

**RONALD SCOTT** 

Chief Executive Officer

# "THE CHMP'S RECOMMENDATION TO APPROVE CRESEMBA IS A MAJOR STEP FORWARD IN MAKING ISAVUCONAZOLE AVAILABLE IN EUROPE FOR IMMUNOCOMPROMISED PATIENTS SUFFERING FROM SERIOUS INVASIVE FUNGAL INFECTIONS – SUCH AS CANCER PATIENTS."

**BASILEA IN BRIEF** 

#### **OUR COMPANY**

Basilea Pharmaceutica Ltd. is a biopharmaceutical company developing products that address the increasing resistance and non-response to current treatment options in the therapeutic areas of bacterial infections, fungal infections, and cancer. The company uses the integrated research, development, and commercial operations of its Swiss subsidiary Basilea Pharmaceutica International Ltd. to discover, develop and commercialize innovative pharmaceutical products to meet the medical needs of patients with serious and potentially lifethreatening conditions. Basilea Pharmaceutica Ltd. is headquartered in Basel, Switzerland and listed on the SIX Swiss Exchange (SIX: BSLN).

www.basilea.com

# PATIENTS

#### **KEY EVENTS**

#### **FINANCIALS**

- Half-year cash and short-term investments of CHF 218.4 million
- Financial guidance for the full year 2015: total operating expenses are estimated at CHF 9 million on average per month and operating loss at CHF 4 to 5 million on average per month

#### PROGRAM UPDATES

#### CRESEMBA® (ISAVUCONAZOLE)

- FDA granted regulatory approval for the treatment of invasive aspergillosis and invasive mucormycosis in adults in the United States, following a positive recommendation by the FDA's Anti-Infective Drugs Advisory Committee
- ► CRESEMBA® launched in the United States by Basilea's license partner Astellas Pharma Inc.
- Clinical data presented at European Congress of Clinical Microbiology and Infectious Diseases (ECCMID) demonstrate broad-spectrum activity and tolerability in invasive mold infections
- Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency recommended approval for the treatment of patients with invasive aspergillosis and mucormycosis
- ▶ Topline results reported from phase 3 ACTIVE study for the treatment of invasive yeast (Candida) infections; the study did not meet its primary endpoint but the secondary endpoint was comparable between the two study groups and data analysis is ongoing

#### ZEVTERA®/MABELIO® (CEFTOBIPROLE MEDOCARIL)

- Launched in Germany, France, Italy and the United Kingdom
- U.S. FDA granted Qualified Infectious Disease Product (QIDP) designation for the treatment of community-acquired bacterial pneumonia and acute bacterial skin and skin structure infections
- Data presented at ECCMID conference highlight the broad activity spectrum in the treatment of hospital-acquired respiratory tract infections

#### **BAL30072**

- Data presented at ECCMID conference demonstrated enhanced in-vitro and in-vivo activity of BAL30072/meropenem combination against clinically relevant Gram-negative pathogens
- Contract with U.S. Biomedical Advanced Research and Development Authority (BARDA) related to the development of BAL30072's intravenous dosage form will complete at the end of the initial period

#### **BAL3833 AND BAL101553**

- PanRAF kinase inhibitor BAL3833 advanced into phase 1 clinical development
- Phase 1 study initiated with oral dosage form of tumor checkpoint controller BAL101553 to investigate safety and tolerability in adult patients with advanced solid tumors

# ADDRESSING UNMET MEDICAL NEEDS

#### **ANTIBIOTICS**

"A continued rise in resistance by 2050 would lead to 10 million people dying every year and ... would cost the world up to 100 trillion USD."

Review on Antimicrobial Resistance. Antimicrobial Resistance: Tackling a Crisis for the Health and Wealth of Nations (Report commissioned by the UK Prime Minister). 2014

"People with MRSA (methicillin-resistant Staphylo-coccus aureus) are estimated to be 64% more likely to die than people with a non-resistant form of the infection. Resistance also increases the cost of health care with lengthier stays in hospital and more intensive care required."

WHO News release. WHO's first global report on antibiotic resistance reveals serious, worldwide threat to public health. 2014

#### **ANTIFUNGALS**

"Invasive fungal infections ... are associated with unacceptably high mortality rates. Many species of fungi are responsible for these invasive infections, which kill about one and a half million people every year."

G. D. Brown et al. Hidden Killers: Human Fungal Infection. Science Translational Medicine. 2012

"Invasive fungal infections have increased worldwide and represent a threat for immunocompromised patients including ... recipients of solid organ and stem cell transplants, and patients receiving immunosuppressive therapies. High mortality rates and difficulties in early diagnosis characterize pulmonary fungal infections."

