

## INTERIM REPORT

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JANUARY - MARCH 2012

**FOCUSED ON DEVELOPING NOVEL THERAPIES THAT HAVE THE POTENTIAL TO SUBSTANTIALLY LENGTHEN AND IMPROVE THE LIVES OF CRITICALLY ILL PATIENTS IN AREAS OF MAJOR UNMET MEDICAL NEED.**

## CLINICAL DEVELOPMENT PIPELINE

DRUG & INDICATION	STATUS	CLINICAL PHASE		
		I	II	III
<b>ORAL TALACTOFERRIN</b>				
3 <sup>rd</sup> -line+ NSCLC	Phase III (FORTIS-M) trial enrollment completed			
1 <sup>st</sup> -line NSCLC	Phase III (FORTIS-C) trial ongoing at limited U.S. sites			
Severe sepsis	Phase II trial completed. Phase II/III (OASIS) trial halted; continued development under evaluation			
<b>OTHER PROGRAMS</b>				
Topical talactoferrin Diabetic foot ulcers	Phase IIa trial completed. Future focus on partnering			
RGB-286638 multi-targeted kinase inhibitor Oncology	Phase I solid tumors trial completed			

## AGENNIX: HIGHLIGHTS

-  In late-stage development with novel oral immunotherapy that appeared to improve survival in non-small cell lung cancer (NSCLC) patients without many of common toxicities seen with other cancer therapies.
-  NSCLC is an area of major unmet medical need and large market potential.
-  Top-line data from the FORTIS-M Phase III trial in NSCLC patients whose disease has progressed following two or more prior therapies are expected in July/August 2012.
-  Sufficient cash to fund operations through top-line data and into Q1 2013.



**Agennix AG**  
**Interim Report**  
**January - March 2012**

**CONTENTS**

**Interim management report**

**Unaudited interim condensed consolidated financial statements**

## **Interim Management Report**

Agennix AG (“Agennix” or “the Company”) is a publicly traded company organized under the laws of the Federal Republic of Germany. Agennix AG’s registered seat is in Heidelberg, Germany. The Company has three sites of operation: Planegg/Munich, Germany; Princeton, New Jersey, USA and Houston, Texas, USA.

The Company is focused on the development of novel therapies that have the potential to substantially lengthen and improve the lives of critically ill patients in areas of major unmet medical need.

## **Business Performance**

### **Year-to-date performance**

The Company did not recognize any revenue during the three months ended March 31, 2012 and 2011.

Research and development (“R&D”) expenses for the three months ended March 31, 2012 increased 16% to €9.5 million compared to € 8.2 million for the same period in 2011. The increase in R&D expenses is primarily due to costs associated with the Phase II/III OASIS trial with talactoferrin in severe sepsis, which was initiated at the end of the second quarter of 2011 and stopped in the first quarter of 2012.

Administrative expenses for the three months ended March 31, 2012 increased 26% to € 2.9 million compared to €2.3 million for the same period in 2011. Administrative expenses were higher as the Company has engaged in certain critical pre-commercialization activities related to a potential regulatory filing and commercial launch of talactoferrin.

Net loss before tax for the three months ended March 31, 2012 increased 10% to € 12.7 million compared to €11.5 million for the same period in 2011. Income tax benefit for the three months ended March 31, 2012 was € 0 compared to € 2.9 million for the same period in 2011. Income tax benefit relates to the recognition of deferred tax asset on net operating losses incurred by the Company’s subsidiary, Agennix Incorporated, during the period. In the first quarter of 2012, the Company did not recognize any income tax benefit because as of March 31, 2012, it was not probable that future taxable profits or sufficient taxable temporary differences would be available against which the accumulated tax losses could be utilized before they expire. Net loss for the three months ended March 31, 2012, increased 48% to €12.7 million compared to € 8.6 million for the same period in 2011. This increase was primarily due to the recognition of the deferred tax asset during the first quarter of 2011 which did not occur in the current period. Basic and diluted loss per share was € (0.25) for the three months ended March 31, 2012, compared to € (0.21) for the same period in 2011.

## **Going concern**

During the three month period ended March 31, 2012, the Company incurred a net loss of € 12.7 million and used cash in its operations of € 10.7 million. At March 31, 2012, the Company had cash, cash equivalents, other current financial assets and restricted cash of € 32.8 million and current liabilities of € 6.3 million. The Company has incurred recurring operating losses and has generated negative cash flows from operations since its inception and expects such results to continue for the foreseeable future.

Based on the current financial position of the Company, management believes that Agennix will have sufficient cash to fund its operations into the first quarter of 2013. This should enable the Company to obtain top-line data from the FORTIS-M Phase III trial assuming no significant changes to currently projected timelines. The Company will need to raise additional funds through licensing agreements and/or through strategic and/or public equity or debt investments to fund operations beyond that point and to continue as a going concern.

