



Agennix AG
Interim Report
January - September 2012

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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 two sites of operation: Planegg/Munich, Germany, and Princeton, New Jersey, USA. As noted below, a third site in Houston, Texas, USA was closed after the end of the third quarter of 2012 and the Planegg/Munich, Germany is planned to be closed in the first half of 2013.

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.

Business Performance

In August 2012, Agennix announced that the FORTIS-M Phase III registration trial that was evaluating lead development program oral talactoferrin alfa (“talactoferrin”) in patients with non-small cell lung cancer (“NSCLC”) did not meet its primary endpoint of improving overall survival. Following this outcome, the Company ceased various talactoferrin-related activities, including pre-commercialization work and commercial manufacturing preparations. In addition, the Company underwent a major restructuring which included a staff reduction of approximately 55% and the closure of the Company’s Houston site. In October 2012, Agennix made the decision to close its Planegg/Munich, Germany site, which will also involve an additional staff reduction of 6 employees. The anticipated longer-term savings from these cuts will in the near-term offset the one-time cost of the restructuring and expenses related to terminating various activities and operations.

Going concern

During the nine month period ended September 30, 2012, the Company incurred a net loss of € 110.0 million and used cash in its operations of € 32.7 million. At September 30, 2012, the Company had cash, cash equivalents, other current financial assets and restricted cash of € 11.2 million and current liabilities of € 8.6 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 Company’s current financial position and updated estimates of future cash burn, management believes that Agennix will have sufficient cash to fund its operations into the first quarter of 2013. Due to major setbacks with talactoferrin during 2012, the Company’s ability to raise additional cash on a stand-alone basis through equity financing, debt issues or drug development partnering agreements is very limited. As a result, the Company’s ability to continue as a going concern is at immediate risk and its liquidation or insolvency may be imminent if additional funding is not obtained early in the first quarter of 2013.

Management is currently in discussions with existing investors and potential strategic partners regarding corporate strategic options for Agennix, including possible business combinations with other companies and/or acquiring assets with near-term revenue potential. Management believes that it is possible that a

transaction will move forward and expects to undertake a bridge financing to extend its cash reach beyond the first quarter of 2013 to complete any potential strategic transaction.

Agennix cannot accurately predict when or whether it will successfully complete the development of its product candidates or obtain additional funding. There can be no guarantee that a strategic transaction will be successfully completed.

As of September 30, 2012, cash, cash equivalents, other current financial assets and restricted cash totaled € 11.2 million (December 31, 2011: € 44.0 million). Net cash burn for the nine months ended September 30, 2012, was € 33.0 million (for the nine months ended September 30, 2011: € 34.9 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.

Year-to-date performance

The Company did not recognize any revenue during the nine months ended September 30, 2012 and 2011.

Research and development ("R&D") expenses for the nine months ended September 30, 2012, increased 12% to € 27.5 million compared to € 24.6 million for the same period in 2011. The increase in R&D expenses was primarily due to increased costs associated with the FORTIS-M Phase III trial in NSCLC and the OASIS Phase II/III trial in severe sepsis, the majority of which were incurred in the first half of the year, and costs associated with the overall evaluation of the talactoferrin program to determine a potential future development path in the third quarter of 2012.

Administrative expenses for the nine months ended September 30, 2012, increased 17% to € 7.7 million compared to € 6.6 million for the same period in 2011. Administrative expenses were higher as the Company had engaged in certain critical pre-commercialization activities related to talactoferrin ahead of the FORTIS-M trial results. Any ongoing activities were terminated once the FORTIS-M trial results were known.

In the third quarter of 2012, the Company recorded restructuring charges of approximately € 3.0 million related to employee terminations, lease losses and other contract termination costs. Please see Note 2 to the accompanying interim condensed consolidated financial statements for additional details. In addition, the Company recorded approximately € 3.3 million and € 75.8 million of impairment charges for property and equipment and intangible assets, respectively. Please see Note 4 to the accompanying interim condensed consolidated financial statements for additional information about the impairment analysis.

