

Half-year Report 2009



Forward...



Basilea in Brief

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

Basilea's integrated research and development is focused on solving the severe medical challenge of drug resistance in the areas of antibiotics, antifungals and oncology and on the development of dermatology drugs.

Basilea has a diversified product portfolio including two commercialized drugs (Toctino[®], ZEFTERA[™]/Zevtera[™]), one investigational drug in clinical phase III (isavuconazole) as well as substantial innovative early-stage programs.

Toctino[®] (alitretinoin) is the only approved therapy for adults with severe chronic hand eczema (CHE) that is unresponsive to potent topical corticosteroids. It is approved in key European countries and already marketed in the UK, Denmark and Germany. Additional marketing applications have been filed.

ZEFTERA[™]/Zevtera[™] (ceftobiprole) is the first approved anti-MRSA broad-spectrum cephalosporin antibiotic for the treatment of complicated skin infections, including diabetic foot infections. This innovative first-line treatment may be used before knowing the bacteria causing the infection. It is marketed in Canada and Switzerland while marketing applications have been submitted in the U.S., the EU and several other countries. In addition, two pivotal phase III clinical studies have been completed for treatment of hospitalized patients with pneumonia. Both met their primary endpoints of demonstrating non-inferiority results as compared to combination treatment.

Isavuconazole is a novel broad-spectrum antifungal for the treatment of severe invasive fungal infections that has the potential to become the best-in-class azole. Isavuconazole is currently being tested in an international phase III program.

Basilea has set up commercial organizations in Germany, the UK, Denmark and Canada while it is building sales and marketing organizations in additional countries to commercialize alitretinoin and to co-promote ceftobiprole, subject to approval.

→ www.basilea.com

“The successful launch of Toctino in key European countries is the result of a great team effort. Going forward, we focus on expanding the availability of Toctino and on working towards ceftobiprole regulatory approval in key markets.”

Dr. Anthony Man, Chief Executive Officer

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Half-year Key Events

May 18, **BAL30072**

European Congress of Clinical Microbiology and Infectious Disease

New *in-vitro* efficacy data presented on BAL30072, a novel antibiotic against multi-resistant Gram-negative bacteria.

April 30, **Toctino® (alitretinoin)**

Preliminary NICE recommendations

Preliminary positive recommendations with some limitations on the use of Toctino® within its licensed indication developed by Appraisal Committee of the UK National Institute for Health and Clinical Excellence.

March 31, **Toctino® (alitretinoin)**

Expansion of potential European commercial availability

Marketing Authorization Application submitted for Toctino® in 13 additional European Union (EU) Member States as well as in Norway and Iceland.

March 26, **Toctino® (alitretinoin)**

Inclusion in new German dermatology treatment guidelines

Toctino® incorporated in the new treatment guidelines for the management of hand eczema from the German Society of Dermatology.

March 9, **Toctino® (alitretinoin)**

Acceptance for use by the Scottish Medicines Consortium

Toctino® accepted by Scottish Medicines Consortium (SMC) for use within the National Health Service for the treatment of adults with severe chronic hand eczema (CHE) unresponsive to potent topical corticosteroids. The SMC considered Toctino's® economic case demonstrated.

March to May, **Toctino® (alitretinoin)**

Series of European approvals

Marketing authorizations for Toctino® received in Austria, Belgium, Luxemburg, the Netherlands and Spain for the treatment of adults with severe CHE unresponsive to potent topical corticosteroids.

February 24, **ZEFTERA™/Zevtera™ (ceftobiprole)**

Arbitration claims filed against Johnson&Johnson over its handling of ceftobiprole clinical studies

Arbitration claims filed by Basilea against Johnson&Johnson and affiliated companies related to delays in approval of ceftobiprole.

February 24, **ZEFTERA™/Zevtera™ (ceftobiprole)**

Review process in EU delayed

EU Commission's decision process on ceftobiprole approval halted pending completion of Good Clinical Practice inspections.

