

# Half-Year Report

January-June 2011

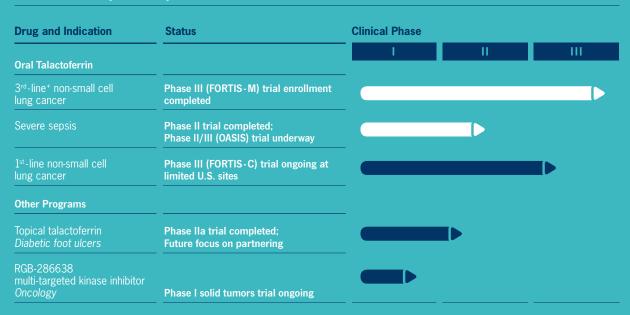
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Agennix is focused on developing novel therapies that have the potential to substantially improve the length and quality of life of critically ill patients in areas of major unmet medical need.

# **Agennix Company Highlights**

## **Clinical Development Pipeline**



## Key Achievements – January-June 2011

## **Talactoferrin – Oncology**

- Enrollment completed in Phase III FORTIS-M trial in non-small cell lung cancer (NSCLC)
- U.S. patent issued covering talactoferrin in NSCLC and renal cell carcinoma
- New data from 2<sup>nd</sup>-line<sup>+</sup> NSCLC Phase II trial presented at American Society of Clinical Oncology (ASCO) Annual Meeting
- ▶ Data from 1st-line NSCLC Phase II trial published in Journal of Thoracic Oncology

## **Talactoferrin – Severe Sepsis**

- Phase II portion of Phase II/III OASIS trial initiated
- Data from Phase II trial presented at several medical conferences
  - 40<sup>th</sup> Critical Care Congress of the Society of Critical Care Medicine
  - American Thoracic Society International Conference
  - ASCO

#### Corporate

> Senior executives hired in critical areas of pharmaceutical development and sepsis clinical development

## **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 improve the length and quality of life 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 six months ended June 30, 2011 and 2010.

Research and development (R&D) expenses for the six months ended June 30, 2011, increased 43% to €16.6 million compared to € 11.6 million for the same period in 2010. The increase in R&D expenses is primarily due to increased patient enrollment in the Company's Phase III FORTIS-M trial with talactoferrin in non-small cell lung cancer (NSCLC) and preparation for the Phase II/III OASIS trial with talactoferrin in severe sepsis, which was initiated at the end of the second quarter of 2011.

Administrative expenses for the six months ended June 30, 2011, were  $\in$  4.5 million, and  $\in$  4.4 million for the same period in 2010.

Net loss before tax for the six months ended June 30, 2011, increased 88% to  $\leq$  22.7 million compared to  $\leq$  12.1 million for the same period in 2010. Income tax benefit for the six months ended June 30, 2011, amounted to  $\leq$  5.7 million ( $\leq$  3.9 million for the same period in 2010) and related to the deferred tax asset on net operating losses incurred by the Company's subsidiary, Agennix Incorporated, during the period. Net loss for the six months ended June 30, 2011, increased 106% to  $\leq$  16.9 million compared to  $\leq$  8.2 million for the same period in 2010. Basic and diluted loss per share was  $\leq$  (0.40) for the six months ended June 30, 2011, compared to  $\leq$  (0.42) for the same period in 2010.

## **Quarterly performance**

The Company did not recognize any revenue during the three months ended June 30, 2011 and 2010. R&D expenses increased 26% for the second quarter of 2011 to €8.3 million compared to €6.6 million for the same period in 2010. The increase in R&D expenses is primarily due to increased patient enrollment in the Company's Phase III FORTIS-M trial with talactoferrin in non-small cell lung cancer (NSCLC) and preparation

for the Phase II/III OASIS trial with talactoferrin in severe sepsis, which was initiated at the end of the second quarter of 2011. Administrative expenses for the second quarter of 2011 decreased 4% to  $\in$  2.2 million compared to  $\in$  2.3 million for the same quarter in 2010. Net loss for the second quarter of 2011 was  $\in$  8.3 million compared to  $\in$  3.9 million for the second quarter of 2010. Basic and diluted loss per share was  $\in$  (0.20) and  $\in$  (0.19) for the second quarter of 2011 and 2010, respectively.