Net loss before tax for the nine months ended September 30, 2012, increased 261% to € 117.1 million compared to € 32.4 million for the same period in 2011, mainly as a result of the impairment and restructuring charges discussed above. Income tax benefit for the nine months ended September 30, 2012, was € 7.0

million compared to € 7.2 million for the same period in 2011. Income tax benefit recorded in 2011 related to the recognition of a deferred tax asset on net operating losses incurred by the Company's subsidiary, Agennix Incorporated. No additional deferred tax asset on net operating losses was recognized during the first nine months of 2012. However, in the third quarter of 2012, in conjunction with the impairment of the intangible asset related to talactoferrin, the recognized deferred tax liability together with the deferred tax asset were adjusted, resulting in a € 7.0 million net tax benefit for the period. Net loss for the nine months ended September 30, 2012, increased to € 110.0 million compared to € 25.2 million for the same period in 2011. Basic and diluted loss per share was € 2.15 for the nine months ended September 30, 2012, compared to € 0.60 for the same period in 2011.

Quarterly performance

The Company did not recognize any revenue during the three months ended September 30, 2012 and 2011.

R&D expenses for the third quarter of 2012 increased 22% to € 9.9 million compared to € 8.1 million for the same period in 2011. The increase in R&D expenses was primarily due to increased costs associated with the FORTIS-M Phase III trial of talactoferrin before its termination and costs associated with the overall evaluation of the talactoferrin program to determine a potential future development path.

Administrative expenses for the third quarter of 2012 decreased 5% to € 2.0 million compared to € 2.1 million for the same quarter in 2011. Administrative expenses were lower as any ongoing activities relating to pre-commercialization were terminated once the FORTIS-M trial results were known.

In the third quarter of 2012, the Company recorded a restructuring charge of approximately € 3.0 million related to employee terminations, lease loss and other contract termination costs. In addition, approximately € 3.3 million and € 75.8 million of impairment charges for property and equipment and intangible assets, respectively, were recorded.

Net loss before tax for the third quarter of 2012 was € 93.8 million compared to € 9.7 million for the third quarter of 2011. Basic and diluted loss per share was € 1.69 and € 0.20 for the third quarter of 2012 and 2011, respectively.

Research and Development

Agennix focuses 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. The Company's investigational agents include: oral talactoferrin; a topical gel formulation of talactoferrin for treating chronic wounds, with which a clinical trial in diabetic foot ulcers has been completed; and RGB-286638 multi-targeted kinase inhibitor in Phase I clinical testing for cancer.

In August 2012, the Company reported that the FORTIS-M Phase III trial with talactoferrin did not meet its primary endpoint of improving overall survival. The FORTIS-M trial evaluated talactoferrin plus best supportive care compared to placebo plus best supportive care in patients with NSCLC whose disease had progressed following two or more prior treatment regimens. Median overall survival in the talactoferrin arm was 7.5 months compared to 7.7 months for placebo (hazard ratio 1.04, p-value 0.66). The nature and incidence of adverse events in the talactoferrin arm were similar to that of placebo and consistent with previous clinical trials. The FORTIS-M trial design was based on a randomized, double-blind, placebo-controlled Phase II study in NSCLC patients whose disease had progressed following one or more prior treatment regimens. In that Phase II study, talactoferrin appeared to improve survival, and patients receiving talactoferrin had fewer side effects than the placebo arm.

Following the outcome of the FORTIS-M trial, Agennix made the decision to stop enrollment and analyze the results from a second Phase III trial in NSCLC called FORTIS-C. The FORTIS-C trial evaluated talactoferrin in combination with a standard chemotherapy regimen, carboplatin plus paclitaxel, compared to placebo plus carboplatin and paclitaxel in first-line NSCLC patients with advanced or metastatic disease (patients who have not yet been treated for their disease). At the time the FORTIS-C trial was stopped, 94 of the planned 1,100 patients had been enrolled and received study drug; all patients were enrolled at five U.S. sites. The study had co-primary endpoints of progression-free survival ("PFS") and overall survival ("OS"). Investigator-reported median PFS in the talactoferrin arm was 5.8 months compared to 5.6 months for placebo (hazard ratio 0.97, p-value 0.89). Median OS in the talactoferrin arm was 11.4 months compared to 12.7 months for placebo (hazard ratio 1.25, p-value 0.36). The nature and incidence of adverse events in the talactoferrin arm were similar to that of placebo. The FORTIS-C trial design was based on the results of a randomized, double-blind, placebo-controlled Phase II trial in first-line NSCLC in which talactoferrin showed activity and patients receiving chemotherapy plus talactoferrin had fewer side effects than those receiving chemotherapy and a placebo.