Our Product Pipeline



Toctino® (alitreinoin)

The first and only approved treatment for use in adults with severe chronic hand eczema refractory to potent topical corticosteroids. A phase III clinical trial on alitreinoin for the treatment of severe chronic hand eczema is ongoing in the U.S.



ZEFTERA™/Zevtera™ (ceftobiprole)

The first approved anti-MRSA (methicillin-resistant *Staphylococcus aureus*) broad-spectrum cephalosporin antibiotic for the treatment of complicated skin, skin structure and soft tissue infections, including diabetic foot infections.

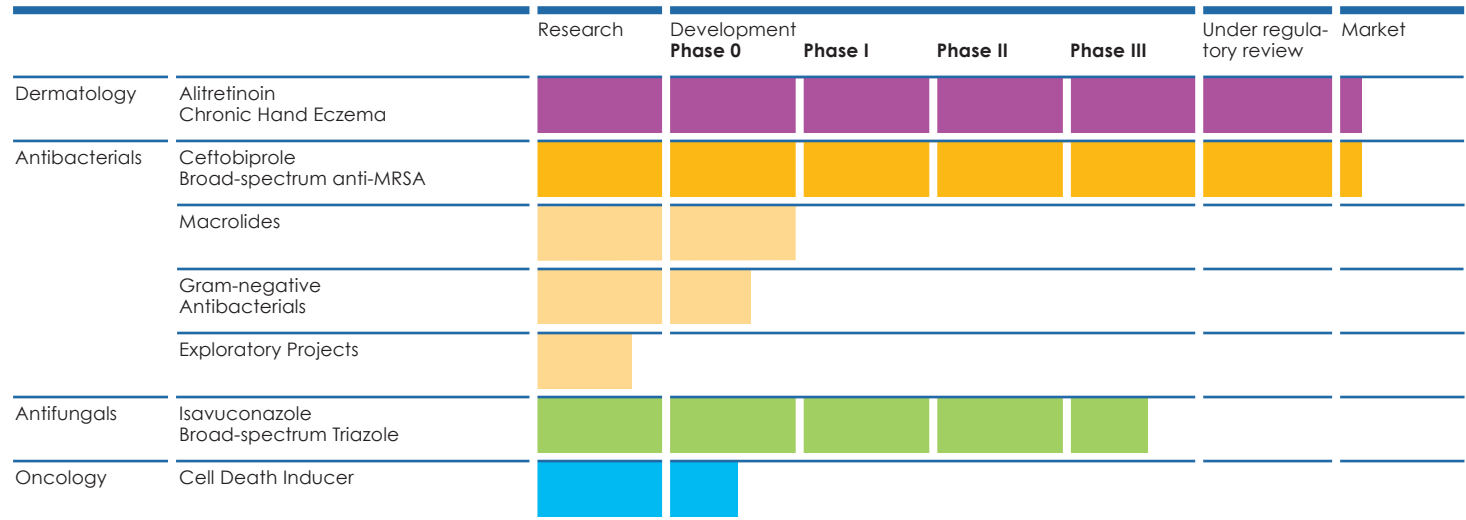


Isavuconazole (phase III)

A novel broad-spectrum antifungal azole with excellent *in-vitro* activity against yeast and mold infections. In contrast to currently marketed azole antifungals, isavuconazole shows reliable and consistent delivery of therapeutic drug levels through both intravenous and oral routes, an important consideration in life-threatening infections. In addition, isavuconazole has the potential to be used in renally impaired patients.

Balanced Late-stage Product Portfolio

With its diversified portfolio including two commercialized drugs (Toctino®, ZEFTERA™/Zevtera™), one investigational drug (isavuconazole) as well as substantial innovative early-stage programs, Basilea is well positioned to provide innovative medicines to patients with high medical needs.