#### **Financial position**

During the six months period ended June 30, 2011, the Company incurred a net loss of  $\in$  16.9 million (net loss before tax of  $\in$  22.7 million) and used cash in its operations of  $\in$  22.7 million. At June 30, 2011, the Company had cash, cash equivalents, other current financial assets and restricted cash of  $\in$  54.2 million and current liabilities of  $\in$  23.1 million, including the  $\in$  15 million short-term loan from dievini Hopp BioTech holding GmbH & Co. KG ("dievini") and accrued interest thereon of  $\in$  0.8 million. The Company has incurred recurring operating losses and has generated negative cash flows from operations since its inception and it 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 well into the second half of 2012. This should enable the Company to obtain top-line data in the FORTIS-M trial in NSCLC, expected in the first half of 2012, and to complete the Phase II portion of the OASIS trial with talactoferrin in severe sepsis that was initiated at the end of the second quarter of 2011, assuming no significant changes to currently projected timelines. This projected cash reach also assumes that the € 15 million loan, made to the Company by dievini, will not need to be repaid prior to the release of top-line results from both the FORTIS-M trial and the Phase II portion of the OASIS trial. 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. Management is currently evaluating various options to further finance the Company past the second half of 2012.

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

As of June 30, 2011, cash, cash equivalents, other current financial assets and restricted cash totaled  $\in$  54.2 million (December 31, 2010:  $\in$  79.3 million). Net cash burn for the six months ended June 30, 2011, was  $\in$  23.1 million (June 30, 2010:  $\in$  17.5 million). The increase in net cash burn was mainly due to clinical trial costs related to increased patient enrollment in the Company's Phase III FORTIS-M trial and preparations for the Phase II/III OASIS trial. 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 improve the length and quality of life of critically ill patients in areas of major unmet medical needs. The Company's most advanced program, and the main focus of its R&D efforts, is talactoferrin. Talactoferrin is an oral immunotherapy that is being studied for the treatment of cancer and severe sepsis and has demonstrated activity in randomized, double-blind, placebo-controlled Phase II studies in NSCLC, as well as in severe sepsis.

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. FORTIS-M 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.

Agennix is conducting a second Phase III trial in NSCLC called FORTIS-C. FORTIS-C is a randomized, double-blind, placebo-controlled trial evaluating oral talactoferrin plus the 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.

In March 2011, Agennix announced the issuance of a U.S. patent which covers the use of oral talactoferrin for the treatment of NSCLC and renal cell carcinoma. The patent term expires in 2025.

During the first half of 2011, data from the Phase II trials with talactoferrin in NSCLC and in severe sepsis were presented at major medical meetings in the U.S. and in Europe, including at the American Society of Clinical Oncology (ASCO) Annual Meeting. In addition, data from the Phase II trial in first-line NSCLC were published in the peer-reviewed medical publication, *Journal of Thoracic Oncology*.

In June 2011, the OASIS (**O**ral Talactoferrin in **S**evere Sepsis) Phase II/III trial was initiated. The OASIS trial is evaluating talactoferrin plus standard care compared to placebo plus standard care in adult patients with severe sepsis. The Phase II part of the trial is planned to enroll approximately 350 patients at clinical sites predominantly in Western Europe and North America. The study's primary objective is to determine the effect of talactoferrin on 28-day all-cause mortality. Secondary endpoints include three-month, six-month and twelve-month all-cause mortality. The study will also evaluate the safety and tolerability of talactoferrin in this patient population, and data will be collected to further elucidate the mechanism of action of talactoferrin. The purpose of the Phase II component of the OASIS trial, which builds on the promising results seen in an earlier Phase II trial in severe sepsis using the Company, is to generate additional meaningful clinical data with oral talactoferrin in severe sepsis using the Company's existing financial resources.

The U.S. Food and Drug Administration (FDA) has strongly recommended that Agennix conduct two adequate and well-controlled Phase III studies to support a potential Biologic License Application (BLA) submission for talactoferrin in this indication. The planned Phase II/III trial incorporates the initial Phase III trial the Company plans to conduct. The Company expects to review with regulatory authorities the results of the Phase II part of the OASIS trial after they are available.

In addition to oral talactoferrin, the Company has a topical gel formulation of talactoferrin. A clinical trial with this formulation has been completed in 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 is also developing RGB-286638, a multi-targeted kinase inhibitor. A Phase I trial in advanced solid tumors is ongoing and preliminary results from the study have been presented. The Company plans to complete this clinical trial. However, additional clinical testing will not be initiated with this compound at this time as the Company is focusing its resources on talactoferrin.