The Company was also developing talactoferrin for the treatment of severe sepsis. Agennix 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 the Company stopped further enrollment and treatment in the trial upon the recommendation of the study Data Safety Monitoring Board (DSMB). 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.

Final data from the trial were presented in November at the International Sepsis Forum Sepsis 2012 meeting. Data presented included 28-day and three-month all-cause mortality. As the Company previously reported, talactoferrin did not improve 28-day all-cause mortality, the primary endpoint of the study, nor did it improve mortality at three months. The most commonly reported adverse events in the study were in line with those

that generally occur with sepsis patients in the intensive care unit and were generally similar between placebo and talactoferrin.

In November 2012, Agennix also reported final data from a Phase I/II randomized, placebo-controlled trial, funded by a U.S. National Institutes of Health (NIH) grant, evaluating talactoferrin's potential to reduce the incidence of nosocomial (hospital acquired) infections in infants born prematurely, which was the primary endpoint. The study enrolled a total of 120 patients. Ten percent of patients (6 of 60) in the talactoferrin arm developed nosocomial infections compared to fifteen percent (9 of 60) in the placebo arm. This difference, while in favor of talactoferrin, was not statistically significant. The nature and incidence of adverse events in the talactoferrin arm were generally similar to that of placebo and consistent with expectations for the population under study.

The Company has performed extensive analyses of the data from the FORTIS trials, as well as earlier studies to determine if there is a potential explanation for the negative outcomes of those trials as compared to earlier successful clinical studies with talactoferrin. If the hypotheses generated from these analyses can be confirmed by additional research, a new development path forward for talactoferrin may be considered.

The Company is not doing any work on its other development programs at this time.

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 September 30, 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 September 30, 2012, as well as significant transactions with related parties for the period, are presented in Note 4 to the accompanying interim condensed consolidated financial statements.

Risks and Opportunities

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"). As noted above, due to major setbacks with talactoferrin during 2012, the Company's ability to raise additional cash on a stand-alone basis through equity financing, debt issues or drug development partnering agreements is very limited. As a result, the Company's ability to continue as a going concern is at immediate risk and its liquidation or insolvency may be imminent if additional funding is not obtained early in the first quarter of 2013. Refer to Section "Going Concern" above. 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 cash reach, financing and strategic transactions. 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. The achievement of positive results in early stage clinical studies does not ensure that later stage or large scale clinical studies will be successful. There can be no guarantee that the Company will have or be able to obtain the financial resources to conduct additional studies with its product candidates or that it will be successful in pursuing a strategic transaction. 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.

The Company has performed extensive analyses of the data from the FORTIS trials, as well as earlier studies to determine if there is a potential explanation for the negative outcomes of those trials as compared to earlier successful clinical studies with talactoferrin. If the hypotheses generated from these analyses can be confirmed by additional research, a new development path forward for talactoferrin may be considered.

In the Company's current situation, no revenues are expected to be generated during the remainder of 2012 or in 2013. The Company has taken significant steps to reduce expenses, including staff reductions, site closures and ceasing various activities, such as commercial manufacturing preparations and pre-commercialization activities related to talactoferrin. The anticipated longer-term savings from these cuts will in the near-term offset the one-time cost of the restructuring and expenses related to terminating various

activities and operations. In the current situation, expenses in 2013 would be expected to be significantly lower than in 2012. Management believes that Agennix will have sufficient cash to fund operations into the first quarter of 2013.

Management is currently in discussions with existing investors and potential strategic partners regarding corporate strategic options for Agennix, including possible business combinations with other companies and/or acquiring assets with near-term revenue potential. Management believes that it is possible that a transaction will move forward and expects to undertake a bridge financing to extend its cash reach beyond that point in order to complete any potential strategic transaction.