If Agennix were to experience significant delays in obtaining top-line data from the FORTIS-M trial, the Company's ability to continue as a going concern could be at risk if it were unable to secure interim funding to get to that important event. If the FORTIS-M trial were to have negative results, the Company's ability to continue as a going concern would be at immediate risk, as the Company's ability to obtain additional funding would be limited. In this situation, the Company would quickly reduce costs through restructuring activities in order to preserve cash. Furthermore, the Company would evaluate other business opportunities, including mergers and acquisitions and/or partnering and/or advancing other internal development programs.

Agennix cannot accurately predict when or whether it will successfully complete the development of its product candidates or obtain additional funding.

As of March 31, 2012, cash, cash equivalents, other current financial assets and restricted cash totaled € 32.8 million (December 31, 2011: € 44.0 million). Net cash burn for the three months ended March 31, 2012 was € 10.8 million (for the three months ended March 31, 2011: € 11.5 million). Net cash burn is derived by adding net cash used in operating activities and purchases of property, equipment and intangible assets. The figures used to calculate net cash burn are contained in the Company's interim consolidated cash flow statement for the respective periods.

## **Research and Development**

Agennix is focused on the development of novel therapies that have the potential to substantially lengthen and improve the lives of critically ill patients in areas of major unmet medical need. The Company's most advanced investigational agent, and the main focus of its R&D efforts, is the oral Dendritic Cell Mediated Immunotherapy ("DCMI"), talactoferrin. Talactoferrin is currently being studied for the treatment of non-small cell lung cancer ("NSCLC").

Two Phase III trials with oral talactoferrin in NSCLC are currently ongoing. Enrollment in the Phase III FORTIS-M trial was completed in March 2011. The Company reported that the pre-specified number of events required for conducting the primary analysis of overall survival in the trial has been reached and confirmed its guidance that the Company expects to report top-line data from the trial in July/August 2012. The FORTIS-M trial is a randomized, double-blind, placebo-controlled study evaluating talactoferrin plus best supportive care compared to placebo plus best supportive care in patients with NSCLC whose disease has progressed following two or more prior treatment regimens. The FORTIS-M trial design is based on a randomized, double-blind, placebo-controlled Phase II study in NSCLC patients whose disease progressed following one or more prior treatment regimens. In that Phase II study, talactoferrin appeared to improve survival without many of the common toxicities seen with other cancer therapies.

Agennix is conducting a second Phase III trial in NSCLC called FORTIS-C. The FORTIS-C trial is a randomized, double-blind, placebo-controlled study evaluating oral talactoferrin plus a standard chemotherapy regimen, carboplatin and paclitaxel, versus placebo plus carboplatin and paclitaxel in first-line NSCLC patients (patients who have not yet received chemotherapy to treat their cancer). Enrollment is currently ongoing at a limited number of sites in the U.S. The FORTIS-C trial design is based on the results of a randomized, double-blind, placebo-controlled Phase II trial in first-line NSCLC in which talactoferrin showed preliminary activity and again did not have many of the common toxicities seen with other cancer therapies.

The Company initiated the Phase II/III OASIS trial with talactoferrin in severe sepsis in June 2011 following compelling results from an earlier Phase II study in this condition. However, in February 2012, Agennix announced that, upon the recommendation of the study Data Safety Monitoring Board (“DSMB”) the Company had stopped further enrollment and treatment in the trial. The DSMB made this recommendation based on a review of the available data from the trial, which indicated that 28-day mortality, the primary endpoint of the study, in the talactoferrin arm of the study was greater than in the placebo arm. Agennix subsequently unblinded the data from the trial and reported that its review of the available results confirmed the finding of the DSMB. The Company reported that 28-day all-cause mortality was 25% in the talactoferrin arm compared to 18% in the placebo arm, which was an unexpectedly low mortality rate for placebo compared to other recent late-stage clinical trials in severe sepsis. The difference between the two groups in the OASIS trial was not statistically significant. Further analyses have indicated that the key predictors of mortality in the study were age, site of infection, number of organ dysfunctions and how sick the patients were before enrolling in the study (as measured by APACHE II score and Charlson co-morbidity score). Imbalances between the arms in favor of the placebo group in some of these factors could have contributed to the outcome. Neither treatment with talactoferrin versus placebo nor gender was a predictor of mortality in the study. The results are based on 305 patients enrolled in the study, with 153 in the talactoferrin group and 152 in the placebo group. These results are still preliminary and subject to change. Further analyses are ongoing, including evaluating mortality over a longer time period. Once the review is completed and Agennix has held further discussions with the critical care community and consultants, the Company will make a

decision on whether further development of talactoferrin in severe sepsis is warranted. Until that time, Agennix does not intend to invest further in the development of talactoferrin in severe sepsis.

The Company has discussed the results of the OASIS trial with the DSMB of the FORTIS trials. The FORTIS DSMB has agreed with Agennix's assessment that, based on the available data from the OASIS trial, no changes to the conduct of the ongoing FORTIS-M trial are necessary and the FORTIS-M trial can continue as planned.