M. Bassetti et al. Current and future therapies for invasive aspergillosis. Pulmonary Pharmacology & Therapeutics. 2015

#### **CANCER THERAPY**

44 Although chemotherapy of tumors has scored successes, drug resistance remains the major cause of death of cancer patients. Initial treatment often leaves residual disease, from which the tumor regrows. \*\*\*

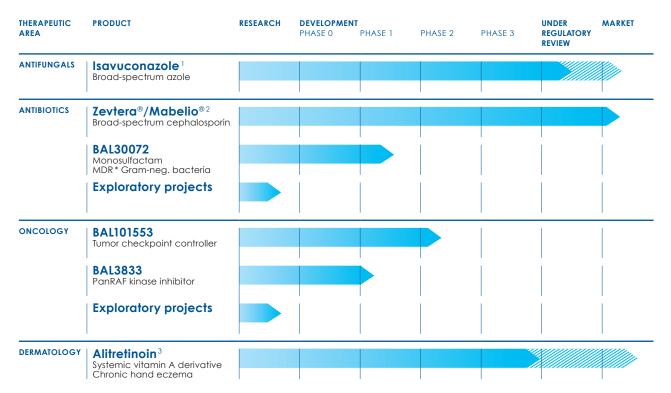
P. Borst. Cancer drug pan-resistance: pumps, cancer stem cells, quiescence, epithelial to mesenchymal transition, blocked cell death pathways, persisters or what? Open Biology. 2012

"Modern cancer treatments often suppress patients' immune systems, making them more susceptible to infections. Therefore without effective antibiotics to prevent or treat infection, chemotherapy would become a much riskier proposition."

Review on Antimicrobial Resistance. Antimicrobial Resistance: Tackling a Crisis for the Health and Wealth of Nations (Report commissioned by the UK Prime Minister). 2014

# **OUR PORTFOLIO**

- ▶ Isavuconazole recommended for regulatory approval in the European Union (EU); marketed in the United States as CRESEMBA® by Basilea's partner Astellas Pharma Inc. for the treatment of invasive aspergillosis and invasive mucormycosis
- ► Zevtera®/Mabelio® (ceftobiprole medocaril) currently launched in four European markets: Germany, France, Italy and the UK
- ▶ PanRAF kinase inhibitor BAL3833 in clinical phase 1 development
- Oral dosage form of tumor checkpoint controller BAL101553 investigated in phase 1 study;
   phase 2a study with intravenous dosage form ongoing



<sup>&</sup>lt;sup>1</sup> Partnered with Astellas Pharma Inc., Basilea has exclusive commercial rights outside the U.S. CRESEMBA® (isavuconazonium sulfate) is approved in the U.S. for adults in the treatment of invasive aspergillosis and invasive mucormycosis. Isavuconazole is not registered outside the United States; it is recommended for approval in the European Union.

<sup>&</sup>lt;sup>2</sup> Zevtera®/Mabelio® (ceftobiprole medocaril) has received national licenses in 13 European countries for the treatment of adult patients with community- and hospital-acquired pneumonia, excluding ventilator-associated pneumonia: in Austria, Belgium, Denmark, Finland, France, Germany, Italy, Luxembourg, Norway, Spain, Sweden, Switzerland and the UK. Ceftobiprole is not registered in the United States.

<sup>&</sup>lt;sup>3</sup> Participation with Stiefel/GSK; Basilea eligible for a milestone payment related to the launch of alitretinoin in the United States and participation in future U.S. product sales.

<sup>\*</sup> Multidrug-resistant



Monosulfactam antibiotic against MDR Gram-negative bacteria

PanRAF kinase inhibitor targeting tumor growth pathways

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### **OUR PRODUCTS**

#### **ANTI-INFECTIVES**

**ISAVUCONAZOLE** is an intravenous (i.v.) and oral broad-spectrum antifungal for the treatment of invasive fungal infections. Severe and life-threatening fungal infections are on the rise due to the increasing number of immunosuppressed patients such as cancer patients.

Isavuconazole was recommended for regulatory approval in the EU by the EMA's CHMP for the treatment of adult patients with invasive aspergillosis and those with mucormycosis for whom amphotericin B is inappropriate. A final decision from the European Commission is expected within the coming months. The drug is approved in the U.S. for adult patients with invasive aspergillosis and invasive mucormycosis and is marketed as CRESEMBA® by Basilea's partner Astellas.

Basilea reported topline data from the phase 3 ACTIVE study assessing i.v. and oral isavuconazole in the treatment of invasive Candida infections in adults versus i.v. caspofungin followed by oral voriconazole. The study did not meet the primary endpoint of demonstrating non-inferior efficacy of isavuconazole versus the comparator at the end of i.v. therapy. The key secondary endpoint, overall response at two weeks after treatment, was, however, comparable between the two treatment groups. In addition, all-cause mortality was comparable at study day 14 and 56 in both treatment groups. Additional data analyses will be performed to assess the potential role of isavuconazole in invasive Candida infections.

#### ZEVTERA®/MABELIO® (CEFTOBIPROLE MEDOCARIL)

is a broad-spectrum i.v. cephalosporin with bactericidal activity covering Gram-positive and Gramnegative pathogens such as MRSA (methicillinresistant *Staphylococcus aureus*) and susceptible *Pseudomonas* spp.