Agennix AG
Interim consolidated statement of operations

	Note	Three months ended September 30,		Nine months ended September 30,	
		2012 (unaudited) €000	2011 (unaudited) €000	2012 (unaudited) €000	2011 (unaudited) €000
Revenue		-	-	-	-
Research and development expenses	4	(9,855)	(8,078)	(27,526)	(24,636)
Administrative expenses	4	(1,953)	(2,147)	(7,734)	(6,617)
Amortization of intangible assets		(3)	(1)	(7)	(5)
Impairment of property and equipment and intangible assets	4	(79,081)	-	(79,081)	-
Restructuring expenses	2	(3,043)	-	(3,043)	-
Other income		70	703	226	17
Other expense		-	-	-	(625)
Finance income		62	52	111	195
Finance costs		(2)	(230)	(7)	(680)
Net loss before tax		(93,805)	(9,701)	(117,061)	(32,351)
Income tax benefit	4	7,020	1,464	7,020	7,187
Net loss for the period		(86,785)	(8,237)	(110,041)	(25,164)
Basic and diluted loss per share, euro		(€ 1.69)	(€ 0.20)	(€ 2.15)	(€ 0.60)
Average number of shares used in computing basic and diluted loss per share		51,270,258	41,915,639	51,270,258	41,906,475

See accompanying Notes to unaudited interim condensed consolidated financial statements

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

	Three months ended September 30,		Nine months ended September 30,	
	2012 (unaudited) €000	2011 (unaudited) €000	2012 (unaudited) €000	2011 (unaudited) €000
Net loss	(86,785)	(8,237)	(110,041)	(25,164)
Other comprehensive (loss) income:				
Exchange differences on translating foreign operations (Note 4)	(2,002)	5,854	937	(2,325)
	(2,002)	5,854	937	(2,325)
Total comprehensive loss	(88,787)	(2,383)	(109,104)	(27,489)

See accompanying Notes to unaudited interim condensed consolidated financial statements

Agennix AG
Interim consolidated statement of financial position

		September 30, 2012 (unaudited) €000	December 31, 2011 €000
ASSETS			
Non-current assets			
Property and equipment	4	139	3,678
Intangible assets	4	27,248	101,962
Other non-current assets		402	545
Total non-current assets		27,789	106,185
Current assets			
Prepayments		249	430
Other current assets		928	5,376
Other current financial assets		5,289	20,024
Cash and cash equivalents		5,794	23,912
Total current assets		12,260	49,742
TOTAL ASSETS		40,049	155,927
EQUITY AND LIABILITIES			
Equity attributable to the Company's equity holders			
Issued capital		51,270	51,270
Share premium		168,939	169,199
Other reserves	4	5,797	4,860
Retained loss		(194,690)	(84,649)
Total equity		31,316	140,680
Non-current liabilities			
Convertible bonds		65	178
Other non-current liabilities		102	-
Deferred tax liability	4	-	6,950
Total non-current liabilities		167	7,128
Current liabilities			
Trade payables		1,326	3,013
Accruals and other liabilities	2	7,240	5,106
Total current liabilities		8,566	8,119
Total liabilities		8,733	15,247
TOTAL EQUITY AND LIABILITIES		40,049	155,927

See accompanying Notes to unaudited interim condensed consolidated financial statements