In addition to oral talactoferrin, the Company has a topical gel formulation of talactoferrin. A clinical trial with this formulation has been completed in patients with diabetic foot ulcers. The Company plans to partner this program, although it may conduct additional clinical work in this indication in the future to maximize the partnering opportunity and potential for success.

The Company also owns rights to RGB-286638, a multi-targeted kinase inhibitor. A Phase I trial in advanced solid tumors has completed, and preliminary results from the study have been presented. At this time, Agennix is not initiating further clinical testing with this compound. However, the Company may develop RGB-286638 for hematological (blood) tumors when additional financial resources are available and once data from the FORTIS-M Phase III trial with oral talactoferrin are known.

## **Agennix AG Management and Supervisory Boards**

### **Management Board**

The Company is being led by a two-person Management Board comprised of Dr. Torsten Hombeck, Spokesperson of the Management Board and Chief Financial Officer, and Dr. Rajesh Malik, Chief Medical Officer.

### **Supervisory Board**

As of March 31, 2012, the Supervisory Board of Agennix AG had six members: Christof Hettich, L.L.D. (Chairman); Frank Young, M.D., Ph.D. (Vice Chairman); Friedrich von Bohlen und Halbach, Ph.D.; Alan Feinsilver; Bernd Seizinger, M.D., Ph.D. and James Weaver III.

The shareholdings of the members of the Management Board and Supervisory Board as of March 31, 2012, as well as significant transactions with related parties for the period, are presented in Note 3 to the accompanying interim condensed consolidated financial statements.

### **Litigation**

The Company's activities, especially in the area of drug development, expose it to many risks that are inherent to the industry and stage of the Company's programs and operations. The Company's business

opportunities and risk management help the Company to identify such risks in advance, analyze them, and plan for the Company's success. The Company is currently not party to any material litigation. Information on the Company's opportunities and risk management system, and the risk position of the Company, can be found in the Annual Report of Agennix AG for the year ended December 31, 2011 ("2011 Annual Report"). Also, refer to Note 1 to the accompanying interim condensed consolidated financial statements.

## **Outlook**

This section contains forward-looking statements, which express the current beliefs and expectations of the management of Agennix AG, including statements about the Company's future cash position and the timing of clinical trial results. Such statements are based on current expectations and are subject to risks and uncertainties, many of which are beyond the Company's control, which could cause future results, performance or achievements to differ significantly from those expressed or implied by such forward-looking statements. Actual results could differ materially depending on a number of factors, and investors should not place undue reliance on the forward-looking statements contained herein. There can be no guarantee that the Company will have sufficient cash to fund operations into the first quarter of 2013. The achievement of positive results in early stage clinical studies does not ensure that later stage or large scale clinical studies will be successful. Even if the results from later stage trials with talactoferrin, including the ongoing FORTIS-M trial in NSCLC, are considered positive, there can be no guarantee that they will be sufficient to gain marketing approval in the United States or any other country, and regulatory authorities may require additional information, data and/or further pre-clinical or clinical studies to support approval. In such event, there can be no guarantee that the Company will have or be able to obtain the financial resources to conduct any such additional studies or that such studies will yield results sufficient for approval. Even if the results from the FORTIS-M trial are considered positive, there can be no guarantee that the Company will be able to partner talactoferrin or obtain additional financial resources. Forward-looking statements speak only as of the date on which they are made and Agennix undertakes no obligation to update these forward-looking statements, even if new information becomes available in the future.

## **Financials**

The Company's financial outlook for 2012 and 2013 is highly dependent on the outcome of the FORTIS-M Phase III trial in NSCLC, which is expected to read out in July/August 2012. The Company provided the following financial guidance:

### ***Revenues***

Management expects no substantial cash generating revenues for 2012 or 2013. This guidance does not consider cash revenue from the potential partnering of the Company's product candidates due to the uncertainty of the timing of such events. However, if the FORTIS-M trial is positive, Agennix expects to generate revenue from one or more collaboration and license agreements for talactoferrin during this time period.



***R&D expenses***

The Company expects R&D expenses for the first half of 2012 to be reasonably in line with the first half of 2011. For the second half of 2012 and for 2013, the amount of R&D expenses is dependent on the outcome of the FORTIS-M trial. Should the FORTIS-M trial be positive, the Company expects to incur additional costs related to regulatory filings and increased manufacturing costs in preparation for a potential market launch. In addition, in such a positive scenario, Agennix is likely to expand its clinical development activities.

***Administrative expenses***

Administrative expenses in 2012 and 2013 are expected to increase compared to 2011 as the Company expects to continue to moderately ramp up certain critical pre-commercialization activities for a potential market launch of talactoferrin. Should the FORTIS-M trial be positive, these activities and related expenses would increase significantly, potentially including costs related to beginning to build a commercial infrastructure in the U.S.