Zevtera® is licensed in thirteen European countries for the treatment of adults with community and hospital-acquired pneumonia (CAP, HAP) excluding ventilator-associated pneumonia. It is the first anti-MRSA cephalosporin antibiotic approved for both HAP and CAP. The product has been launched in Germany, France, Italy and the United Kingdom. A launch in Spain is planned by end-2015 or the beginning of 2016.

Basilea intends to expand the product's commercial availability through distribution and licensing partnerships in additional territories.

The U.S. FDA designated ceftobiprole as a Qualified Infectious Disease Product (QIDP) relating to the potential use of the drug in the treatment of community-acquired bacterial pneumonia and acute bacterial skin and skin structure infections.

## **OUR PRODUCTS**

**BAL30072** is a monosulfactam antibiotic with *in-vitro* and *in-vivo* activity against difficult-to-treat multidrug-resistant Gram-negative pathogens, such as Acinetobacter baumannii and Pseudomonas aeruginosa, as well as other, less common pathogens causing serious infections for which there are currently few or no treatments available.

The development funding contract with BARDA regarding the i.v. dosage form will complete at the end of the initial period. Transiently elevated liver enzyme levels were observed as dose-limiting factor during phase 1 development. Basilea is discussing further development options with potential partners and collaborators including additional antibiotic combinations and new dosage forms such as inhaled forms of BAL30072.

phase 1 for the oral dosage form in patients with recurrent solid cancers. Basilea is testing biomarkers to evaluate dosing and to identify the patient populations most likely to respond. Phase 2a data are expected in the second half of 2015.

BAL101553 is currently in phase 2a for the i.v. and in

**BAL3833** is an oral panRAF kinase inhibitor, targeting tumor growth and therapeutic resistance.

BAL3833 is the lead compound of a series of drug candidates in-licensed by Basilea that interfere with RAF kinase-related cell growth signaling pathways, which are involved in many resistant cancers. A phase 1 study was initiated, investigating the safety and tolerability of BAL3833 in adult patients with advanced solid tumors.

#### **ONCOLOGY**

Immunocompromised cancer patients are at high risk of contracting serious bacterial and fungal infections.

**BAL101553** is a small-molecule drug candidate for the potential treatment of cancers including resistant cancer types, with the potential for i.v. and oral administration. The agent acts as a tumor checkpoint controller, inducing tumor cell death when certain key steps in cell division are no more properly regulated.



# CONDENSED CONSOLIDATED INTERIM FINANCIAL STATEMENTS

BASILEA PHARMACEUTICA LTD. AND SUBSIDIARIES

Condensed consolidated balance sheets as of June 30, 2015 and December 31, 2014 (in CHF '000)

Footnote re	eference	Unaudited <b>2015</b>	2014
ASSETS			
Current assets			
Cash and cash equivalents		136 887	156 125
Short-term investments	6	81 561	70 000
Accounts receivable	7	2 745	1 171
Other receivables		3 673	7 041
Inventories	8	5 474	4 904
Other current assets		4 276	5 330
Total current assets		234 616	244 571
Non-current assets			
Tangible assets, net	3	11 166	12 158
Intangible assets, net	4	188	224
Other non-current assets		2 908	425
Total non-current assets		14 262	12 807
TOTAL ASSETS		248 878	257 378
LIABILITIES			
Current liabilities			
Accounts payable		1 303	2 113
Deferred revenue	5	49 479	43 405
Accruals and other current liabilities	9	13 761	16 173
Total current liabilities		64 543	61 691
Non-current liabilities			
Deferred revenue, less current portion	5	131 502	128 564
Other non-current liabilities	13	8 784	9 192
Total non-current liabilities		140 286	137 756
Total liabilities		204 829	199 447
Commitments and contingencies	16		
SHAREHOLDERS' EQUITY			
Share capital <sup>1</sup>	11	10 789	10 575
Additional paid-in capital		896 191	879 925
Accumulated other comprehensive income/loss	11	(14 256)	(14 010)
Accumulated deficit		(848 675)	(818 559)
Total shareholders' equity		44 049	57 931
TOTAL LIABILITIES AND EQUITY		248 878	257 378

<sup>&</sup>lt;sup>1</sup> As of June 30, 2015, 10,789,027 registered shares were issued and outstanding with a par value of CHF 1 per share. As of December 31, 2014, 10,575,288 registered shares were issued and outstanding with a par value of CHF 1 per share.

