



**Agennix AG**  
**Interim Report**  
**January - March 2011**

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## **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 for the three months ended March 31, 2011 and 2010.

Research and development (R&D) expenses for the three months ended March 31, 2011, increased 64% to € 8.2 million compared to € 5.0 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 3 FORTIS-M trial with talactoferrin and preparation for the planned Phase 2/3 trial with talactoferrin in severe sepsis.

Administrative expenses for the three months ended March 31, 2011, increased 10% to € 2.3 million, from € 2.1 million for the same period in 2010 due mainly to the Company engaging in certain critical pre-commercialization activities.

Net loss before tax for the three months ended March 31, 2011, increased 92% to € 11.5 million compared to € 6.0 million for the same period in 2010. Income tax benefit for the three months ended March 31, 2011, amounted to € 2.9 million (€ 1.7 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 three months ended March 31, 2011, increased 100% to € 8.6 million compared to € 4.3 million for the same period in 2010. Basic and diluted loss per share was € (0.21) for the three months ended March 31, 2011, compared to € (0.23) for the same period in 2010.

### ***Financial position***

During the three months period ended March 31, 2011, the Company incurred a net loss of € 8.6 million (net loss before tax of € 11.5 million) and used cash in its operations of € 11.5 million. At March 31, 2011, the Company had cash, cash equivalents, other current financial assets and restricted cash of € 66.2 million and current liabilities of € 22.7 million, including the € 15 million short-term loan from dievini and accrued interest thereon of € 0.6 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, expected in the first half of 2012, and to complete the Phase 2 portion of the planned Phase 2/3 trial with talactoferrin in severe sepsis, 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, will not need to be re-paid prior to the release of top-line results from both the FORTIS-M trial and the Phase 2 portion of the Phase 2/3 trial in severe sepsis. 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.

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

As of March 31, 2011, cash, cash equivalents, other current financial assets and restricted cash totaled € 66.2 million (December 31, 2010: € 79.3 million). Net cash burn for the three months ended March 31, 2011, was € 11.5 million (March 31, 2010: € 7.6 million). The increase in net cash burn was mainly due to clinical trial costs related to increased patient enrollment in the Company's Phase 3 FORTIS-M trial and preparations for the planned Phase 2/3 trial in severe sepsis. 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 biologic therapy that has been shown to impact the immune system and also has anti-bacterial properties. Oral talactoferrin is being studied for the treatment of cancer and severe sepsis and has demonstrated activity in randomized, double-blind, placebo-controlled Phase 2 studies in non-small cell lung cancer (NSCLC), as well as in severe sepsis.

Two Phase 3 trials with oral talactoferrin are currently ongoing. Enrollment in the Phase 3 FORTIS-M trial evaluating talactoferrin for the treatment of NSCLC was completed in March 2011. The FORTIS-M trial is a randomized, double-blind, placebo-controlled study evaluating talactoferrin plus best supportive care compared to placebo plus best supportive care in patients with NSCLC whose disease has progressed following two or more prior treatment regimens.

Agennix is conducting a second Phase 3 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.

Data from a randomized, double-blind, placebo-controlled Phase 2 trial evaluating oral talactoferrin in severe sepsis were presented at international medical conferences in the first quarter of 2011. In this trial, talactoferrin was shown to significantly reduce 28-day all-cause mortality and this effect was sustained over longer time periods of three and six months. Talactoferrin was well tolerated in this patient population. A Phase 2/3 trial evaluating talactoferrin in patients with severe sepsis is expected to begin during the second quarter of 2011. This Phase 2/3 trial will have two distinct components. A randomized, double-blind, placebo-controlled Phase 2 portion in approximately 350 adult patients with severe sepsis will be conducted prior to initiating the Phase 3 portion. The purpose of this Phase 2 component, which builds on the promising results seen in the first Phase 2 trial conducted by 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 3 studies to support a potential Biologic License Application (BLA) submission for talactoferrin in this indication. The planned Phase 2/3 trial incorporates the initial Phase 3 trial the Company plans to conduct. The Company expects to review with regulatory authorities the results of the Phase 2 study 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 1 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***

Dr. Friedrich von Bohlen und Halbach's term as interim Chief Executive Officer expired on February 28, 2011. Effective March 1, 2011, as resolved by the Supervisory Board, the Company is being led by a two-person Management Board comprised of Dr. Torsten Hombeck, Chief Financial Officer, and Dr. Rajesh Malik, Chief Medical Officer. Dr. Hombeck also was appointed to serve as spokesperson of the Management Board.