***Cash position***

Management believes that Agennix will have sufficient cash to fund its operations into the first quarter of 2013. This should enable the Company to obtain top-line data from the FORTIS-M trial, expected in July/August of 2012, assuming no significant changes to currently projected timelines, and to advance potential partnering discussions. The Company will need to raise additional funds through licensing agreements and/or through strategic and/or public equity or debt investments to fund the Company's operations beyond this point.

***Key activities***

The Company will continue to focus on advancing its lead product candidate, oral talactoferrin. Top-line data from the FORTIS-M trial are expected in July/August of 2012. If the FORTIS-M trial is positive, Agennix plans to submit a Biologics License Application ("BLA") to the U.S. FDA, and a Marketing Authorization Application ("MAA") to the European Medicines Agency ("EMA"), requesting marketing approval of talactoferrin.

The Company also will continue critical production and pre-commercialization activities in anticipation of potential regulatory submissions and a future commercial launch of talactoferrin. Should the data from the FORTIS-M trial be positive, Agennix anticipates entering into one or more partnerships with large biotechnology or pharmaceutical firms for the further development and commercialization of talactoferrin. The Company may retain some or all of the North American rights to this program.

**Agennix AG**  
**Interim consolidated statement of operations**

		<b>Three months ended March 31,</b>	
		<b>2012</b>	<b>2011</b>
	<b>Note</b>	<b>(unaudited)</b>	<b>(unaudited)</b>
		<b>€000</b>	<b>€000</b>
<b>Revenue</b>		-	-
Research and development expenses	3	(9,480)	(8,238)
Administrative expenses	3	(2,944)	(2,293)
Amortization of intangible assets		(2)	(1)
Other expenses	3	(340)	(820)
Finance income		37	78
Finance costs		(2)	(225)
		<hr/>	<hr/>
<b>Net loss before tax</b>		<b>(12,731)</b>	<b>(11,499)</b>
Income tax benefit	3	-	2,905
		<hr/>	<hr/>
<b>Net loss for the period</b>		<b>(12,731)</b>	<b>(8,594)</b>
		<hr/> <hr/>	<hr/> <hr/>
Basic and diluted loss per share, euro		(€0.25)	(€0.21)
Average number of shares used in computing basic and diluted loss per share		51,270,258	41,898,695

*See accompanying Notes to unaudited interim condensed consolidated financial statements*

**Agennix AG****Interim consolidated statement of comprehensive income (loss)**

	<b>Three months ended March 31,</b>	
	<b>2012</b>	<b>2011</b>
	<b>(unaudited)</b>	<b>(unaudited)</b>
	<b>€000</b>	<b>€000</b>
<b>Net loss</b>	<b>(12,731)</b>	<b>(8,594)</b>
<b>Other comprehensive (loss) income:</b>		
Exchange differences on translating foreign operations (Note 3)	<u>(2,763)</u>	<u>(6,256)</u>
	<b>(2,763)</b>	<b>(6,256)</b>
<b>Total comprehensive loss</b>	<u><b>(15,494)</b></u>	<u><b>(14,850)</b></u>

*See accompanying Notes to unaudited interim condensed consolidated financial statements*

**Agennix AG**  
**Interim consolidated statement of financial position**

		March 31, 2012 (unaudited)	December 31, 2011
	Note	€000	€000
<b>ASSETS</b>			
<b>Non-current assets</b>			
Property and equipment		3,539	3,678
Intangible assets	3	98,992	101,962
Other non-current assets		494	545
<b>Total non-current assets</b>		<b>103,025</b>	<b>106,185</b>
<b>Current assets</b>			
Prepayments		398	430
Other current assets		2,482	5,376
Other current financial assets		11,715	20,024
Cash and cash equivalents		21,027	23,912
<b>Total current assets</b>		<b>35,622</b>	<b>49,742</b>
<b>TOTAL ASSETS</b>		<b>138,647</b>	<b>155,927</b>
<b>EQUITY AND LIABILITIES</b>			
<b>Equity attributable to the Company's equity holders</b>			
Issued capital		51,270	51,270
Share premium		169,340	169,199
Other reserves		2,097	4,860
Retained loss		(97,380)	(84,649)
<b>Total equity</b>		<b>125,327</b>	<b>140,680</b>
<b>Non-current liabilities</b>			
Convertible bonds		178	178
Other non-current liabilities		58	-
Deferred tax liability	3	6,748	6,950
<b>Total non-current liabilities</b>		<b>6,984</b>	<b>7,128</b>
<b>Current liabilities</b>			
Trade payables		1,553	3,013
Accruals and other liabilities		4,783	5,106
<b>Total current liabilities</b>		<b>6,336</b>	<b>8,119</b>
<b>Total liabilities</b>		<b>13,320</b>	<b>15,247</b>
<b>TOTAL EQUITY AND LIABILITIES</b>		<b>138,647</b>	<b>155,927</b>

*See accompanying Notes to unaudited interim condensed consolidated financial statements*