Condensed Consolidated Interim Financial Statements

Basilea Pharmaceutica Ltd. and subsidiaries

Condensed Consolidated Balance Sheets
as of June 30, 2009 and December 31, 2008,
in CHF

	Footnote reference	Unaudited Jun 30, 2009	Dec 31, 2008
ASSETS			
Current assets			
Cash and cash equivalents		1 69 857 455	78 630 493
Short-term investments	4	55 000 000	215 000 000
Accounts receivable		2 060 507	2 257 810
Other receivables		2 332 283	5 872 216
Accrued interest		17 522	1 061 910
Inventories	5	114 008	53 480
Other current assets		2 996 909	1 805 892
Total current assets		232 378 684	304 681 801
Non-current assets			
Tangible assets, net		18 773 202	20 247 544
Intangible assets, net		2 415 345	2 774 828
Other non-current assets		381 187	422 323
Total non-current assets		21 569 734	23 444 695
TOTAL ASSETS		253 948 418	328 126 496
LIABILITIES			
Current liabilities			
Accounts payable		981 021	1 794 996
Deferred revenue	3	8 237 570	8 220 649
Accrued liabilities and other current liabilities	6	22 794 372	33 298 604
Total current liabilities		32 012 963	43 314 249
Non-current liabilities			
Deferred revenue, less current portion	3	78 145 345	82 222 495
Other non-current liabilities	10	2 356 506	2 846 999
Total non-current liabilities		80 501 851	85 069 494
Total liabilities		112 514 814	128 383 743
Commitments and contingencies	14		
SHAREHOLDERS' EQUITY			
Share capital ¹	8	9 579 904	9 571 403
Additional paid-in capital		828 437 518	820 214 323
Accumulated other comprehensive income/loss		(9 892 034)	(9 900 570)
Accumulated deficit		(686 691 784)	(620 142 403)
Total shareholders' equity		141 433 604	199 742 753
TOTAL LIABILITIES AND EQUITY		253 948 418	328 126 496

¹ As of June 30, 2009, 9,579,904 shares issued and outstanding with a par value of CHF 1 per share.

As of December 31, 2008, 9,571,403 shares issued and outstanding with a par value of CHF 1 per share.

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

Basilea Pharmaceutica Ltd. and subsidiaries

Condensed Consolidated Statements
of Operations for the six months ended
June 30, 2009 and 2008 (unaudited), in CHF

	Footnote reference	Jun 30, 2009	Jun 30, 2008
Product sales		7 394 116	–
Contract revenue	3	4 178 092	4 077 150
Revenue from R&D services		446 634	1 093 239
Other income		169 362	152 215
Total operating income		12 188 204	5 322 604
Cost of sales		(724 057)	–
Research & development expenses		(44 528 592)	(49 025 399)
Selling, general & administrative expenses		(34 823 360)	(29 382 683)
Total operating expenses		(80 076 009)	(78 408 082)
Operating loss		(67 887 805)	(73 085 478)
Interest income		885 936	5 094 809
Other financial income/expenses, net		452 488	78 053
Loss before taxes		(66 549 381)	(67 912 616)
Income taxes		–	–
Net loss		(66 549 381)	(67 912 616)
Loss per share		2009 6 months	2008 6 months
Basic and diluted loss per share, in CHF		(6.95)	(7.11)

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

Basilea Pharmaceutica Ltd. and subsidiaries

Condensed Consolidated Statements of
Cash Flows for the six months ended
June 30, 2009 and 2008 (unaudited), in CHF

	Jun 30, 2009	Jun 30, 2008
Net cash used for operating activities	(68 249 437)	(66 496 798)
Cash flow from investing activities		
Payments for financial investments	(55 000 000)	(265 000 000)
Maturities of financial investments	215 000 000	225 000 000
Investments in tangible assets, net of disposals	(103 078)	(1 689 992)
Investments in intangible assets, net of disposals	(920 140)	(574 895)
Net cash provided by/used for investing activities	158 976 782	(42 264 887)
Cash flow from financing activities		
Net proceeds from exercise of stock options	553 452	724 346
Repayments of capital lease liabilities	(3 229)	(3 485)
Net cash provided by financing activities	550 223	720 861
Effect of exchange rate changes on cash and cash equivalents	(50 606)	(67 360)
Net increase/decrease in cash and cash equivalents	91 226 962	(108 108 184)
Cash and cash equivalents, beginning of period	78 630 493	169 819 448
Cash and cash equivalents, end of period	169 857 455	61 711 264