Agennix AG
Interim consolidated statement of cash flows

Nine months ended September 30,
2012
(unaudited)
€000

2011
(unaudited)
€000

Cash flows from operating activities

Net loss before tax for the period	(117,061)	(32,351)
Adjustments for:		
Depreciation	490	437
Amortization	7	5
Impairment of property and equipment and intangible assets	79,081	-
Compensation costs (reversal of costs) for share-based payments	(260)	330
Unrealized foreign exchange loss (gain) on monetary assets and liabilities	(198)	855
Finance income	(111)	(195)
Finance costs	7	680
Net loss /(gain) from the disposal of property and equipment	2	(2)
	(38,043)	(30,241)
Decrease in other assets, non-current and current	4,824	151
Decrease in trade receivables	-	4
Decrease in trade payables	(1,698)	(3,621)
Increase /(decrease) in accruals and other liabilities	2,102	(742)
	(32,815)	(34,449)
Cash used in operating activities		
Interest received	110	73
Interest paid	-	(1)
	(32,705)	(34,377)
Cash flows from investing activities		
Purchase of property, equipment and intangible assets	(346)	(514)
Proceeds from the sale of property, equipment and intangible assets	3	3
Proceeds from the repayment of held to maturity investments upon their maturity	-	5,000
Proceeds from / (purchase of) financial assets held for trading, net	14,735	(4,512)
	14,392	(23)
Net cash provided by / (used in) investing activities		
Cash flows from financing activities		
Repayment of convertible bonds	(11)	-
Proceeds from the exercise of share options	-	73
	(11)	73
Net cash (used in) / provided by financing activities		
Effect of exchange rate changes on cash and cash equivalents	206	66
Changes in restricted cash	-	(1)
	(18,118)	(34,262)
Net decrease in cash and cash equivalents		
Cash and cash equivalents at beginning of period	23,912	49,016
Cash and cash equivalents at end of period	5,794	14,754

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							
Balance at January 1, 2011 as previously reported	41,884,176	41,884	150,931	(43,499)	720	2,756	152,792
Adjustment to reclassify convertible bond reserve to retained loss (Note 1)	-	-	-	676	(676)	-	-
Balance at January 1, 2011, as adjusted	41,884,176	41,884	150,931	(42,823)	44	2,756	152,792
Loss for the period	-	-	-	(25,164)	-	-	(25,164)
Other comprehensive loss	-	-	-	-	-	(2,325)	(2,325)
Total comprehensive (loss)	-	-	-	(25,164)	-	(2,325)	(27,489)
Exercise of share options	47,976	48	25	-	-	-	73
Compensation cost for share-based payments	-	-	330	-	-	-	330
Balance at September 30, 2011 (unaudited) as previously reported	41,932,152	41,932	151,286	(68,663)	720	431	125,706
Balance at September 30, 2011 (unaudited), as adjusted	41,932,152	41,932	151,286	(67,987)	44	431	125,706
Balance at January 1, 2012	51,270,258	51,270	169,199	(84,649)	44	4,816	140,680
Loss for the period	-	-	-	(110,041)	-	-	(110,041)
Other comprehensive income	-	-	-	-	-	937	937
Total comprehensive (loss) income	-	-	-	(110,041)	-	937	(109,104)
Reversal of compensation cost for share-based payments (Note 4)	-	-	(260)	-	-	-	(260)
Balance at September 30, 2012 (unaudited)	51,270,258	51,270	168,939	(194,690)	44	5,753	31,316

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 currently has two sites of operation: Planegg/Munich, Germany, and Princeton, New Jersey, USA. As noted below, a third site in Houston, Texas, USA was closed after the end of the third quarter of 2012 and the Planegg/Munich, Germany is planned to be closed in the first half of 2013.

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 nine months ended September 30, 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 nine months 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 nine month period ended September 30, 2012, the Company incurred a net loss of € 110.0 million and used cash in its operations of € 32.7 million. At September 30, 2012, the Company had cash, cash equivalents, other current financial assets and restricted cash of € 11.2 million and current liabilities of € 8.6 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.

In August 2012, Agennix announced that the FORTIS-M Phase III registration trial that was evaluating lead development program oral talactoferrin alfa ("talactoferrin") in patients with non-small cell lung cancer ("NSCLC") did not meet its primary endpoint of improving overall survival. Following this outcome, the Company ceased various talactoferrin-related activities, including pre-commercialization work and commercial manufacturing preparations. In addition, the Company underwent a major restructuring which included a staff reduction of approximately 55% and the closure of the Company's Houston site. In October 2012, Agennix made a decision to close its Planegg/Munich, Germany site, which will also involve an additional staff reduction of 6 employees (see Note 5). The anticipated longer-term savings from these cuts will in the near term offset the one-time cost of the restructuring and expenses related to terminating various activities and operations.

Based on the Company's current financial position and updated estimates of future cash burn, management believes that Agennix will have sufficient cash to fund its operations into the first quarter of 2013. Due to major setbacks with talactoferrin during 2012, the Company's ability to raise additional cash on a stand-alone basis through equity financing, debt issues or drug development partnering agreements is very limited. As a result, the Company's ability to continue as a going concern is at immediate risk and its liquidation or insolvency may be imminent if additional funding is not obtained early in the first quarter of 2013.