**Agennix AG**  
**Interim consolidated statement of cash flows**

**Three months ended March 31,**  
**2012**  
**(unaudited)**  
**€000**

**2011**  
**(unaudited)**  
**€000**

**Cash flows from operating activities**

Net loss before tax for the period	(12,731)	(11,499)
Adjustments for:		
Depreciation	172	151
Amortization	2	1
Compensation costs for share-based payments	140	142
Unrealized foreign exchange loss (gain) on monetary assets and liabilities	441	879
Finance income	(37)	(78)
Finance costs	2	225
Net (gain) / loss from the disposal of property and equipment	-	3
	<u>(12,011)</u>	<u>(10,176)</u>
Increase/(decrease) in other assets, non-current and current	2,868	1,173
Decrease in trade receivables	-	7
(Decrease) / increase in trade payables	(1,418)	(2,152)
Decrease in accruals and other liabilities	(154)	(428)
	<u>(10,715)</u>	<u>(11,576)</u>
Cash used in operating activities		
Interest received	36	73
Interest paid	-	(1)
<b>Net cash used in operating activities</b>	<b><u>(10,679)</u></b>	<b><u>(11,504)</u></b>
<b>Cash flows from investing activities</b>		
Purchase of property, equipment and intangible assets	(143)	(18)
Proceeds from / (purchase of) financial assets held for trading, net	8,309	(18,752)
<b>Net cash provided by / (used in) investing activities</b>	<b><u>8,166</u></b>	<b><u>(18,770)</u></b>
<b>Cash flows from financing activities</b>		
Proceeds from the exercise of share options	-	30
<b>Net cash provided by financing activities</b>	<b><u>-</u></b>	<b><u>30</u></b>
Effect of exchange rate changes on cash and cash equivalents	(372)	(142)
Changes in restricted cash	-	1
<b>Net decrease in cash and cash equivalents</b>	<b><u>(2,885)</u></b>	<b><u>(30,385)</u></b>
<b>Cash and cash equivalents at beginning of period</b>	<b><u>23,912</u></b>	<b><u>49,016</u></b>
<b>Cash and cash equivalents at end of period</b>	<b><u>21,027</u></b>	<b><u>18,631</u></b>

*See accompanying Notes to unaudited interim condensed consolidated financial statements*

## Agennix AG

### Interim consolidated statement of changes in equity

	Shares	Issued capital	Share premium	Retained loss	Conv. bonds	Foreign transl. reserve	Total equity
in € 000, excluding number of shares							
<b>Balance at January 1, 2011 as previously reported</b>	<b>41,884,176</b>	<b>41,884</b>	<b>150,931</b>	<b>(43,499)</b>	<b>720</b>	<b>2,756</b>	<b>152,792</b>
Adjustment to reclassify convertible bond reserve to retained loss (Note 1)	-	-	-	676	(676)	-	-
<b>Balance at January 1, 2011, as adjusted</b>	<b>41,884,176</b>	<b>41,884</b>	<b>150,931</b>	<b>(42,823)</b>	<b>44</b>	<b>2,756</b>	<b>152,792</b>
Loss for the period	-	-	-	(8,594)	-	-	(8,594)
Other comprehensive loss	-	-	-	-	-	(6,256)	(6,256)
<b>Total comprehensive (loss)</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>(8,594)</b>	<b>-</b>	<b>(6,256)</b>	<b>(14,850)</b>
Exercise of share options	19,565	20	12	-	-	-	32
Compensation cost for share-based payments	-	-	142	-	-	-	142
<b>Balance at March 31, 2011 (unaudited) as previously reported</b>	<b>41,903,741</b>	<b>41,904</b>	<b>151,085</b>	<b>(52,093)</b>	<b>720</b>	<b>(3,500)</b>	<b>138,116</b>
<b>Balance at March 31, 2011 (unaudited), as adjusted</b>	<b>41,903,741</b>	<b>41,904</b>	<b>151,085</b>	<b>(51,417)</b>	<b>44</b>	<b>(3,500)</b>	<b>138,116</b>
<b>Balance at January 1, 2012</b>	<b>51,270,258</b>	<b>51,270</b>	<b>169,199</b>	<b>(84,649)</b>	<b>44</b>	<b>4,816</b>	<b>140,680</b>
Loss for the period	-	-	-	(12,731)	-	-	(12,731)
Other comprehensive loss	-	-	-	-	-	(2,763)	(2,763)
<b>Total comprehensive loss</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>(12,731)</b>	<b>-</b>	<b>(2,763)</b>	<b>(15,494)</b>
Compensation cost for share-based payments	-	-	141	-	-	-	141
<b>Balance at March 31, 2012 (unaudited)</b>	<b>51,270,258</b>	<b>51,270</b>	<b>169,340</b>	<b>(97,380)</b>	<b>44</b>	<b>2,053</b>	<b>125,327</b>

*See accompanying Notes to unaudited interim condensed consolidated financial statements*

**Agennix AG**  
**Notes to the unaudited interim condensed consolidated financial statements**

**1. Basis of Presentation and Accounting Policies**

Agennix AG (“Agennix” or “the Company”) is a publicly traded company organized under the laws of the Federal Republic of Germany. Agennix AG’s registered seat is in Heidelberg, Germany. The Company has three sites of operation: Planegg/Munich, Germany; Princeton, New Jersey, USA and Houston, Texas, USA.