Condensed consolidated statements of operations for the six months ending June 30, 2015 and June 30, 2014 (unaudited, in CHF '000)

	Footnote reference	2015	2014
Contract revenue	5	24 412	20 214
Revenue from research & development services		373	22
Other revenue		203	17
Total revenue		24 988	20 253
Research & development expenses, net		(31 179)	(27 467)
Selling, general & administration expenses		(23 806)	(12 306)
Total operating expenses		(54 985)	(39 773)
Operating loss		(29 997)	(19 520)
Interest income		115	188
Other financial income		2 024	138
Other financial expenses		(2 192)	(187)
Loss before taxes		(30 050)	(19 381)
Income taxes		(66)	(49)
Net loss		(30 116)	(19 430)
Earnings/Loss per share	12	2015	2014
Basic and diluted loss per share, in CHF		(3.0)	(1.97)

# BASILEA PHARMACEUTICA LTD. AND SUBSIDIARIES

Condensed consolidated statements of comprehensive income/loss for the six months ending June 30, 2015 and June 30, 2014 (unaudited, in CHF '000)

	Footnote reference	2015	2014
Net loss		(30 116)	(19 430)
Currency translation adjustments		(667)	(24)
Amortization of unrecognized pension costs		421	267
Other comprehensive loss/income, net of tax	11	(246)	243
Comprehensive loss		(30 362)	(19 187)

Condensed consolidated statements of cash flows for the six months ending June 30, 2015 and June 30, 2014 (unaudited, in CHF '000)

Footnote reference	2015	2014
Cash flow from operating activities		
Net loss	(30 116)	(19 430)
Adjustments to reconcile net loss to net cash		
used for/provided by operating activities:		
Depreciation and amortization	1 308	1 261
Gain on disposal of assets, net	(9)	(4)
Stock-based compensation	3 948	2 913
Change in operating assets/liabilities:		
Accounts receivable	(1 584)	(1 638)
Other receivables	3 342	(2 635)
Inventories	(653)	(233)
Accounts payable	(807)	(391)
Deferred revenue	9 012	(19 416)
Accruals and other current liabilities	(2 393)	(6 753)
Other operating cash flow items	(1 376)	1 429
Net cash used for operating activities	(19 328)	(44 897)
Cash flow from investing activities		
Payments for short-term investments 6	(81 588)	(90 000)
Maturities of short-term investments 6	70 000	130 000
Investments in tangible assets, net of disposals	(283)	(562)
Investments in intangible assets, net of disposals	(86)	(33)
Net cash used for/provided by investing activities	(11 957)	39 405
Cash flow from financing activities		
Net proceeds from exercise of stock options	12 531	17 513
Net cash provided by financing activities	12 531	17 513
Effect of exchange rate changes on cash and cash equivalents	(484)	(31)
Net change in cash and cash equivalents	(19 238)	11 990
Cash and cash equivalents, beginning of period	156 125	118 897
Cash and cash equivalents, end of period	136 887	130 887

Condensed consolidated statements of changes in shareholders' equity for the six months ending June 30, 2015 and June 30, 2014 (unaudited, in CHF '000, except for number of shares)

			Additional	Accumulated other		
	Number of shares	Share capital	paid-in capital	comprehensive income/loss	Accumulated deficit	Total
Balance at December 31, 2013	10 200 233	10 200	849 519	(11 832)	(777 013)	70 874
Net loss	_	_	_	_	(19 430)	(19 430)
Other comprehensive income		_	_	243	-	243
Exercise of stock options, net	277 889	278	17 235	_	_	17 513
Stock-based compensation, net		_	2 913	_	_	2 913
Balance at June 30, 2014	10 478 122	10 478	869 667	(11 589)	(796 443)	72 113
Balance at December 31, 2014	10 575 288	10 575	879 925	(14 010)	(818 559)	57 931
Net loss	_	_	_	_	(30 116)	(30 116)
Other comprehensive loss		_	_	(246)	_	(246)
Exercise of stock options, net	213 739	214	12 317	-	_	12 531
Stock-based compensation, net		_	3 949	_	_	3 949
Balance at June 30, 2015	10 789 027	10 789	896 191	(14 256)	(848 675)	44 049

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 consolidated 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, 2014, as included in the Annual Report 2014, for further information. The financial statements are presented in Swiss Francs (CHF). As per June 30, 2015 and for the period then ended, the primary statements are disclosed in CHF '000. The comparative prior year figures are disclosed accordingly.

In the opinion of management, these condensed consolidated interim financial statements reflect all adjustments necessary, which are of a normal recurring nature, to fairly state 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**Fair value measurements

The Company applies the Accounting Standard Codification (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, other receivables, other current assets, accounts payable and accruals and other current liabilities, approximate the fair values due to the short-term nature of these positions.

#### 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 nominal value which approximates fair value classified based on the input as level two of the fair value hierarchy according to ASC 820. Level two uses observable inputs other than quoted prices in level one that are not observable for the asset or liability either directly or indirectly. These inputs may include quoted prices for the identical instrument on an inactive market, prices for similar instruments, interest rates, yield curves and similar data. Gains and losses resulting from such investments are included as a component of other financial income or other financial expenses in the statement of operations.

#### Accounts receivable and other receivables

Accounts receivable and other receivables are recorded at net realizable value after consideration of an allowance for doubtful accounts. The Company generally maintains allowances for estimated uncollectible receivables based on historical experience and specifically identified at-risk accounts. The adequacy of the allowance is evaluated on an ongoing and periodic basis and adjustments are made in the period in which a change in condition occurs. Other receivables mainly include various prepayments as well as unbilled revenue, which consists in revenue earned but not invoiced yet.