## Agennix AG Management and Supervisory Boards

#### Management Board

Effective March 1, 2011, 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. Dr. Friedrich von Bohlen und Halbach's term as interim Chief Executive Officer expired on February 28, 2011.

## Supervisory Board

On February 14, 2011, Alan Feinsilver filled the Supervisory Board seat opened by the resignation of Dr. Robert van Leen, which was announced in November 2010.

On March 4, 2011, Dr. Juergen Drews informed the Company that he was resigning from the Board. Dr. von Bohlen und Halbach filled this seat.

As of June 30, 2011, 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 June 30, 2011, 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. 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, 2010 (2010 Annual Report). Also refer to Note 2 to the accompanying interim condensed consolidated financial statements.

In December 2009, the Company was served with a lawsuit filed by certain shareholders of the Company in the local court in Munich, Germany commencing appraisal proceedings in accordance with Section 15 of the German Transformation Act (*Umwandlungsgesetz*), and seeking judicial review of the fairness of the exchange ratio set forth in the merger agreement pursuant to which shares of GPC Biotech AG were exchanged for shares of Agennix AG. Other shareholders commenced similar proceedings in January and February 2010 and the proceedings were consolidated before the same court in Munich. The plaintiffs sought an additional cash payment to certain shareholders of the Company.

On February 11, 2011, the court issued a decision rejecting the claims of the plaintiffs for an additional cash payment and ordered that the Company pay the court costs and out–of-court costs of the plaintiffs. The Company estimated the expense relating to this ruling to be approximately  $\in 0.3$  million, which was accrued at December 31, 2010 and included in administrative expense for the year then ended. Two shareholders filed an appeal to the court's decision, which is now under review by an appellate court. Management believes that the appeal is without merit and no additional provision was recognized in connection with this litigation.

## 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. Such statements are based on current expectations and are subject to risks and uncertainties, many of which are beyond the Company's control, that could cause future results, performance or achievements to differ significantly from the results, performance or achievements 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 second half of 2012. Even if the results from later stage trials with talactoferrin, including the ongoing FORTIS-M trial in non-small cell lung cancer, 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. 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 provided the following financial guidance:

## Revenues

Management expects no substantial cash generating revenues for the remainder of 2011 or for 2012. 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.

## R&D expenses

For 2011 and 2012, the Company expects R&D expenses to increase compared to 2010 due to an expected increase in talactoferrin clinical trial-related costs. Enrollment in the talactoferrin Phase III FORTIS-M trial in NSCLC was completed in March 2011. Agennix initiated the OASIS Phase II/II trial with talactoferrin in severe sepsis in June 2011. Please refer to the "Research and Development" section of this Management Report for further information.

## Administrative expenses

Administrative expenses for the remainder of 2011 and 2012 are expected to increase slightly compared to 2010 as the Company engages in certain critical pre-commercialization activities.

## Cash position

Management believes that the Company will have sufficient cash to fund its operations well into the second half of 2012. This should enable the Company to obtain top-line data in the FORTIS-M trial, expected in the first half of 2012, and to complete the Phase II portion of OASIS trial, assuming no significant changes to current projected timelines. This projected cash reach also assumes that the € 15 million loan made to the Company by dievini in 2010 will not need to be re-paid prior to the release of top-line results from both the FORTIS-M trial and the OASIS trial. 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. Management is currently evaluating various options to further finance the Company past the second half of 2012.

## Key activities

The Company is focused on advancing its lead development program, oral talactoferrin. Enrollment in the talactoferrin FORTIS-M trial was completed in March 2011, and topline data are expected to be available in the first half of 2012. Should the data so warrant, Agennix would then prepare to submit marketing authorizations to the FDA and European Medicines Agency ("EMA") requesting marketing approval of talactoferrin. The Company initiated the Phase II portion of the Phase II/III OASIS trial in severe sepsis in June 2011. Should the data from the Phase II portion so warrant, the Company then plans to initiate the Phase III part of the trial. It is expected that data from clinical trials with talactoferrin will continue to be presented at major medical meetings and published in peer-reviewed medical journals. The Company is seeking a commercial partner or partners for oral talactoferrin.