### **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 is filling this seat.

As of March 31, 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.

Shareholdings of the members of the Company's Management Board and Supervisory Board as of March 31, 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 former shareholders of GPC Biotech AG 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 former shareholders of GPC Biotech AG commenced similar proceedings in January and February 2010 and the proceedings have been consolidated before the same court in Munich. The plaintiffs sought an additional cash payment to former shareholders of GPC Biotech AG.

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 €0.3 million which was accrued at December 31, 2010 and included in administrative expense for the year then ended. The plaintiffs had the right to appeal the decision until March 21, 2011, and two shareholders did file an appeal to the court's decision. Management believes that the appeals are 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 financial projections and forecasts relating to the Company's operations and financial situation, as well as statements about the Company's development programs. Such statements are subject to risks and uncertainties. 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.

### ***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 3 FORTIS-M trial in NSCLC was completed in March 2011. Agennix is also planning to initiate a Phase 2/3 trial with talactoferrin in severe sepsis. Please refer to "Research and development" section of this Management Report for further information.

*Administrative expenses:* Administrative expenses in 2011 and 2012 are expected to increase compared to 2010 as the Company plans to initiate certain critical pre-commercialization efforts.

*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 2 portion of the planned Phase 2/3 trial with talactoferrin in severe sepsis, 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 Phase 2 portion of the Phase 2/3 trial in severe sepsis. The Company will need to raise additional funds through licensing agreements and/or through strategic and/or public equity or debt investments to fund the Company's operations beyond this point.

### ***Key activities***

The Company is focused on advancing its lead development program, oral talactoferrin.

The talactoferrin FORTIS-M trial in 3<sup>rd</sup>-line NSCLC achieved target enrollment 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 requesting

marketing approval of talactoferrin. The Company also expects to initiate the Phase 2 portion of a Phase 2/3 trial in severe sepsis during the second quarter of 2011. Should the data from the Phase 2 portion so warrant, the Company then plans to initiate the Phase 3 part of the trial. The Company is seeking a commercial partner or partners for oral talactoferrin.

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

|   |             | <b>Three months ended March 31,</b> |                    |
|---|-------------|-------------------------------------|--------------------|
|   |             | <b>2011</b>                         | <b>2010</b>        |
|   |             | <b>(unaudited)</b>                  | <b>(unaudited)</b> |
|   | <b>Note</b> | <b>€000</b>                         | <b>€000</b>        |
| <b>Revenue</b>  |             | -                                   | -                  |
| Research and development expenses   | <b>3</b>    | (8,238)                             | (4,977)            |
| Administrative expenses   |             | (2,293)                             | (2,089)            |
| Amortization of intangible assets   |             | (1)                                 | (39)               |
| Other income  | <b>1, 3</b> | -                                   | 1,119              |
| Other expenses  | <b>1, 3</b> | (820)                               | -                  |
| Finance income  |             | 78                                  | 1                  |
| Finance costs   |             | (225)                               | (2)                |
|   |             | <hr/>                               | <hr/>              |
| <b>Net loss before tax</b>  |             | <b>(11,499)</b>                     | <b>(5,987)</b>     |
| Income tax benefit  | <b>3</b>    | 2,905                               | 1,656              |
|   |             | <hr/>                               | <hr/>              |
| <b>Net loss for the period</b>  |             | <b>(8,594)</b>                      | <b>(4,331)</b>     |
|   |             | <hr/> <hr/>                         | <hr/> <hr/>        |
| Basic and diluted loss per share, euro                                      |             | (€0.21)                             | (€0.23)            |
| Average number of shares used in computing basic and diluted loss per share |             | 41,898,695                          | 18,706,253         |