#### Revenue recognition

The Company recognizes revenue when it is realized or realizable and earned in accordance with 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.

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 or realizable amounts from upfront and milestone payments in connection with licensing and distribution agreements and royalties. Contract revenue also includes consideration received or receivable from a licensee for services provided by the Company in accordance with the respective license agreement.

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 value 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 to be considered substantive: the 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 recognized over the estimated remaining agreement period, depending on the terms of the agreement.

Revenue related to royalties received from licensees is recognized when earned, meaning 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 research & development 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 & 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 the equipment's useful life. No amount was capitalized in any period presented.

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 are recorded in research and development expenses, net and the mark-up in contract revenue respectively, since the company is acting as an agent in the arrangement.

Payments the Company makes or receives related to the contract with the Biomedical Advanced Research and Development Authority ("BARDA") for development of Basilea's antibiotic BAL30072 are both recorded in research and development expenses, net since the company is acting as an agent in the arrangement.

#### **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.

#### 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 May 2014, the Financial Accounting Standards Board (FASB) issued the Accounting Standards Update (ASU) 2014-09, "Revenue from Contracts with Customers" (Topic 606): the development of this new standard is a part of the joint project of the FASB and the International Accounting Standards Board (IASB) to clarify the principles for revenue recognition and to develop a common standard. The core principle of the guidance is that an entity should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. Thereby, this core principle is achieved by applying following five steps: identify the contract with a customer, identify the performance obligations in the contract, determine the transaction price, allocate the transaction price to the performance obligations in the contract, and recognize revenue when the Company satisfies each performance obligation.

The FASB voted on July 9, 2015 to approve a one-year deferral of the effective date of Accounting Standards Update No. 2014-09, "Revenue from Contracts

with Customers" to make it effective for public companies for annual periods beginning after December 15, 2018. The FASB expects to issue its final Accounting Standards Update formally amending the effective date by the end of the third quarter of 2015. The Company is currently assessing the impact on the financial statements of this new accounting pronouncement.

In August 2014, FASB issued the ASU 2014-15, "Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern" (Subtopic 205-40): under the new standard all entities will be required to perform a going concern assessment at each financial reporting period and make certain disclosures when management concludes that there is substantial doubt about an entity's ability to continue as a going concern. In this assessment, management would evaluate conditions and events known and reasonably knowable as of the financial statement issuance date to determine if it is probable that the entity will be unable to meet its obligations within one year from the date the financial statements are issued. Management's assessment would consider the mitigating effect of its plans to the extent that it is probable that those plans will be effectively implemented and alleviate the adverse conditions within the assessment period. If substantial doubt is alleviated primarily by management's plans, limited disclosures would still be required.

The new standard will be effective for annual periods beginning after December 15, 2016 and interim periods thereafter. Early adoption is permitted. The Company currently does not anticipate a significant impact on the existing disclosures.

In July 2015, the FASB issued the ASU 2015-11, "Inventory: Simplifying the Measurement of Inventory" (Topic 330): the amendments apply to the subsequent measurement all inventory, which includes inventory that is measured using the first-in first-out principle or average cost. An entity should subsequent measure inventory within the scope of this update at the lower of cost and net realizable value. The net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation.

The amendments in this update are effective for public companies for annual periods, including interim periods within those annual periods, beginning after December 15, 2016. The amendments in this update should be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The Company currently does not anticipate a significant impact on the existing accounting treatment for inventory.

#### 3 Tangible assets

In CHF million	Land/Land- use rights	Buildings	Equipment	Total
H1 2015	030 1191113	Dollali 193	Ефогритети	ioiai
Cost				
January 1, 2015	1.5	18.9	25.8	46.2
Additions	0.0	0.0	0.3	0.3
Disposals	0.0	0.0	(0.7)	(0.7)
Currency effect	(0.1)	(0.0)	(0.5)	(0.6)
June 30, 2015	1.4	18.9	24.9	45.2
Accumulated depreciation				
January 1, 2015	0.0	11.5	22.5	34.0
Additions	0.0	0.5	0.7	1.2
Disposals	0.0	0.0	(0.7)	(0.7)
Currency effect	0.0	(0.1)	(0.4)	(0.5)
June 30, 2015	0.0	11.9	22.1	34.0
Net book value as of June 30, 2015	1.4	7.0	2.8	11.2
H1 2014				
Cost				
January 1, 2014	1.4	18.6	25.5	45.5
Additions	0.0	0.0	0.6	0.6
Disposals	0.0	0.0	(1.0)	(1.0)
Currency effect	0.0	0.0	0.1	0.1
June 30, 2014	1.4	18.6	25.2	45.2
Accumulated depreciation				
January 1, 2014	0.0	10.4	22.1	32.5
Additions	0.0	0.5	0.7	1.2
Disposals	0.0	0.0	(1.0)	(1.0)
Currency effect	0.0	0.0	0.0	0.0
June 30, 2014	0.0	10.9	21.8	32.7
Net book value as of June 30, 2014	1.4	7.7	3.4	12.5