## Agennix AG Interim consolidated statement of operations

|   | Th<br>Note        | nree months end<br>2011<br>(unaudited)<br>€000         | ded June 30,<br>2010<br>(unaudited)<br>€000            | Six months end<br>2011<br>(unaudited)<br>€000 | led June 30,<br>2010<br>(unaudited)<br>€000             |
|---|-------------------|--|--|---|---|
| Revenue   |                   | -  | -  | -   | -   |
| Research and development<br>expenses<br>Administrative expenses<br>Amortization of intangible assets<br>Other income<br>Other expenses<br>Finance income<br>Finance costs | 3<br>1, 3<br>1, 3 | (8,320)<br>(2,177)<br>(3)<br>9<br>(500)<br>65<br>(226) | (6,635)<br>(2,306)<br>(11)<br>2,850<br>(1)<br>4<br>(2) | (4,470)<br>(4)<br>9                           | (11,612)<br>(4,395)<br>(50)<br>3,970<br>(1)<br>5<br>(4) |
| Net loss before tax   |                   | (11,152)   | (6,101)  | (22,650)                                      | (12,087)  |
| Income tax benefit  | -                 | 2,818  | 2,248  | 5,723   | 3,905   |
| Net loss for the period   | -                 | (8,334)  | (3,853)  | (16,927)                                      | (8,182)   |
| Basic and diluted loss per share,<br>euro<br>Average number of shares used<br>in computing basic and diluted  |                   | (€0.20)  | (€0.19)  | (€0.40)                                       | (€0.42)   |
| loss per share  |                   | 41,913,591   | 20,589,577   | 41,906,171                                    | 19,658,314  |

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

|   | Three months e<br>2011<br>(unaudited)<br>€000 | ended June 30,<br>2010<br>(unaudited)<br>€000 | Six months en<br>2011<br>(unaudited)<br>€000 | ded June 30,<br>2010<br>(unaudited)<br>€000 |
|---|---|---|--|---|
| Net loss  | (8,334)                                       | (3,853)                                       | (16,927)                                     | (8,182)                                     |
| Other comprehensive (loss) income:<br>Exchange differences on translating |   |   |  |   |
| foreign operations (Note 3)   | (1,925)                                       | 6,206   | (8,177)                                      | 10,301                                      |
|   | (1,925)                                       | 6,206   | (8,177)                                      | 10,301                                      |
| Total comprehensive (loss) income   | (10,259)                                      | 2,353   | (25,104)                                     | 2,119                                       |

## Agennix AG Interim consolidated statement of financial position

|   | Note | June 30, 2011<br>(unaudited)<br>€000                       | December 31, 2010<br>€000                                |
|---|------|--|--|
| ASSETS  |      |  |  |
| Non-current assets  |      |  |  |
| Property and equipment  |      | 3,226  | 3,462  |
| Intangible assets   | 3    | 91,751   | 99,466   |
| Other non-current assets  |      | 1,969  | 2,153  |
| Total non-current assets  |      | 96,946   | 105,081  |
| Current assets  |      |  |  |
| Trade receivables   |      | -  | 4  |
| Prepayments   |      | 293  | 316  |
| Other current assets  |      | 1,398  | 1,443  |
| Other current financial assets  |      | 37,806   | 30,197   |
| Cash and cash equivalents   | -    | 16,295   | 49,016   |
| Total current assets  |      | 55,792   | 80,976   |
| TOTAL ASSETS  | =    | 152,738  | 186,057  |
| EQUITY AND LIABILITIES<br>Equity attributable to the Company's equity holders<br>Issued capital<br>Share premium<br>Other reserves<br>Retained loss<br>Total equity | 3    | 41,906<br>151,153<br>(4,701)<br>(60,426)<br><b>127,932</b> | 41,884<br>150,931<br>3,476<br>(43,499)<br><b>152,792</b> |
| Non-current liabilities   |      |  |  |
| Convertible bonds   |      | 210  | 210  |
| Other non-current liabilities   |      | 8  | 18   |
| Deferred tax liability  | 3    | 1,449  | 7,631  |
| Total non-current liabilities   |      | 1,667  | 7,859  |
| Current liabilities   |      |  |  |
| Trade payables  |      | 2,294  | 5,020  |
| Accruals and other liabilities  |      | 5,007  | 4,994  |
| Note payable  | 3_   | 15,838   | 15,392   |
| Total current liabilities   |      | 23,139   | 25,406   |
| Total liabilities   |      | 24,806   | 33,265   |
| TOTAL EQUITY AND LIABILITIES  | =    | 152,738  | 186,057  |