The Company is focused on the development of novel therapies that have the potential to substantially lengthen and improve the lives of critically ill patients in areas of major unmet medical need.

**Basis of presentation**

The accompanying interim condensed consolidated financial statements of the Company for the three months ended March 31, 2012, have been prepared in accordance with International Accounting Standard 34, *Interim Financial Reporting*, (“IAS 34”) as adopted by the European Union (“EU”). The interim condensed consolidated financial statements do not include all the information and disclosures required in the annual financial statements prepared in accordance with International Financial Reporting Standards (“IFRS”), as adopted by the EU, and should be read in conjunction with Agennix AG’s annual consolidated financial statements for the year ended December 31, 2011, contained in the Annual Report of Agennix AG for the year ended December 31, 2011 (“2011 Annual Report”).

**Accounting policies**

The accounting policies adopted and valuation methods applied in the preparation of the interim condensed consolidated financial statements are consistent with those followed in the preparation of Agennix AG’s annual consolidated financial statements for the year ended December 31, 2011, except for the adoption of new standards and interpretations as of January 1, 2012, as noted below:

**IFRS 7 *Financial Instruments: Disclosures* — *Enhanced De-recognition Disclosure Requirements***

The amendment requires additional disclosure about financial assets that have been transferred but not de-recognized to enable the user of the Company’s financial statements to understand the relationship between those assets that have not been de-recognized and their associated liabilities. In addition, the amendment requires disclosures about continuing involvement in de-recognized assets to enable the user to evaluate the nature of, and risks associated with, the entity’s continuing involvement in those de-recognized assets. The amendment becomes effective for annual periods beginning on or after July 1, 2011. The amendment affects disclosure only and has no impact on the Company’s financial position or performance.

### **Amendment to IFRS 7, *Financial Instruments: Disclosures – Transfers of Financial Assets***

The amendment specifies the disclosure requirements on transfers of financial assets and is effective for annual periods beginning on or after July 1, 2011; comparative information is not required for any period beginning before that date. The adoption of this standard did not have any impact on the financial position or performance of the Company.

Consistent with presentation in the annual consolidated financial statements for the year ended December 31, 2011, the Company adjusted its comparative interim consolidated statement of changes in equity for the first quarter of 2011. This adjustment resulted from prior period cancellations of convertible bonds and resulted in a reclassification between convertible bond reserves and retained loss. There was no impact on the total equity of the Company.

### **Going concern**

These interim condensed consolidated financial statements have been prepared on a going concern basis, which assumes that the Company will continue in operation for the foreseeable future and will be able to realize its assets and discharge its liabilities in the normal course of operations.

During the three month period ended March 31, 2012, the Company incurred a net loss of € 12.7 million and used cash in its operations of € 10.7 million. At March 31, 2012, the Company had cash, cash equivalents, other current financial assets and restricted cash of € 32.8 million and current liabilities of € 6.3 million. The Company has incurred recurring operating losses and has generated negative cash flows from operations since its inception and expects such results to continue for the foreseeable future.

Based on the current financial position of the Company, management believes that Agennix will have sufficient cash to fund its operations into the first quarter of 2013. This should enable the Company to obtain top-line data from the FORTIS-M Phase III trial assuming no significant changes to currently projected timelines. The Company will need to raise additional funds through licensing agreements and/or through strategic and/or public equity or debt investments to fund operations beyond that point and to continue as a going concern.

If Agennix were to experience significant delays in obtaining top-line data from the FORTIS-M trial, the Company's ability to continue as a going concern could be at risk if it were unable to secure interim funding to get to that important event. If the FORTIS-M trial were to have negative results, the Company's ability to continue as a going concern would be at immediate risk, as the Company's ability to obtain additional funding would be limited. In this situation, the Company would quickly reduce costs through restructuring activities in order to preserve cash. Furthermore, the Company would evaluate other business opportunities, including mergers and acquisitions and/or partnering and/or advancing other internal development programs.



Agennix cannot accurately predict when or whether it will successfully complete the development of its product candidates or obtain additional funding.

These interim condensed consolidated financial statements do not reflect adjustments in the carrying values of the Company's assets and liabilities, the reported income and expenses, and the current/non-current classifications in the statement of financial position that would be necessary if the going concern assumption was not appropriate. The potential adjustments, if any, could be material and would be recorded when events and circumstances occurred or when they could be estimated reliably.