#### 4 Intangible assets

The intangible assets as of June 30, 2015 and 2014 consist of acquired software for internal use:

In CHF million	H1 2015	H1 2014
Cost		
January 1	4.5	4.5
Additions	0.1	0.0
Disposals	0.0	0.0
Currency effect	0.0	0.0
June 30	4.6	4.5
Accumulated amortization		
January 1	4.3	4.1
Additions	0.1	0.1
Disposals	0.0	0.0
Currency effect	0.0	0.0
June 30	4.4	4.2
Net book value as of June 30	0.2	0.3

#### 5 Agreements

#### 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 was eligible for a non-refundable upfront payment of CHF 75 million and non-refundable milestone payments of up to CHF 478 million based on the achievement of milestones related to regulatory filing, regulatory approval and commercialization of isavuconazole. In addition, the Company was also eligible for double digit-tiered royalty payments.

The agreement was amended as of February 27, 2014, providing the Company full rights to isavuconazole in all markets outside of the U.S. and Canada in return for foregoing the Company's right to co-promote the product in the U.S. and Canada, its right to receive payments related to co-promotion, and EU milestone payments.

Under the terms of the amended agreement, the Company continued to be entitled to receive milestone and royalty payments relating to the U.S. and Canadian

territories from Astellas. Basilea continued to be entitled to receive the same regulatory milestone and royalty payments in terms of value from Astellas relating to the U.S. and Canadian territories, with total milestone payments of up to CHF 374 million, including sales milestones.

Astellas will remain responsible for the continued development and funding of the isavuconazole global candidemia phase 3 study and will be responsible for the regulatory filings in the U.S. and Canada. The Company and Astellas will continue to coordinate their development and manufacturing activities and each company will be responsible for commercial activities in its respective territory. As such the agreement consists in a multiple-element arrangement with several deliverables identified, namely the grant of an exclusive license, compensation for co-payment of development services, development related manufacturing services and commercial related manufacturing services, and sale of clinical supplies, each of those deliverables being a single unit of accounting. The arrangement provides for a separate pricing for commercial related manufacturing services and sale of clinical supplies.

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). This net upfront payment was recognized as deferred revenue. The upfront payment covered the grant of an exclusive license, compensation for co-payment of development services and development related manufacturing services.

A portion of this upfront payment was allocated to the compensation for copayment of development services and development related manufacturing services for CHF 26.6 million and CHF 3.8 million respectively. The rest of the upfront payment (CHF 37.1 million) was allocated to the grant of the license to Astellas under the residual method. The revenue related to the compensation for co-payment of development services was recognized through 2012 as it related to past services already rendered with no remaining obligation from the Company, while the revenue related to development related manufacturing services was recognized over the period over which the services were rendered through 2011.

Lastly, the revenue related to the grant of an exclusive license is recognized as revenue on a straight line basis over the remaining estimated contribution term of the arrangement, expected to be October 2020. 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, was recognized as co-development payments were made by the Company or the respective services were provided by the Company. Based on the amended agreement in 2014, the Company reassessed the remaining contractual contribution term of the arrangement and reduced it from July 2029 to October 2020. As of June 30, 2015, the Company presented deferred revenue of CHF 24.2 million on its balance sheet, of which CHF 4.5 million is presented as current liabilities. For the six months ending June 30, 2015, the Company recognized CHF 2.3 million (six months ending June 30, 2014: CHF 1.0 million) as contract revenue related to this upfront payment related to the grant of license.

In September 2014, the U.S. Food and Drug Administration ("FDA") accepted the filing of Astellas' New Drug Application for isavuconazole, seeking approval of isavuconazole for the treatment of invasive aspergillosis and invasive mucormycosis in adults. Based on such acceptance, the Company received a non-refundable milestone payment of CHF 12.0 million from Astellas. The Company deemed the milestone not to be substantive and as such the milestone payment was deferred and is recognized on a straight line basis as contract revenue over the remaining contractual contribution term of the arrangement expected to be October 2020. As of June 30, 2015, the Company presented deferred revenue of CHF 10.4 million on its balance sheet, of which CHF 2.0 million is presented as current liabilities. For the six months ending June 30, 2015, the Company recognized CHF 1.0 million as contract revenue related to this additional milestone payment received upon acceptance of filing.

In March 2015, the FDA approved Astellas' New Drug Application for the use of isavuconazole for patients 18 years of age and older in the treatment of invasive aspergillosis and invasive mucormycosis. Based on the approval, the Company received a non-refundable milestone payment of CHF 30.0 million from Astellas. The Company deemed the milestone not to be substantive and as such the milestone payment was deferred and is recognized on a straight line basis as contract revenue over the remaining contractual contribution term of the arrangement expected to be October 2020. As of June 30, 2015, the Company presented deferred revenue of CHF 28.3 million on its balance sheet, of which CHF 5.3 million is presented as current liabilities. For the six months ending June 30, 2015, the Company recognized CHF 1.7 million as contract revenue related to this additional milestone payment received upon approval.