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

Basilea Pharmaceutica Ltd.
and subsidiaries

Condensed Consolidated
Statement of changes in
Shareholders' Equity for the six
months ended June 30, 2009
and 2008 (unaudited), in CHF,
except for number of shares

	Number of shares	Share capital	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive income/loss	Total
Balance at December 31, 2007	9 543 678	9 543 678	802 509 264	(476 904 169)	(43 907)	335 104 866
Currency translation adjustment	-	-	-	-	186 642	186 642
Net loss	-	-	-	(67 912 616)	-	(67 912 616)
Comprehensive income/loss	-	-	-	(67 912 616)	186 642	(67 725 974)
Exercise of stock options, net	10 159	10 159	714 187	-	-	724 346
Stock-based compensation, net	-	-	7 721 607	-	-	7 721 607
Balance at June 30, 2008	9 553 837	9 553 837	810 945 058	(544 816 785)	142 735	275 824 845
Balance at December 31, 2008	9 571 403	9 571 403	820 214 323	(620 142 403)	(9 900 570)	199 742 753
Currency translation adjustment	-	-	-	-	(218 464)	(218 464)
Amortization of pension-related net gains/losses	-	-	-	-	227 000	227 000
Net loss	-	-	-	(66 549 381)	-	(66 549 381)
Comprehensive income/loss	-	-	-	(66 549 381)	8 536	(66 540 845)
Exercise of stock options, net	8 501	8 501	544 951	-	-	553 452
Stock-based compensation, net	-	-	7 678 244	-	-	7 678 244
Balance at June 30, 2009	9 579 904	9 579 904	828 437 518	(686 691 784)	(9 892 034)	141 433 604

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

1 Basis of Presentation

The condensed consolidated interim financial statements of Basilea Pharmaceutica Ltd. ("Basilea") and its subsidiaries (together the "Company") have been prepared in accordance with Generally Accepted Accounting Principles in the United States of America ("US GAAP") for interim financial information and accordingly do not include all information and disclosures as required by US GAAP for complete financial statements. The year-end condensed balance sheet data was derived from audited financial statements, but does not include all disclosures required by US GAAP. Please refer to the consolidated financial statements as of December 31, 2008, as included in the Annual Report 2008, for further information. The financial statements are presented in Swiss Francs (CHF).

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

2 Significant Accounting Policies and New Accounting Pronouncements

Revenue Recognition

The Company generally recognizes revenue if the criteria of Staff Accounting Bulletin ("SAB") No. 104 are met. For agreements with multiple deliverables, the Company recognizes revenue separately for each deliverable in accordance with Emerging Issues Task Force ("EITF") Issue No. 00-21.

Product Sales

The Company recognizes revenue from the sale of its products when realizable, which is 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 chargebacks. When the Company grants rights of return to its customers, revenue is recognized if all of the conditions of Statement of Financial Accounting Standards ("SFAS") No. 48 "Revenue recognition when right of return exists" are met.

Contract Revenue

Contract revenue includes realized amounts from upfront and milestone payments, royalties as well as the income from reimbursement of costs related to the co-promotion activities of the Company in connection with ZEFTERA™/Zevtera™. The costs related to the co-promotion activities are included in selling, general and administrative expenses.

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

Revenue related to royalties received from licensees is recognized on an accrual basis based on the sales of the underlying products. Royalties are recognized as earned when the royalties can be reasonably estimated and when collectability is reasonably assured.

