 1111  
Fax +41 61 606 1112

### **INVESTOR & PUBLIC RELATIONS**

Barbara Zink, PhD, MBA  
Head of Corporate Development

Phone +41 61 606 1233  
Fax +41 61 606 1238  
E-mail [investor\\_relations@basilea.com](mailto:investor_relations@basilea.com)