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



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

|  | <b>Three months ended March 31,</b> |                     |
|--|-------------------------------------|---------------------|
|  | <b>2011</b>                         | <b>2010</b>         |
|  | <b>(unaudited)</b>                  | <b>(unaudited)</b>  |
|  | <b>€000</b>                         | <b>€000</b>         |
| <b>Net loss</b>  | <b>(8,594)</b>                      | <b>(4,331)</b>      |
| <b>Other comprehensive (loss) income:</b>                          |                                     |                     |
| Exchange differences on translating<br>foreign operations (Note 3) | (6,256)                             | 4,087               |
|  | <u>(6,256)</u>                      | <u>4,087</u>        |
| <b>Total comprehensive loss</b>                                    | <b><u>(14,850)</u></b>              | <b><u>(244)</u></b> |

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

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

|  | March 31, 2011<br>(unaudited) | December 31, 2010 |
|--|-------------------------------|-------------------|
| Note   | €000                          | €000              |
| <b>ASSETS</b>  |                               |                   |
| <b>Non-current assets</b>                                  |                               |                   |
| Property and equipment                                     | 3,121                         | 3,462             |
| Intangible assets  | 93,508                        | 99,466            |
| Other non-current assets                                   | 2,015                         | 2,153             |
| <b>Total non-current assets</b>                            | <b>98,644</b>                 | <b>105,081</b>    |
| <b>Current assets</b>                                      |                               |                   |
| Trade receivables  | -                             | 4                 |
| Prepayments  | 338                           | 316               |
| Other current assets                                       | 264                           | 1,443             |
| Other current financial assets                             | 47,513                        | 30,197            |
| Cash and cash equivalents                                  | 18,631                        | 49,016            |
| <b>Total current assets</b>                                | <b>66,746</b>                 | <b>80,976</b>     |
| <b>TOTAL ASSETS</b>  | <b>165,390</b>                | <b>186,057</b>    |
| <b>EQUITY AND LIABILITIES</b>                              |                               |                   |
| <b>Equity attributable to the Company's equity holders</b> |                               |                   |
| Issued capital   | 41,904                        | 41,884            |
| Share premium  | 151,085                       | 150,931           |
| Other reserves   | (2,780)                       | 3,476             |
| Retained loss  | (52,093)                      | (43,499)          |
| <b>Total equity</b>  | <b>138,116</b>                | <b>152,792</b>    |
| <b>Non-current liabilities</b>                             |                               |                   |
| Convertible bonds  | 210                           | 210               |
| Other non-current liabilities                              | 13                            | 18                |
| Deferred tax liability                                     | 4,358                         | 7,631             |
| <b>Total non-current liabilities</b>                       | <b>4,581</b>                  | <b>7,859</b>      |
| <b>Current liabilities</b>                                 |                               |                   |
| Trade payables   | 2,704                         | 5,020             |
| Accruals and other liabilities                             | 4,375                         | 4,994             |
| Note payable   | 15,614                        | 15,392            |
| <b>Total current liabilities</b>                           | <b>22,693</b>                 | <b>25,406</b>     |
| <b>Total liabilities</b>                                   | <b>27,274</b>                 | <b>33,265</b>     |
| <b>TOTAL EQUITY AND LIABILITIES</b>                        | <b>165,390</b>                | <b>186,057</b>    |