Management is currently in discussions with existing investors and potential strategic partners regarding corporate strategic options for Agennix, including possible business combinations with other companies and/or acquiring assets with near-term revenue potential. Management believes that it is possible that a transaction will move forward and expects to undertake a bridge financing to extend its cash reach beyond the first quarter of 2013 to complete any potential strategic transaction.

Agennix cannot accurately predict when or whether it will successfully complete the development of its product candidates or obtain additional funding. There can be no guarantee that a strategic transaction will be successfully completed.

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. Restructuring Activities

The Company records costs associated with restructuring activities in accordance with IAS 37, *Provisions, Contingent Liabilities and Contingent Assets*.

In August 2012, the Company announced a restructuring plan that involved staff reductions of approximately 55 percent (or 37 employees) of the Company's workforce. The staff reductions occurred at all three of the Company's sites of operation, and the Houston, Texas location was shut down. The Company incurred a total restructuring charge of approximately € 3.0 million related to this restructuring plan in the third quarter of 2012, which consisted of employee severance and termination benefits, lease losses and other contract termination costs. This restructuring is expected to be completed by the end of 2012. The Company did not incur such charges in the first nine months of 2011.

Below is a summary of the significant components of the restructuring liability as of September 30, 2012, (in thousand €):

	Employee Termination Benefits	Lease Termination Costs	Other Contract Termination Costs ⁽¹⁾	Total
January 1, 2012 balance	-	-	-	-
Restructuring charges	527	390	2,126	3,043
Restructuring payments	(97)	-	-	(97)
Lease loss amortization	-	(18)	-	(18)
Exchange differences	(1)	(1)	(6)	(8)
September 30, 2012 balance	<u>429</u>	<u>371</u>	<u>2,120</u>	<u>2,920</u>

⁽¹⁾ Includes € 1.8 million related to DSM and Lonza (Note 3) along with approximately € 0.3 million of other contract termination costs

The restructuring liability of € 2.9 million at September 30, 2012, is included in accruals and other liabilities in the accompanying consolidated statement of financial position which explains the increase in this line item as compared to year end 2011.

3. Commitments and Contingencies

Commitments

DSM Capua S.p.A.

In August 2012 the Company terminated its manufacturing and supply agreement with DSM Capua S.p.A. (“DSM”) under which DSM was to manufacture talactoferrin for Agennix at commercial levels in anticipation of positive Phase III clinical data and product approval. Under the terms of this contract, the Company is liable for certain redundancy costs related to the contract termination, up to a maximum of € 1.5 million. The € 1.5 million was expensed in the third quarter of 2012. Based on the terms of the contract and management’s best estimates, at September 30, 2012, the Company had no further commitments related to the termination of this contract.

Lonza Sales AG

In August 2012, the Company terminated its manufacturing services agreement with Lonza Sales AG (“Lonza”) under which Lonza was to manufacture talactoferrin for Agennix at commercial levels in anticipation of positive Phase III clinical data and product approval. Under the terms of this contract, the Company is liable for € 0.3 million in costs, which were expensed in the third quarter of 2012. Based on the terms of the contract and

management's best estimates, at September 30, 2012, the Company had no further commitments related to the termination of this contract.

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

4. Additional Disclosures

Research and development expenses

Research and development ("R&D") expenses for the nine months ended September 30, 2012, increased 12% to € 27.5 million compared to € 24.6 million for the same period in 2011. The increase in R&D expenses was primarily due to increased costs associated with the FORTIS-M Phase III trial in NSCLC and the OASIS Phase II/III trial in severe sepsis, the majority of which were incurred in the first half of the year, and costs associated with the overall evaluation of the talactoferrin program to determine whether there is a potential future development path in the third quarter of 2012.

Administrative expense

Administrative expenses for the nine months ended September 30, 2012, increased 17% to € 7.7 million compared to € 6.6 million for the same period in 2011. Administrative expenses were higher as the Company had engaged in certain critical pre-commercialization activities related to talactoferrin ahead of the FORTIS-M trial results. Any ongoing activities were terminated once the FORTIS-M trial results were known.