|  | Six months ended June 30,<br>2010 as adjusted |                                 |  |  |
|--|---|---------------------------------|--|--|
|  | 2011<br>(unaudited)<br>€000                   | (Note 1)<br>(unaudited)<br>€000 |  |  |
| Cash flows from operating activities   |   |                                 |  |  |
| Net loss before tax for the period   | (22,650)                                      | (12,087)                        |  |  |
| Adjustments for:<br>Depreciation   | 292   | 390                             |  |  |
| Amortization   | 4<br>210                                      | 50                              |  |  |
| Compensation costs for share-based payments  | 1,213   | 472                             |  |  |
| Unrealized foreign exchange loss (gain) on monetary assets and liabilities<br>Finance income | (143)   | (3,836)                         |  |  |
| Finance income   | 451   | (5)<br>4                        |  |  |
| Net gain from the disposal of property and equipment   | (2)   | +                               |  |  |
|  | (20,625)                                      | (15,012)                        |  |  |
| <b>-</b>   |   |                                 |  |  |
| Decrease in other assets, non-current and current  | 109<br>4                                      | 203                             |  |  |
| Decrease in trade receivables  | (2,540)                                       | 35<br>(609)                     |  |  |
| Decrease in trade payables<br>Increase/(decrease) in accruals and other liabilities          | (2,540)<br>280                                | (1,909)                         |  |  |
| Cash used in operating activities  | (22,772)                                      | (17,292)                        |  |  |
| Interest received  |   | · · ·                           |  |  |
|  | 109   | 2                               |  |  |
| Interest paid  | (1)   | (2)                             |  |  |
| Net cash used in operating activities  | (22,664)                                      | (17,292)                        |  |  |
| Cash flows from investing activities   |   |                                 |  |  |
| Purchase of property, equipment and intangible assets  | (482)   | (179)                           |  |  |
| Proceeds from the sale of property, equipment and intangible assets                          | 5   | 4                               |  |  |
| Proceeds from the repayment of held to maturity investments upon their maturity              | 5,000   | -                               |  |  |
| Purchase of financial assets held for trading, net   | (14,459)                                      | (1,117)                         |  |  |
| Net cash used in investing activities  | (9,936)                                       | (1,292)                         |  |  |
| Cash flows from financing activities   |   |                                 |  |  |
| Proceeds from issuance of share capital in private placement                                 | -   | 9,764                           |  |  |
| Proceeds from the exercise of share options  | 34  | 143                             |  |  |
| Repayment of convertible bonds   | -   | (202)                           |  |  |
| Net cash provided by financing activities  | 34  | 9,705                           |  |  |
|  |   |                                 |  |  |
| Effect of exchange rate changes on cash and cash equivalents                                 | (154)   | 266                             |  |  |
| Changes in restricted cash   | (1)   | 2                               |  |  |
| Net decrease in cash and cash equivalents  | (32,721)                                      | (8,611)                         |  |  |
| Cash and cash equivalents at beginning of period   | 49,016  | 11,413                          |  |  |
| Cash and cash equivalents at end of period   | 16,295  | 2,802                           |  |  |

## Agennix AG Interim consolidated statement of changes in equity

|                                      |            | Issued  | Share   | Retained | Conv. | Foreign<br>transl. | Total    |
|--------------------------------------|------------|---------|---------|----------|-------|--------------------|----------|
|                                      | Shares     | capital | premium | loss     | bonds | reserve            | equity   |
| in €000, excluding number of shares  |            |         |         |          |       |                    |          |
| Balance at January 1, 2010           | 18,705,232 | 18,705  | 86,237  | (16,497) | 720   | (2,583)            | 86,582   |
| Loss for the period                  | -          | -       | -       | (8,182)  | -     | -                  | (8,182)  |
| Other comprehensive income           | -          | -       | -       | -        | -     | 10,301             | 10,301   |
| Total comprehensive income (loss)    | -          | -       | -       | (8,182)  | -     | 10,301             | 2,119    |
| Issue of share capital – March 2010  |            |         |         |          |       |                    |          |
| private placement                    | 1,870,523  | 1,871   | 7,893   | -        | -     | -                  | 9,764    |
| Exercise of share options            | 90,771     | 91      | 52      | -        | -     | -                  | 143      |
| Compensation costs for               |            |         |         |          |       |                    |          |
| share-based payments                 | -          | -       | 472     | -        | -     | -                  | 472      |
| Balance at June 30, 2010 (unaudited) | 20,666,526 | 20,667  | 94,654  | (24,679) | 720   | 7,718              | 99,080   |
| Balance at January 1, 2011           | 41,884,176 | 41,884  | 150,931 | (43,499) | 720   | 2,756              | 152,792  |
| Loss for the period                  | -          | -       | -       | (16,927) | -     | -                  | (16,927) |
| Other comprehensive loss             | -          | -       | -       | -        | -     | (8,177)            | (8,177)  |
| Total comprehensive loss             | -          | -       | -       | (16,927) | -     | (8,177)            | (25,104) |
| Exercise of share options            | 21,698     | 22      | 12      | -        | -     | -                  | 34       |
| Compensation cost for                |            |         |         |          |       |                    |          |
| share-based payments                 |            | -       | 210     | -        | -     | -                  | 210      |
| Balance at June 30, 2011 (unaudited) | 41,905,874 | 41,906  | 151,153 | (60,426) | 720   | (5,421)            | 127,932  |