The Company recognized CHF 5.3 million as contract revenue for the six months ending June 30, 2015 (six months ending June 30, 2014: CHF 1.0 million) related

to these payments and revenues related to royalties, and recognized additional contract revenue in the total amount of CHF 0.3 million (six months ending June 30, 2014: CHF 0.7 million) related to services provided by the Company to Astellas for isayuconazole.

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

The Company entered into a contract with BARDA for the development of Basilea's antibiotic BAL30072 on June 24, 2013. Under this contract, BARDA provides funding of up to USD 17 million over the initial agreement period in the form of reimbursement of agreed development costs. Considering the agent vs. principal criteria of ASC 605, the fact that the arrangement is not part of the Company's on-going, major or central operations and the fact that BARDA is actively involved in the development, the Company determined that it is acting as an agent in the arrangement and as such records reimbursements received against the related development costs incurred.

For the six months ending June 30, 2015, the Company recognized reimbursement of CHF 3.6 million (six months ending June 30, 2014: CHF 3.3 million) in research and development expenses, net.

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

In June 2012, the Company signed with Stiefel a global agreement for Toctino<sup>®</sup> (alitretinoin), including a license to know-how and related transfer of Toctino<sup>®</sup> assets and business. Under this agreement, Stiefel gained exclusive worldwide rights to Toctino<sup>®</sup>. The Company is eligible to receive an initial non-refundable upfront payment of GBP 145.6 million and for an additional payment of GBP 30 million to 50 million related to a regulatory milestone of alitretinoin and double-digit participation in U.S. sales. Existing Toctino<sup>®</sup> 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 related transfer of the business.

Neither the grant of the license to know-how nor the transfer of the business have stand-alone value as both are required to operate the Toctino<sup>®</sup> business, and the license to know-how includes obligations of the Company related to the business over the term of the agreement, and therefore have to be considered together as a single unit of accounting.

In July 2012, 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 in August 2018. As of June 30, 2015, the Company presented deferred revenue of CHF 118.1 million on its balance sheet, of which CHF 37.7 million is presented as current liabilities.

For the six months ending June 30, 2015, the Company recognized CHF 18.8 million (six months ending June 30, 2014: CHF 18.5 million) as contract revenue related to this upfront payment.

#### License agreement for targeted cancer therapy

In March 2015, the Company entered into a license agreement for panRAF kinase inhibitors with a consortium of organizations including The Institute of Cancer Research, London, Cancer Research Technology, the Wellcome Trust and The University of Manchester. The agreement provides the Company exclusive worldwide rights to develop, manufacture and commercialize panRAF kinase inhibitors which originate from research at The Institute of Cancer Research by scientists funded by Cancer Research UK and the Wellcome Trust.

Under the terms of the agreement, the consortium will conduct clinical phase 1 development for the lead compound. The Company will assume full operational responsibility thereafter. The consortium receives an upfront payment and is eligible to potential milestone payments on achievement of pre-specified clinical, regulatory and commercial milestones, as well as tiered royalties on future net sales.

#### 6 Short-term investments

The short-term investments as of June 30, 2015 contain short-term time deposits with banks, denominated in Swiss Francs, in the amount of CHF 80.0 million and denominated in Euro, in the amount of EUR 1.5 million (December 31, 2014: CHF 70.0 million).

#### 7 Accounts receivable

The accounts receivable primarily consist of receivables related activities for isavuconazole for Astellas. The Company did not record an allowance for estimated uncollectible receivables as of June 30, 2015 and December 31, 2014.

#### 8 Inventories

The following table shows the components of inventories as of June 30, 2015 and December 31, 2014:

In CHF million	2015	2014
Raw materials	4.6	5.0
Semi-finished products	9.3	11.7
Finished products	0.7	0.0
Inventory provisions	(9.1)	(11.8)
Total	5.5	4.9

The Company owns manufacturing material valued at cost which was partly produced prior to obtaining regulatory approval for ceftobiprole. As ceftobiprole obtained regulatory approval in 2013, the ceftobiprole inventory is presented gross in the above inventory table. Inventory provisions reflect that material was produced prior to approval. The Company intends to use such material to manufacture products for commercialization.

#### 9 Accruals and other current liabilities

Accruals and other current liabilities as of June 30, 2015 and December 31, 2014 consisted of the following:

In CHF million	2015	2014
Accrued research & development expenses	3.2	5.1
Accrued personnel and compensation costs	7.5	7.7
Other	3.1	3.4
Total accruals and other current liabilities	13.8	16.2

#### 10 Stock-based compensation

The Company has established a stock option plan effective on December 13, 2000, to incentize directors, executives and certain 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 2.0 million remain available as of June 30, 2015. CHF 1.4 million of this remaining available conditional capital are reserved for stock options, which were issued and outstanding as of June 30, 2015.