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

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

|  | <b>Three months ended March 31,</b> |                         |
|--|-------------------------------------|-------------------------|
|  | <b>2011</b>                         | <b>2010 as adjusted</b> |
|  | <b>(unaudited)</b>                  | <b>(Note 1)</b>         |
|  | <b>€000</b>                         | <b>(unaudited)</b>      |
|  |                                     | <b>€000</b>             |
| <b>Cash flows from operating activities</b>                                |                                     |                         |
| Net loss before tax for the period   | (11,499)                            | (5,987)                 |
| Adjustments for:   |                                     |                         |
| Depreciation   | 151                                 | 190                     |
| Amortization   | 1                                   | 39                      |
| Compensation costs for share-based payments                                | 142                                 | 408                     |
| Unrealized foreign exchange loss (gain) on monetary assets and liabilities | 879                                 | (1,086)                 |
| Finance income   | (78)                                | (1)                     |
| Finance costs  | 225                                 | 2                       |
| Net loss from the disposal of property and equipment                       | 3                                   | -                       |
|  | <u>(10,176)</u>                     | <u>(6,435)</u>          |
| Decrease /(increase) in other assets, non-current and current              | 1,173                               | (204)                   |
| Decrease in trade receivables  | 7                                   | 35                      |
| (Decrease) / increase in trade payables                                    | (2,152)                             | 2,079                   |
| Decrease in accruals and other liabilities                                 | (428)                               | (3,047)                 |
|  | <u>(11,576)</u>                     | <u>(7,572)</u>          |
| Cash used in operating activities  |                                     |                         |
| Interest received  | 73                                  | 1                       |
| Interest paid  | (1)                                 | -                       |
|  | <u>(11,504)</u>                     | <u>(7,571)</u>          |
| <b>Cash flows from investing activities</b>                                |                                     |                         |
| Purchase of property, equipment and intangible assets                      | (18)                                | (13)                    |
| Purchase of financial assets held for trading, net                         | (18,752)                            | (868)                   |
|  | <u>(18,770)</u>                     | <u>(881)</u>            |
| <b>Cash flows from financing activities</b>                                |                                     |                         |
| Proceeds from issuance of share capital in private placement               | -                                   | 9,764                   |
| Proceeds from the exercise of share options                                | 30                                  | 3                       |
| Repayment of convertible bonds   | -                                   | (202)                   |
|  | <u>30</u>                           | <u>9,565</u>            |
| Effect of exchange rate changes on cash and cash equivalents               | (142)                               | 92                      |
| Changes in restricted cash   | 1                                   | 2                       |
|  | <u>(30,385)</u>                     | <u>1,207</u>            |
| <b>Net (decrease) increase in cash and cash equivalents</b>                | <b>(30,385)</b>                     | <b>1,207</b>            |
| <b>Cash and cash equivalents at beginning of period</b>                    | <b>49,016</b>                       | <b>11,413</b>           |
| <b>Cash and cash equivalents at end of period</b>                          | <b>18,631</b>                       | <b>12,620</b>           |

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

**Agennix AG****Interim consolidated statement of changes in equity**

|   | Shares            | Issued capital | Share premium  | Retained loss   | Conv. bonds | Foreign transl. reserve | Total equity    |
|---|-------------------|----------------|----------------|-----------------|-------------|-------------------------|-----------------|
| in € 000, excluding number of shares                  |                   |                |                |                 |             |                         |                 |
| <b>Balance at January 1, 2010</b>                     | <b>18,705,232</b> | <b>18,705</b>  | <b>86,237</b>  | <b>(16,497)</b> | <b>720</b>  | <b>(2,583)</b>          | <b>86,582</b>   |
| Loss for the period                                   | -                 | -              | -              | (4,331)         | -           | -                       | (4,331)         |
| Other comprehensive income                            | -                 | -              | -              | -               | -           | 4,087                   | 4,087           |
| <b>Total comprehensive income (loss)</b>              | <b>-</b>          | <b>-</b>       | <b>-</b>       | <b>(4,331)</b>  | <b>-</b>    | <b>4,087</b>            | <b>(244)</b>    |
| Issue of share capital – March 2010 private placement | 1,870,523         | 1,871          | 7,893          | -               | -           | -                       | 9,764           |
| Exercise of share options                             | 2,200             | 2              | 1              | -               | -           | -                       | 3               |
| Compensation costs for share-based payments           | -                 | -              | 408            | -               | -           | -                       | 408             |
| <b>Balance at March 31, 2010 (unaudited)</b>          | <b>20,577,955</b> | <b>20,578</b>  | <b>94,539</b>  | <b>(20,828)</b> | <b>720</b>  | <b>1,504</b>            | <b>96,513</b>   |
| <b>Balance at January 1, 2011</b>                     | <b>41,884,176</b> | <b>41,884</b>  | <b>150,931</b> | <b>(43,499)</b> | <b>720</b>  | <b>2,756</b>            | <b>152,792</b>  |
| Loss for the period                                   | -                 | -              | -              | (8,594)         | -           | -                       | (8,594)         |
| Other comprehensive loss                              | -                 | -              | -              | -               | -           | (6,256)                 | (6,256)         |
| <b>Total comprehensive loss</b>                       | <b>-</b>          | <b>-</b>       | <b>-</b>       | <b>(8,594)</b>  | <b>-</b>    | <b>(6,256)</b>          | <b>(14,850)</b> |
| Exercise of share options                             | 19,565            | 20             | 12             | -               | -           | -                       | 32              |
| Compensation cost for share-based payments            | -                 | -              | 142            | -               | -           | -                       | 142             |
| <b>Balance at March 31, 2011 (unaudited)</b>          | <b>41,903,741</b> | <b>41,904</b>  | <b>151,085</b> | <b>(52,093)</b> | <b>720</b>  | <b>(3,500)</b>          | <b>138,116</b>  |