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 & 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 net realizable value. Cost is determined based on the first-in first-out principle. If inventory costs exceed net realizable value a provision is recorded. In addition, provisions are recorded due to obsolescence or lack of demand.

New Accounting Pronouncements

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

In September 2006, the Financial Accounting Standards Board ("FASB") issued SFAS No. 157 related to fair value measurements. This statement defines fair value,

establishes a framework for measuring fair value and expands disclosures about fair value measurements. The Company adopted SFAS No. 157 as of January 1, 2008 with no significant impact on its financial position or results of operations. The effective date of SFAS No. 157 for nonfinancial assets and nonfinancial liabilities was deferred to the fiscal year 2009. The Company adopted SFAS No. 157 for nonfinancial assets and nonfinancial liabilities as of January 1, 2009. The adoption did not have a significant impact on the Company's financial position or results of operations.

In December 2007, the FASB ratified the consensus reached by the EITF on the EITF Issue No. 07-1 "Accounting for Collaborative Arrangements". EITF No. 07-1 prohibits the application of the equity method of accounting for collaborative arrangements unless a legal entity exists. In addition, EITF No. 07-1 states that payments between collaborative partners would be evaluated and reported in the income statement based on applicable accounting principles. The Company adopted this accounting treatment as of January 1, 2009, without significant impact on its financial position or results of operations.

In May 2009, the FASB issued SFAS No. 165 related to subsequent events. This statement is intended to establish general standards of accounting for and disclosure of events that occur after the balance sheet date but before financial statements are issued or are available to be issued. This statement is effective for interim and annual periods ending after June 15, 2009. The Company adopted SFAS No. 165 as of June 30, 2009.

3 Licensing Agreement

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

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

The Company recognized CHF 4.1 million as revenue in the first six months of 2009 related to these payments (CHF 4.1 million in the first six months of 2008). In the first six months of 2009, the Company recognized contract revenue related to the reimbursement of costs in connection with its co-promotion activities for ZEFTERA™/Zevtera™ in the amount of CHF 0.1 million. No corresponding revenue was realized in the first six months of 2008.

4 Short-Term Investments and Financial Instruments

The short-term investments as of June 30, 2009 contain short-term time deposits with banks, all denominated in Swiss Francs, in the amount of CHF 55.0 million (CHF 215.0 million as of December 31, 2008).

The book values of the short-term financial assets and liabilities, including cash and cash equivalents, short-term investments, accrued interest 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.

5 Inventories

The following table shows the components of inventories as of June 30, 2009 and December 31, 2008:

In CHF million	Jun 30, 2009	Dec 31, 2008
Semi-finished products	10.0	9.8
Finished products	0.3	0.1
Inventory provisions	(10.2)	(9.8)
Total	0.1	0.1

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 uses such material for commercialization as regulatory approval was obtained in 2008. The Company recognized CHF 0.3 million as research and development expenses in the first six months of 2008 related to manufacturing of such pharmaceutical material.

6 Accrued Liabilities and Other Current Liabilities

Accrued liabilities and other current liabilities as of June 30, 2009 and December 31, 2008 consisted of the following:

In CHF million	Jun 30, 2009	Dec 31, 2008
Accrued R&D expenses	11.8	19.7
Accrued personnel and compensation costs	7.2	8.3
Other	3.8	5.3
Total accruals and other current liabilities	22.8	33.3

7 Stock-Based Compensation

The Company has established a stock option plan effective on December 13, 2000, to provide incentives to directors, executives and employees with an opportunity to obtain stock options on registered shares of Basilea. The shareholders approved conditional capital necessary for the issuance of shares upon the exercise of stock options, of which CHF 2.2 million remains available as of June 30, 2009. CHF 1.7 million of this remaining available conditional capital is reserved for stock options, which are issued and outstanding as of June 30, 2009.

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

For the six months ended June 30, 2009 and 2008, the Company recognized compensation expenses of CHF 7.7 million, respectively, related to this stock option plan.