## 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 improve the length and quality of life 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 six months ended June 30, 2011, 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 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, 2010, contained in the Annual Report of Agennix AG for the year ended December 31, 2010 ("2010 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, 2010, except for the adoption of new standards and interpretations as of January 1, 2011, as noted below:

## IAS 24, Related Party Disclosures, (Revised)

The revised standard is effective for annual periods beginning on or after January 1, 2011. It clarifies the definition of a related party to simplify the identification of such relationships and to eliminate inconsistencies in its application. The revised standard introduces a partial exemption of disclosure requirements for government-related entities. The Company has adopted this revision, effective January 1, 2011. The adoption of this standard did not have any impact on the financial position or performance of the Company.

## Improvements to IFRSs (issued in May 2010)

In May 2010, the International Accounting Standards Board (IASB) issued *Improvements to IFRSs*, an omnibus of amendments to its IFRS standards, primarily with a view to removing inconsistencies and clarifying wording. There are separate transitional provisions for each standard. The adoption of the following amendments effective January 1, 2011, resulted in changes to accounting policies but did not have any impact on the financial position or performance of the Company:

- IFRS 3, Business Combinations
- IFRS 7, Financial Instruments: Disclosures
- IAS 1, Presentation of Financial Statements
- IAS 27, Consolidated and Separate Financial Statements
- IAS 34, Interim Financial Reporting

## IFRIC 19, Extinguishing Financial Liabilities with Equity Instruments

IFRIC 19 is effective for annual periods beginning on or after July 1, 2010. The interpretation clarifies that equity instruments issued to a creditor to extinguish a financial liability qualify as consideration paid. The equity instruments issued are measured at their fair value. If fair value cannot be reliably measured, the instruments are measured at the fair value of the liability extinguished. Any gain or loss is recognized immediately in profit or loss. The Company has adopted this standard, effective January 1, 2011. The adoption of this standard did not have any impact on the financial position or performance of the Company.

Beginning with the third quarter of 2010, the Company decided to present foreign exchange gains and losses arising from routine purchases, transfers of U.S. dollars in intercompany settlements, and translation of regular intercompany accounts on a net basis as other income or other expense, as appropriate, in order to avoid inflating line items of the statement of operations in case of significant fluctuations of foreign exchange rates. Accordingly, the comparative financial information for the three and six months ended June 30, 2010, was adjusted. In the consolidated statement of operations for the three and six months ended June 30, 2010, other income and other expense were decreased by approximately  $\leq 0.1$  million and  $\leq 0.6$  million respectively.

It is the Company's accounting policy to classify its investments in money market funds as financial assets at fair value through profit or loss and present them within other current financial assets in the consolidated statement of financial position. Purchases and sales of investments in money market funds are presented on a net basis within cash flows from investing activities in the consolidated statement of cash flows. To conform with its accounting policies, the Company was required to reclassify amounts previously reported in the interim consolidated statements of cash flows. Below is a summary of the adjustments to the comparative interim consolidated statement of cash flows for the six months ended June 30, 2010:

|  | As previously |             |
|--|---------------|-------------|
| €000                                       | reported      | As adjusted |
| Net cash used in investing activities      | (175)         | (1,292)     |
| Net decrease in cash and cash equivalents  | (7,494)       | (8,611)     |
| Cash and cash equivalents at end of period | 3,919         | 2,802       |

## 2. Commitments and Contingencies

## Commitments

The Company has a manufacturing and supply agreement with DSM Capua S.p.A. (DSM) to supply the Company with talactoferrin bulk drug substance. This agreement, which includes an annual minimum purchase commitment of  $\in$  1.8 million, automatically renews on January 1, of each year, for an additional one-year term unless terminated by either party with an 18-month written notice. In addition, the Company has an agreement with DSM to expand the existing production facility. Total estimated cost of the expansion is approximately  $\in$  0.5 million. As of June 30, 2011 the Company's remaining total minimum purchase commitment to DSM for 2011 and 2012 would amount to  $\in$  3.4 million.