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

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

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

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

The Company is focused on the development of novel therapies that have the potential to substantially 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 three months ended March 31, 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 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, 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 clarified 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 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. In the case that 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 months ended March 31, 2010, was adjusted. In the consolidated statement of operations for the three months ended March 31, 2010, other income and other expense were decreased by approximately €0.5 million.

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 three months ended March 31, 2010:

| €000                                       | As previously reported | As adjusted |
|--|------------------------|-------------|
| Net cash used in investing activities      | (13)                   | (881)       |
| Net increase in cash and cash equivalents  | 2,075                  | 1,207       |
| Cash and cash equivalents at end of period | 13,488                 | 12,620      |

## 2. Commitments and Contingencies

In 2010, the Company entered into an agreement with DSM Capua S.p.A. (Italy) on further expansion of the existing production facility. Total estimated cost of the expansion is approximately €0.5 million representing the Company's purchase commitment as of March 31, 2011.

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 International Accounting Standard No. 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 former shareholders of GPC Biotech AG 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 former shareholders of GPC Biotech AG 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 former shareholders of GPC Biotech AG.

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 €0.3 million which was accrued at December 31, 2010, and included in administrative expenses for the year then ended. The plaintiffs had the right to appeal the decision until March 21, 2011, and two shareholders filed an appeal to the court's decision. Management believes that the appeals are without merit and no additional provision has been recognized in connection with this litigation.

### **3. Additional Disclosures**

#### ***Financial position***

During the three month period ended March 31, 2011, the Company incurred a net loss of € 8.6 million (net loss before tax of € 11.5 million) and used cash in its operations of € 11.5 million. At March 31, 2011, the Company had cash, cash equivalents, other current financial assets and restricted cash of € 66.2 million and current liabilities of € 22.7 million, including the € 15 million short term loan from dievini and accrued interest thereon of € 0.6 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, expected in the first half of 2012, and to complete the Phase 2 portion of the planned Phase 2/3 trial with talactoferrin in severe sepsis, 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 re-paid prior to the release of top-line results from both the FORTIS-M trial and the Phase 2 portion of the Phase 2/3 trial in severe sepsis. 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.

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 three months ended March 31, 2011 increased 64% to € 8.2 million compared to € 5.0 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 3 FORTIS-M trial with talactoferrin and preparation for the planned Phase 2/3 trial with talactoferrin in severe sepsis.

#### ***Other income / other expense***

The functional currency of Agennix AG is the Euro. Foreign exchange gains or losses arise mainly on U.S. dollar-denominated intercompany receivables, including, in the past, promissory note receivable, 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*", intercompany receivables represent a commitment to convert one currency into another, and expose Agennix AG to a gain or loss through currency fluctuations.



During the first three months of 2010 the Euro weakened against the U.S. dollar. As a result the Company recognized approximately € 1.1 million net foreign exchange gains as Other income. During the three months ended March 31, 2011 the Euro rebounded significantly against the U.S. dollar. As a result, the Company recognized approximately € 0.8 million net foreign exchange losses as Other expenses in the first quarter of 2011.

### ***Intangible assets***

Intangible assets decreased 6% to € 93.5 million at March 31, 2011, from € 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 three months of 2011 the Euro rebounded significantly against the U. S. dollar.