Restructuring charges and impairment of equipment and intangible assets

In the third quarter of 2012 the Company recorded a restructuring charge of approximately € 3.0 million related to employee terminations, lease losses and other contract termination costs. In addition, approximately € 3.3 million and € 75.8 million of impairment charges for property and equipment and intangible assets, respectively, were also recorded.

Intangible assets and related impairment

The vast majority of the Company's intangible assets is represented by the in-licensed R&D related to talactoferrin acquired in the November 2009 business combination and initially measured at fair value at the acquisition date. Since the acquisition date, the value of the asset was increased to capitalize the minimum annual royalty payments to Baylor College of Medicine ("Baylor"). As of June 30, 2012 and shortly before the impairment was recorded, the value of the intangible asset amounted to \$132 million (approximately € 105.0 million based on the exchange rate on June 30, 2012). Due to the major setbacks with talactoferrin during 2012, Agennix has performed extensive analyses of the data from the FORTIS trials, as well as earlier studies, to determine if there is a potential explanation for the negative outcomes of those trials as compared to earlier successful clinical studies with talactoferrin. If the hypotheses generated from these analyses can be confirmed by additional research, a new development path forward for talactoferrin may be considered. In this context, the Company reassessed the value assigned to the intangible asset related to talactoferrin and associated property and equipment.

For the purposes of these interim condensed consolidated financial statements, the Company updated the talactoferrin intangible asset's fair value less costs to sell valuation model used in the prior year and determined, on a preliminary basis, the asset's recoverable amount as of September 30, 2012. These determinations are preliminary and represent management's best estimates as of the date of these interim financial statements and will be revised once more information about potential development paths forward for talactoferrin becomes known and when annual consolidated financial statements are prepared.

In the current model, management assumed that the Company takes talactoferrin through the entire drug development process, obtains regulatory approval and markets the product in the U.S. and Europe from 2022 onwards. The Company applied industry-specific risks to the success of the various stages of drug development and of gaining regulatory approval, as well as adjusted expectations for the probability that necessary financing could be obtained to complete development. Patent exclusivity, estimated market share and product life-cycle were also assessed. Post-tax cash flows were discounted using a post-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the indications for which the future cash flow estimates had not been adjusted. Management used post-tax discount rate and cash flows as it believed that discounting post-tax cash flows at a post-tax discount rate and discounting pre-tax cash flows at a pre-tax discount rate provide results that are not materially different.

The following are the main assumptions (updated from the prior year):

- The period covered by the estimate is from the fourth quarter of 2012 to 2040.
- Development activities are performed in the fourth quarter of 2012 through 2022, with an estimated launch date in the third quarter of 2022 in the U.S. and in the third quarter of 2023 in Europe (provided that the clinical studies are successful and respective regulatory approval can be obtained).

- First sales proceeds start in 2022 and increase at annual double digit growth rates until 2026. From 2027 onwards, the annual growth rates start to slow down, as peak market shares are attained.
- Sales forecasts are based on the population of patients treated and estimated frequency, volume and price of treatment. The patient population is estimated using the most recent market information with area-specific growth rates applied. The price estimates take into consideration pricing of existing competitive products and estimated inflation rates.
- Cost of sales is estimated at 15% of sales. Minimum royalty payments payable under the agreement with Baylor also were taken into consideration.
- The Company estimated development costs and costs to build a sales and marketing force, including launch costs, based on the most recent management projections.
- Post-tax discount rate used is 14%.

The intangible asset's estimated recoverable amount is sensitive to the following main assumptions:

- Probability of getting necessary financing;
- Discount rate;
- Market share estimates;
- Product price estimate at launch date;
- Estimated sales and marketing expenses compared to total estimated sales.

These assumptions are the result of management's best estimates and judgment. If, on a standalone basis, peak market share estimates are reduced by 50%, or if estimated price at launch is reduced by 40%, or if the discount rate is increased to 18%, the resulting recoverable amount would be approximately 70% lower than currently estimated. In the worst case scenario, or if adverse changes to the main assumptions are considered in aggregate, recoverable amount could drop to zero and full impairment of the intangible asset may be required.