## 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 these and future 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. In accordance with IAS 37, *Provisions, Contingent Liabilities and Contingent Assets*, (IAS 37), 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.

#### Litigation related to the merger

In December 2009, the Company was served with a lawsuit filed by certain shareholders the Company in the local court in Munich, Germany commencing appraisal proceedings in accordance with Section 15 of the German Transformation Act (*"Umwandlungsgesetz"*), and seeking judicial review of the fairness of the exchange ratio set forth in the merger agreement pursuant to which shares of GPC Biotech AG were exchanged for shares of Agennix AG. Other shareholders commenced similar proceedings in January and February 2010 and the proceedings were consolidated before the same court in Munich. The plaintiffs sought an additional cash payment to certain shareholders of the Company.

On February 11, 2011, the court issued a decision rejecting the claims of the plaintiffs for an additional cash payment and ordered that the Company pay the court costs and out–of-court costs of the plaintiffs. The

Company estimated the expense relating to this ruling to be approximately  $\in 0.3$  million which was accrued at December 31, 2010, and included in administrative expenses for the year then ended. Two shareholders filed an appeal to the court's decision which is now under review by an appellate court. Management believes that the appeal is without merit and no additional provision has been recognized in connection with this litigation.

## 3. Additional Disclosures

## Financial position

During the six month period ended June 30, 2011, the Company incurred a net loss of  $\in$  16.9 million (net loss before tax of  $\in$  22.7 million) and used cash in its operations of  $\in$  22.7 million. At June 30, 2011, the Company had cash, cash equivalents, other current financial assets and restricted cash of  $\in$  54.2 million and current liabilities of  $\in$  23.1 million, including the  $\in$  15 million short-term loan from dievini Hopp BioTech holding GmbH & Co. KG ("dievini"), and accrued interest thereon of  $\in$  0.8 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 well into the second half of 2012. This should enable the Company to obtain top-line data in the FORTIS-M trial in NSCLC, expected in the first half of 2012, and to complete the Phase II portion of the OASIS trial with talactoferrin in severe sepsis that was initiated at the end of the second quarter of 2011, assuming no significant changes to currently projected timelines. This projected cash reach also assumes that the € 15 million loan made to the Company by dievini will not need to be repaid prior to the release of top-line results from both the FORTIS-M trial and the Phase II portion of the OASIS trial. 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. Management is currently evaluating various options to further finance the Company past the second half of 2012.

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

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

Research and development (R&D) expenses for the six months ended June 30, 2011 increased 43% to  $\in$  16.6 million compared to  $\in$  11.6 million for the same period in 2010. The increase in R&D expenses is primarily due to increased patient enrollment in the Company's Phase III FORTIS-M trial with talactoferrin in non-small cell lung cancer (NSCLC) and preparation for the Phase II/III OASIS trial with talactoferrin in severe sepsis, which was initiated at the end of the second quarter of 2011.

## Other income/other expense

During the first six months of 2010 the euro weakened against the U.S. dollar. As a result, the Company recognized approximately  $\in$  4.0 million in net foreign exchange gains as other income. During the remainder of 2010 and the first half of 2011, the euro rebounded significantly against the U.S. dollar. As a result, the Company recognized approximately  $\in$  1.3 million in net foreign exchange losses as other expenses in the first half of 2011. This resulted in a swing in Other income/Other expenses of approximately  $\in$  5.3 million during the first six months of 2011 when compared to the same period in 2010.

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. Although intercompany balances and transactions are eliminated when 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 8% to  $\in$  91.8 million at June 30, 2011, from  $\in$  99.5 million at December 31, 2010. 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 and during the first six months of 2011, the euro rebounded significantly against the U.S. dollar. The decrease was slightly offset by purchases of intangible assets during the second quarter of 2011 relating to the annual license fee paid to Baylor College of Medicine for talactoferrin.

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 based on its estimated fair value less cost to sell. The key assumptions used to determine the recoverable amount were discussed in Note 19 of the 2010 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 has not identified factors which would indicate that the talactoferrin-related intangible asset may be impaired as of June 30, 2011. The assumptions used to estimate the asset's recoverable amount as of December 31, 2010, remain valid as of June 30, 2011.