## **2. Commitments and Contingencies**

### **Commitments**

#### ***DSM Capua S.p.A.***

The Company has a manufacturing and supply agreement with DSM Capua S.p.A. ("DSM") under which DSM will manufacture for Agennix talactoferrin at commercial levels in anticipation of positive Phase III clinical data and product approval. DSM is manufacturing talactoferrin for use in ongoing clinical trials, and will continue to supply talactoferrin for clinical trials as well as to support a potential commercial launch. Under this agreement, the Company's annual minimum purchase commitment on the current production line is €3.0 million for 2012.

At March 31, 2012, the Company also had commitments to DSM totaling approximately €1.0 million relating to conceptual engineering of the second production line of €0.6 million, as well as R&D activity commitments for talactoferrin totaling €0.4 million.

#### ***Lonza Sales AG***

The Company has a manufacturing services agreement with Lonza Sales AG ("Lonza") under which Lonza will manufacture for Agennix talactoferrin at commercial levels in anticipation of positive Phase III clinical data and product approval. At March 31, 2012, the Company had commitments to Lonza totaling approximately CHF 0.2 million (Swiss francs) (approximately €0.2 million) relating to R&D activities for talactoferrin.

Please refer to Notes 7 and 28 of the 2011 Annual Report of Agennix AG for detailed description of major terms and conditions of agreements with DSM and Lonza.

### **Contingencies**

From time to time, the Company may be party to certain legal proceedings and claims which arise during the ordinary course of business. Legal proceedings are subject to various uncertainties and the outcomes are difficult to predict. The Company may incur significant expense in defending such lawsuits. In the opinion of management, the ultimate outcome of these matters will not have material adverse effects on the Company's financial position, results of operations or cash flows. The Company makes a provision for a liability when it is

the result of a past event for which the outflow of resources is probable and the amount of the loss can be reasonably estimated.

### **3. Additional Disclosures**

#### **Research and development expenses**

Research and development (“R&D”) expenses for the three months ended March 31, 2012 increased 16% to €9.5 million compared to € 8.2 million for the same period in 2011. The increase in R&D expenses is primarily due to costs associated with the Phase II/III OASIS trial with talactoferrin in severe sepsis, which was initiated at the end of the second quarter of 2011 and stopped in the first quarter of 2012.

#### **Administrative expense**

Administrative expenses for the three months ended March 31, 2012 increased 26% to € 2.9 million compared to €2.3 million for the same period in 2011. Administrative expenses were higher as the Company has engaged in certain critical pre-commercialization activities related to a potential regulatory filing and commercial launch of talactoferrin.

#### **Other expenses, net**

In the first quarter of 2012 and 2011, the euro strengthened against the U.S. dollar. As a result, the Company recognized approximately € 0.3 million and € 0.8 million in net foreign exchange losses as other expense in the three months ended March 31, 2012 and 2011, respectively.

The functional currency of Agennix AG is the euro. Foreign exchange gains or losses arise mainly on U.S. dollar-denominated intercompany receivables and Agennix AG’s purchases of foreign currency for intercompany transfers, as well as on Agennix AG’s investments in U.S. dollar-denominated money market funds. Although intercompany balances and transactions are eliminated when the financial position and results of operations of the U.S. subsidiaries of Agennix AG are consolidated, foreign exchange gains or losses on such intercompany receivables continue to be recognized in the consolidated financial statements of Agennix AG pursuant to IAS 21, “*The Effects of Changes in Foreign Exchange Rates.*” As a result, intercompany receivables represent a commitment to convert one currency into another and expose Agennix AG to a gain or loss through currency fluctuations.

#### **Intangible assets**

Intangible assets decreased 3% to € 99.0 million at March 31, 2012, from € 102.0 million at December 31, 2011. This decrease was mainly due to fluctuations in the exchange rate, as virtually all of the intangible assets relate to talactoferrin development projects and are denominated in U.S. dollars, resulting from the euro rebounding against the U.S. dollar during the first three months of 2012.

Intangible assets not yet available for use are tested for impairment annually (as of December 31) and when circumstances indicate the carrying value may be impaired. The Company determines the recoverable amount of the intangible asset capitalized in connection with talactoferrin as the higher of the estimated fair value less cost to sell or the value in use. The key assumptions used to determine the recoverable amount were discussed in Note 17 of the 2011 Annual Report. At each statement of financial position date, the Company assesses whether there is an indication that the talactoferrin-related intangible asset may be impaired. In making this judgment, the Company evaluates, among other factors, the progress of the Company's studies with talactoferrin and feedback from the medical community.

The Company's market capitalization as of the date of these interim condensed consolidated financial statements was below the carrying value of the equity attributable to the Company's equity holders. In the opinion of management, market capitalization below equity is not an indicator of potential impairment of the Company's long-lived assets, since the market may have taken into account factors other than the return on the Company's assets, such as the stage of drug development, lack of history in obtaining regulatory approval and cash constraints in prior years.

In February 2012, the Company stopped further enrollment and treatment in the Phase II/III OASIS trial with talactoferrin in severe sepsis. This event is an indicator of potential impairment of the Company's talactoferrin-related intangible assets. However, the Company believes that this event should have no impact on the conduct of ongoing trials with talactoferrin in NSCLC.