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, 2015 the Company granted 195,566 stock options under its stock option plan with an exercise price of CHF 113.10 and a weighted average grant-date fair value of CHF 46.23 per stock option.

For the six months ending June 30, 2015, the Company recognized stock-based compensation expenses of CHF 3.9 million (six months ending June 30, 2014: CHF 2.9 million) related to this stock option plan.

#### 11 Shareholders' equity

As of June 30, 2015, Basilea had 10,789,027 registered shares (Namenaktien) issued and outstanding with a par value of CHF 1 per share. As of December 31, 2014, Basilea had 10,575,288 registered shares issued and outstanding with a par value of CHF 1 per share.

For the six months ending June 30, 2015, 213,739 stock options were exercised, using conditional capital, which resulted in the issuance of 213,739 registered shares with a par value of CHF 1 per share. For the six months ending June 30, 2014, 277,889 stock options were exercised.

Basilea had a total approved conditional capital of CHF 2,611,114 as of June 30, 2015 for the issuance of a maximum of 2,611,114 registered shares with a par value of CHF 1 per share. This conditional capital contained CHF 1,971,114 (1,971,114 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 certain 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 each, available for the exercise of option or conversion rights granted with new option or convertible bonds.

By shareholder approval at the 2014 ordinary general meeting of shareholders, Basilea is authorized to increase its share capital by a maximum of CHF 2,000,000 by issuing a maximum of 2,000,000 registered shares with a par value of CHF 1 per share. This authorization is valid for two years.

Changes in accumulated other comprehensive income/loss for the six months ending June 30, 2015 and 2014:

	Currency	Upropognizod	
In CHF million	translation adjustment	Unrecognized	Total
		pension cost	
December 31, 2013	(0.6)	(11.2)	(11.8)
Change during the period	(0.1)		(0.1)
Reclassification adjustment, included in the condensed consolidated statements of operations in Selling, general			
& administration expenses	0.01	0.3	0.3
Total change during the period	(0.1)	0.3	0.2
June 30, 2014	(0.7)	(10.9)	(11.6)
December 31, 2014	(0.2)	(13.8)	(14.0)
Change during the period	(0.7)		(0.7)
Reclassification adjustment, included in the condensed consolidated statements of operations in Selling, general			
& administration expenses		0.4	0.4
Total change during the period	(0.7)	0.4	(0.3)
June 30, 2015	(0.9)	(13.4)	(14.3)

<sup>&</sup>lt;sup>1</sup> Currency translation adjustment related to the dormant entities in Denmark, France, Germany and UK.

#### 12 Earnings/Loss per share

For the six months ending June 30, 2015 and 2014, 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, 2015 and 2014 were as follows:

	2015	2014
Net loss in CHF million	(30.1)	(19.4)
Weighted average number of shares outstanding, basic and diluted	10 050 298	9 882 921
Basic and diluted loss per share in CHF	(3.00)	(1.97)

For the six months ending June 30, 2015, 319,967 incremental shares relating to potential exercises of stock options (six months ending June 30, 2014: 586,362 incremental shares) were excluded, as the effect would have been anti-dilutive.

#### 13 Pension plan

As of June 30, 2015, the Company recorded an accrued pension liability of CHF 8.8 million in other non-current liabilities (December 31, 2014: CHF 9.2 million). 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, 2015 and 2014:

In CHF million	2015	2014
Service cost	1.1	1.1
Interest cost	0.5	0.6
Expected return on plan assets	(0.7)	(0.7)
Amortization of pension related net loss	0.4	0.3
Gross benefit expense	1.3	1.3
Darticio ant contributions	(0.7)	(0.5)
Participant contributions	(0.6)	(0.5)
Net periodic pension cost	0.7	0.8

#### 14 Segment information

The Company operates in one segment which is the discovery, development and commercialization of innovative pharmaceutical products. The CEO of the Company reviews the statement of operations of the Company on a consolidated basis and makes decisions and manages the operations of the Company as a single operating segment.

#### 15 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, 2015, the short-term investments were invested with three different banks and amounted to CHF 81.6 million. As of December 31, 2014, the short-term investments were invested with one bank and amounted to CHF 70.0 million.

The cash and cash equivalents as of June 30, 2015 amounted to CHF 136.9 million, of which CHF 133.0 million was held with four different banks. The cash and cash equivalents as of December 31, 2014 amounted to CHF 156.1 million, of which CHF 150.8 million was held with four different banks. As of June 30, 2015, the highest total amount of cash and cash equivalents and short-term investments held at one bank amounted to CHF 70.2 million. As of December 31, 2014, the highest total amount of cash and cash equivalents and short-term investments held at one bank amounted to CHF 80.1 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, 2015 is from Astellas in the amount of CHF 2.5 million in connection with the license agreement related to isavuconazole (December 31, 2014: CHF 1.0 million).

#### 16 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.

As of June 30, 2015, there were no significant contingencies.

#### 17 Subsequent events

The Company has evaluated subsequent events through August 12, 2015, the date on which the financial statements were available to be issued.

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