8 Shareholders' Equity

As of June 30, 2009, Basilea had 9,579,904 registered shares (Namenaktien) issued and outstanding with a par value of CHF 1 per share. As of December 31, 2008, Basilea had 9,571,403 registered shares with a par value of CHF 1 per share issued and outstanding.

In the six months ended June 30, 2009 and 2008, 8,501 and 10,159 stock options were exercised, respectively, using conditional capital, which resulted in the issuance of 8,501 and 10,159 registered shares with a par value of CHF 1 per share in the respective periods.

Basilea had a total approved conditional capital of CHF 2,820,237 as of June 30, 2009 for the issuance of a maximum of 2,820,237 registered shares with a nominal value

of CHF 1 per share. This conditional capital contained CHF 2,180,237 (2,180,237 registered shares with a par value of CHF 1 per share) reserved for the issuance of shares under the stock option plan available to directors, executives and employees. In addition, the shareholders approved conditional capital of CHF 640,000, consisting of 640,000 registered shares with a par value of CHF 1 per share, available for the exercise of option or conversion rights granted with new option or convertible bonds.

In addition, the Company is authorized, through April 2011, 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 nominal value of CHF 1 per share.

Furthermore, due to the liquidation of the two U.S. entities in the first six months of 2009, the related cumulative translation adjustment representing a gain of CHF 0.1 million was transferred from accumulated other comprehensive income/loss to the consolidated statement of operations.

9 Gain/Loss per Share

For the six months ended June 30, 2009 and 2008, there was no difference between basic and diluted loss per share. The weighted average number of shares outstanding and the loss per share for the six months ended June 30, 2009 and 2008 are as follows:

	2009	2008
Net loss in CHF million	(66.5)	(67.9)
Weighted average number of shares outstanding, basic and diluted	9 575 442	9 550 986
Basic and diluted loss per share in CHF	(6.95)	(7.11)

For the six months ended June 30, 2009, there are no incremental shares that would lead to a potential dilution according to the treasury stock method. For the corresponding period in 2008, 196,388 incremental shares relating to potential exercises of stock options were excluded, as the effect would have been anti-dilutive.

10 Pension Plan

The following table provides information on the pension expenses related to the Company's defined benefit pension plan for the six months periods ended June 30, 2009 and 2008:

In CHF million	Jan 1 to Jun 30, 2009	Jan 1 to Jun 30, 2008
Service cost	1.4	1.0
Interest cost	0.6	0.5
Expected return on plan assets	(0.8)	(0.7)
Amortization of unrecognized net loss	0.2	-
Gross benefit expense	1.4	0.8
Participant contributions	(0.5)	(0.4)
Net periodic pension cost	0.9	0.4

As of June 30, 2009, the Company recognized an accrued pension liability of CHF 2.4 million in other non-current liabilities (December 31, 2008: CHF 2.8 million).

11 Segment Information

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

12 Related Party Transactions

The Company entered into an agreement with F. Hoffmann-La Roche Ltd. ("Roche") related to the manufacturing of commercial material for one of the Company's compounds.

For the six months ended June 30, 2009, the Company purchased materials and services from Roche and Roche's subsidiaries, in the amount of CHF 0.1 million (six months ended June 30, 2008: 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, 2009 and December 31, 2008.

13 Restructuring

In the first half of 2009 the Company closed its U.S. organization and liquidated the U.S. subsidiaries as a result of the ZEFTERA™/Zevtera™ U.S. regulatory delay. For the six months ended June 30, 2009, the Company incurred CHF 0.9 million in restructuring costs, which are included in selling, general and administrative expenses. The restructuring costs contain CHF 0.7 million related to severance payments and CHF 0.2 million related to contract termination and other associated costs. As of June 30, 2009, there are no significant remaining liabilities related to this restructuring.

14 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 and 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, 2009, there are no significant contingencies.

15 Subsequent Events

The Company has evaluated subsequent events through August 14, 2009, the date on which the financial statements are issued.

Photography

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