The intangible asset's fair value less cost to sell and recoverable amount was estimated at \$35.0 million (approximately € 27.2 million at the exchange rate on September 30, 2012), and an impairment loss of approximately \$97.2 million (approximately € 75.8 million at the exchange rate average for the nine months ended September 30, 2012) was recorded in the third quarter of 2012.

In addition, the Company fully impaired a talactoferrin production facility held under a finance lease agreement with DSM and included in property and equipment and recognized an impairment loss of approximately € 3.3 million in the third quarter of 2012.

Deferred taxes

A deferred tax liability was recognized on intangible assets acquired in the 2009 business combination and was offset against a deferred tax asset recognized in the past on the net operating losses of the Company's subsidiary in Houston. In the third quarter of 2012, following the impairment of the intangible asset related to

talactoferrin, the related deferred tax liability was adjusted. Deferred tax asset related to net operating losses of the Houston subsidiary was also adjusted in the third quarter of 2012 to its realizable amount (equal to the remaining amount of the deferred tax liability). As a result, net deferred tax liability amounted to € 0.0 as of September 30, 2012, and the net deferred tax benefit included in the accompanying statement of operations amounted to € 7.0 million for the nine months period then ended.

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 six months of 2012, the Company recognized other comprehensive income of € 2.9 million due to positive foreign exchange differences on translating foreign operations. In the third quarter of 2012, the Company recognized other comprehensive loss of € 2.0 million due to the strengthening of the euro against the U.S. dollar. In aggregate, for the first nine months of 2012, the Company recognized other comprehensive income, net of € 0.9 million on translating foreign operations (other comprehensive loss, net of € 2.3 million for the same period of 2011). On an overall basis, in the nine months ended September 30, 2012, the euro weakened against the U.S. dollar compared to the overall strengthening of the euro in the first nine months of 2011, resulting in a swing in positive/negative exchange differences on translating foreign operations of approximately € 3.2 million in the first nine months of 2012.

Other reserves in the statement of financial position are primarily comprised of exchange differences on translating foreign operations and amounted to positive € 5.8 million as of September 30, 2012 (an increase of € 0.9 million compared to a positive € 4.9 million as of December 31, 2011).

Compensation cost for share-based payments

For the first nine months of 2012, the Company recognized net credit to compensation costs for share-based payments of € 0.3 million (compared to share-based compensation expense of € 0.3 million in the same period of 2011). The net credit to compensation costs for share-based payments in the third quarter of 2012 was recorded as a consequence of staff reductions of approximately 55% of employees as part of the August 2012 restructuring, which was treated as a forfeiture (i.e., previously recognized expense for unvested awards was reversed).

Number of employees

As of September 30, 2012 and 2011, the total number of Agennix employees was 52 and 67, respectively.

Shareholdings of Management and Supervisory Boards

As of September 30, 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
Management Board			
Torsten Hombeck, Ph.D.	25,000	304,146	-
Rajesh Malik, M.D.	2,575	339,490	-
Supervisory Board			
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.	100,000	60,000	11,251
James Weaver III	119,016	-	-

Related parties

During the nine months ended September 30, 2012, the Company paid approximately € 167,000 (first nine months of 2011: € 157,000) to Rittershaus, a related party to the Company, and had accrued expenses of approximately € 35,000 at September 30, 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 nine months ended September 30, 2012, the Company paid approximately € 37,000 (first nine months of 2011: € 33,000) to Dr. Frank Young, a related party to the Company, and had accrued expenses of € 0 at September 30, 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 nine months ended September 30, 2012, the Company paid € 0 (first nine months of 2011: € 206,000) to Molecular Health AG (formerly LIFE Biosystems AG), a related party to the Company, and had accrued expenses of € 0 at September 30, 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.

5. Subsequent events

After the close of the third quarter 2012, Agennix made the decision to close its Planegg/Munich, Germany site, which will also involve an additional staff reduction of 6 employees. The closure is expected to occur in the first half of 2013. The effect of these actions on the Company's financial position and results of operations is not expected to exceed € 0.3 million.

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.

November 30, 2012



Dr. Torsten Hombeck



Dr. Rajesh Malik