## 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 six months of 2011, the Company recognized a deferred tax benefit of  $\in$  5.7 million ( $\in$  3.9 million for the same period of 2010) in connection with the net operating losses incurred by the Company's subsidiary, Agennix Incorporated, during this period. The decrease in the net deferred tax liability as of June 30, 2011, compared to December 31, 2010, was due to the recognition of additional deferred tax asset and fluctuations in the exchange rate of approximately  $\in$  0.5 million.

#### Short-term note payable

On July 23, 2010, the Company entered into an agreement with dievini Hopp BioTech holding GmbH & Co. KG ("dievini") pursuant to which dievini provided a  $\in$  15 million loan to Agennix AG at an interest rate of 6% per annum. The loan is unsecured and is payable on demand with thirty days advance notice. As of the date of these interim condensed consolidated financial statements, the Company has not received a notice requiring repayment of the outstanding balance of the loan and interest accrued thereon. Dievini is a related party to the Company because dievini holds more than 50% of the Company's outstanding stock. The outstanding balance of the loan, including accrued interest, amounted to approximately  $\in$  15.8 million as of June 30, 2011. The Company has not made any payments in 2011 under this loan agreement.

## Exchange differences on translating foreign operations

The functional currency of the Company's subsidiaries, Agennix Incorporated 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 2011, the Company recognized other comprehensive loss of  $\in 8.2$  million due to negative foreign exchange differences on translating foreign operations (other comprehensive income of  $\in 10.3$  million for the same period of 2010). During the six months ended June 30, 2011, the euro strengthened against the U.S. dollar compared to the weakened euro in the first six months of 2010, resulting in a swing in positive/negative exchange differences on translating foreign operations of approximately  $\in 18.5$  million. Other reserves in the statement of financial position are primarily comprised of exchange differences on translating foreign operations of approximately  $\in 18.5$  million. Other reserves in the statement of financial position are primarily comprised of exchange differences on translating foreign operations of approximately  $\in 18.5$  million. Other reserves in the statement of financial position are primarily comprised of exchange differences on translating foreign operations of approximately  $\in 18.5$  million compared to a positive  $\in 3.5$  million as of December 31, 2010).

#### Number of employees

As of June 30, 2011 and 2010, the total number of Agennix employees was 63 and 52, respectively.

## Shareholdings of management

As of June 30, 2011, 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   |
|--|-----------|-----------|-------------|
|  | Number of | Number of | Convertible |
|  | Shares    | Options   | Bonds       |
| Management Board                         |           |           |             |
| Torsten Hombeck, Ph.D. <sup>(*)</sup>    | 10,000    | 165,186   | -           |
| Rajesh Malik, M.D.                       | -         | 199,490   | -           |
| Supervisory Board                        |           |           |             |
| Christof Hettich, L.L.D. (Chairman)      | -         | -         | -           |
| Frank Young, M.D., Ph.D. (Vice Chairman) | -         | 30,664    | -           |
| Friedrich von Bohlen und Halbach, Ph.D.  | -         | -         | -           |
| Alan Feinsilver                          | 37,072    | -         | -           |
| Bernd Seizinger, M.D., Ph.D. (**)        | 165,000   | 78,000    | 17,701      |
| James Weaver III                         | 99,016    | -         | -           |
|  |           |           |             |

(\*) Subsequent to the period end Dr. Hombeck purchased an additional 1,870 shares on the open market.

(\*\*) Subsequent to the period end Dr. Seizinger purchased an additional 5,000 shares on the open market.

## **Related parties**

During the six months ended June 30, 2011, the Company paid approximately  $\in$  22,000 (first six months of 2010:  $\in$  123,000) to Rittershaus, a related party to the Company, for legal services and had accrued expenses of approximately  $\in$  132,000 at June 30, 2011 ( $\in$  30,000 at December 31, 2010). 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 six months ended June 30, 2011, the Company paid approximately  $\in$  23,000 (first six months of 2010:  $\in$  34,000) to Dr. Frank Young, a related party to the Company, for consulting and other services and had accrued expenses of  $\in$  0 at June 30, 2011 ( $\in$  1,000 at December 31, 2010). 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 six months ended June 30, 2011, the Company paid approximately € 106,000 (first six months of 2010: € 50,000) to LIFE Biosystems, a related party to the Company, and had accrued expenses of €0 at June

30, 2011 and at December 31, 2010. LIFE Biosystems 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 LIFE Biosystems, which currently performs external R&D for Agennix.

## **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.

August 4, 2011

mpl

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Malle

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## Contacts

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