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's studies with talactoferrin and feedback from the medical community. Based on these criteria, the Company has not identified factors which would indicate that the talactoferrin-related intangible asset may be impaired as of March 31, 2011. The assumptions used to estimate the asset's recoverable amount as of December 31, 2010 remain valid as of March 31, 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 three months of 2011, the Company recognized a deferred tax benefit of € 2.9 million (€ 1.7 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 March 31, 2011, as compared to December 31, 2010, was due to the recognition of additional deferred tax asset and fluctuations in the exchange rate of approximately € 0.3 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 € 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 balance of loan including accrued interest amounted to approximately €15.6 million as of March 31, 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 three months of 2011, the Company recognized other comprehensive loss of €6.3 million due to negative foreign exchange differences on translating foreign operations (other comprehensive income of €4.1 million for the same period of 2010). During the three months ended March 31, 2011 the Euro strengthened against the U.S. dollar, as compared to the weakened Euro in the first three months of 2010, resulting in a swing in positive/negative exchange differences on translating foreign operations of approximately €10.4 million. Other reserves in the statement of financial position comprising mostly the effects of exchange differences on translating foreign operations amounted to negative €2.8 million as of March 31, 2011 (a decrease of €6.3 million as compared to positive €3.5 million as of December 31, 2010).

### ***Number of employees***

As of March 31, 2011 and 2010 Agennix AG employees totalled 59.

### ***Shareholdings of management***

As of March 31, 2011, the members of the Company's Management Board and Supervisory Board held shares, stock options, and convertible bonds in Agennix AG in the amounts set forth in the table below:

|  | <b>Number of Shares</b> | <b>Number of Options</b> | <b>Number of Convertible Bonds</b> |
|--|-------------------------|--------------------------|------------------------------------|
| <b>Management Board</b>                  |                         |                          |                                    |
| Torsten Hombeck, Ph.D.                   | 10,000                  | 165,186                  | -                                  |
| Rajesh Malik, M.D.                       | -                       | 199,490                  | -                                  |
| <b>Supervisory Board</b>                 |                         |                          |                                    |
| Christof Hettich, LL.D. (Chairman)       | -                       | -                        | -                                  |
| Frank Young, M.D., Ph.D. (Vice Chairman) | -                       | 30,664                   | -                                  |
| Friedrich von Bohlen und Halbach, Ph.D.  | -                       | -                        | -                                  |
| Bernd Seizinger, M.D., Ph.D.             | 162,000                 | 78,000                   | 17,701                             |
| Alan Feinsilver                          | 7,658                   | -                        | -                                  |
| James Weaver III                         | 99,016                  | -                        | -                                  |

### ***Related parties***

During the three months ended March 31, 2011, the Company paid approximately € 9,000 (the first three months of 2010: € 26,000) to Rittershaus, a related party to the Company, for legal services, and had accrued expenses of approximately € 70,000 at March 31, 2011 (€30,000 at December 31, 2010). Rittershaus is a related party to the Company because the Chairman of the Company's Supervisory Board, Dr. Christof Hettich, is a partner at this firm which currently advises the Company in matters of law.

During the three months ended March 31, 2011, the Company paid approximately € 1,000 (the first three months of 2010: € 0) to Dr. Frank Young, a related party to the Company, for consulting and other services, and had € 11,000 of accrued expenses at March 31, 2011 (€1,000 at December 31, 2010). Dr. Young is a related party to the Company because he is the Vice Chairman of the Company's Supervisory Board and also advises the Company with respect to regulatory matters and drug development, pursuant to a separate consulting agreement between the two parties.

During the three months ended March 31, 2011, the Company paid approximately € 6,000 (the first three months of 2010: € 0) to LIFE Biosystems, a related party to the Company, and had € 0 of accrued expenses at March 31, 2011 and at December 31, 2010. LIFE Biosystems is a related party to the Company because Dr. Friedrich von Bohlen und Halbach is the Chairman of the Supervisory Board of LIFE Biosystems' Supervisory Board, which currently performs external R&D for the Company.

## Responsibility Statement

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

May 4, 2011



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Dr. Torsten Hombeck



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Dr. Rajesh Malik