Management updated its analysis of the talactoferrin intangible asset's fair value less costs to sell as of December 31, 2011 and ensured that it exceeded the asset's carrying amount as of that date (see Note 17 of the 2011 Annual Report). The assumptions used to estimate the asset's recoverable amount as of December 31, 2011 remain valid as of March 31, 2012. Based on the analysis performed, management concluded that, as of March 31, 2012, no impairment of talactoferrin-related intangible assets was required.

### **Deferred taxes**

A deferred tax asset is offset in the statement of financial position against a deferred tax liability recognized on intangible assets as a result of the business combination in 2009. In the first three months of 2012, the Company did not recognize a deferred tax benefit in connection with the net operating losses incurred by the Company's subsidiary, Agennix Incorporated, (€ 2.9 million for the same period of 2011), as, based on management's analysis, it was not probable that future taxable profits or sufficient taxable temporary differences would be available against which the accumulated tax losses could be utilized before they expire.

### **Exchange differences on translating foreign operations**

The functional currency of the Company's subsidiaries, Agennix Inc. and Agennix USA Inc., is the U.S. dollar. For consolidation purposes, assets and liabilities of the foreign subsidiaries are translated into the reporting currency of the Company at the closing rate on the date of the statement of financial position, while income

and expenses are translated at exchange rates at the dates of the transactions. The translation adjustments resulting from exchange rate movements are accumulated in other comprehensive income (loss).

In the first three months of 2012, the Company recognized other comprehensive loss of €2.8 million due to negative foreign exchange differences on translating foreign operations (other comprehensive loss of €6.3 million for the same period of 2011).

### Number of employees

As of March 31, 2012 and 2011, the total number of Agennix employees was 73 and 59, respectively.

### Shareholdings of management

As of March 31, 2012, the members of the Management Board and Supervisory Board of the Company held shares, stock options, and convertible bonds in Agennix AG in the amounts set forth in the table below:

	Number of Shares	Number of Options	Number of Convertible Bonds
<b>Management Board</b>			
Torsten Hombeck, Ph.D.	25,000	304,146	-
Rajesh Malik, M.D.	2,575	339,490	-
<b>Supervisory Board</b>			
Christof Hettich, LL.D. (Chairman)	-	-	-
Frank Young, M.D., Ph.D. (Vice Chairman)	500	30,664	-
Friedrich von Bohlen und Halbach, Ph.D.	-	-	-
Alan Feinsilver	50,308	-	-
Bernd Seizinger, M.D., Ph.D. (1)	190,000	60,000	17,701
James Weaver III	119,016	-	-

(1) Subsequent to the period end, Dr. Seizinger purchased an additional 10,000 shares on the open market.

### Related parties

During the three months ended March 31, 2012, the Company paid approximately € 95,000 (first three months of 2011: €9,000) to Rittershaus, a related party to the Company, for legal services and had accrued expenses of approximately € 68,000 at March 31, 2012 (€ 113,000 at December 31, 2011). Rittershaus is a related party to the Company because the Chairman of the Supervisory Board, Dr. Christof Hettich, is a partner at this firm, which currently advises the Company in matters of law.

During the three months ended March 31, 2012, the Company paid approximately € 11,000 (first three months of 2011: € 1,000) to Dr. Frank Young, a related party to the Company, for consulting and other services and had accrued expenses of €0 at March 31, 2012 and at December 31, 2011. Dr. Young is a related party to the Company because he is the Vice Chairman of the Supervisory Board and also advises the

Company with respect to regulatory matters and drug development, pursuant to a separate consulting agreement between the two parties.

During the three months ended March 31, 2012, the Company paid €0 (first three months of 2011: €6,000) to Molecular Health AG (formerly LIFE Biosystems AG), a related party to the Company, and had accrued expenses of €0 at March 31, 2012 and at December 31, 2011. Molecular Health AG is a related party to the Company because Dr. Friedrich von Bohlen und Halbach is a member of the Agennix Supervisory Board and the Chairman of the Supervisory Board of Molecular Health AG, which, in the past has performed external R&D for Agennix.

#### **4. Subsequent events**

The Company reported that the pre-specified number of events required for conducting the primary analysis of overall survival has been reached for the ongoing Phase III FORTIS-M trial in NSCLC patients whose disease has progressed following two or more prior therapies. Agennix confirmed that it continues to expect to report top-line data from the trial in the July/August 2012 timeframe.

## Responsibility Statement

To the best of Management's knowledge and in accordance with the applicable reporting principles for interim financial reporting, the interim condensed consolidated financial statements give a true and fair view of the assets, liabilities, financial position and financial results of the Company, and the interim management report of the Company includes a fair review of the development and performance of the business and the position of the Company, together with a description of the principal opportunities and risks associated with the expected development of the Company for the remaining months of the financial year.

May 9, 2012



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Dr. Torsten Hombeck



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Dr. Rajesh Malik

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**CONTACTS**

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