

# **Hansa Medical**

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Annual Report for 2014

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## The year in brief

### 2014 in figures

- › Net sales for the group amounted to KSEK 4,716 for the 2014 financial year, as compared with KSEK 1,727 for the 2013 financial year.
- › The loss for the year after tax for the group amounted to KSEK -29,042 for the 2014 financial year, as compared with KSEK -17,562 for 2013.
- › The operating result for the group for the 2014 financial year amounted to KSEK -24,709, as compared with KSEK -17,629 for 2013.
- › Earnings per share prior to, and after, deletion for the 2014 financial year amounted to SEK -1.16, as compared with SEK -0.75 for 2013.

### Significant events in 2014

- › The Company reported successful completion of a phase I study with IdeS. The study showed that IdeS inactivated antibodies safely, quickly and effectively.
- › The Company carried out a preferential rights issue which brought the Company MSEK 35.6 after issue costs.
- › The Company commenced a clinical phase II study with IdeS in highly-sensitized patients on a waiting list for a kidney transplant.
- › The Company announced that the second patient included in the clinical phase II study had successfully undergone a transplant.
- › Bo Håkansson, Hansa Medical's chairman of the Board of Directors and founder passed away in September 2014 after a motorcycle accident.
- › Birgit Stattin Norinder was appointed chairman of the Board of Directors of Hansa Medical following the passing away of Bo Håkansson.
- › Fredrik Lindgren was appointed the new CEO.

### Significant events after the expiration of the 2014 financial year

- › The clinical phase II study in highly-sensitized patients on a waiting list for a kidney transplant was concluded successfully meaning that IdeS quickly and effectively reduces the levels of HLA antibodies.
- › Göran Arvidson was appointed CFO and later also acting CEO.
- › Cooperation was commenced with the leading US transplant expert, Dr. Stanley Jordan at Cedars-Sinai Medical Center in Los Angeles.
- › The Company announced that it is developing, and has submitted, a patent application for, a second-generation IdeS molecule, which is intended to make possible repeated dosages and potentially provide IdeS with a role in the treatment of chronic autoimmune diseases.
- › The Company filed a preliminary application for admission to trading on Nasdaq Stockholm.
- › The Company carried out a fully underwritten preferential rights issue which generated MSEK 246 for the Company prior to issue costs.

### Financial calendar

Annual General Meeting	2 June 2015
Interim report for January – June 2015	25 August 2015
Interim report for January – September 2015	28 Oktober 2015

Financial reports, press releases, and other information is available on Hansa Medical's website at [www.hansamedical.com](http://www.hansamedical.com) starting at the time of publication. Hansa Medical's financial reports and press releases can be downloaded from the website. Hansa Medical uses electronic distribution as the primary form of distribution of financial reports. The annual report and printouts of interim reports are posted to the shareholders and other interested parties who specifically so request. For further information, please contact the Company at tel. +46 46 16 56 70 or email at [info@hansamedical.com](mailto:info@hansamedical.com).

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## Hansa Medical in brief

### About Hansa Medical

Hansa Medical (the "**Company**" or "**Hansa Medical**") is a biopharmaceutical company focused on novel immunomodulatory enzymes. Its lead project IdeS is an antibody-degrading enzyme in clinical development, with potential use in transplantation and rare autoimmune diseases. Other projects include HBP, a market-launched diagnostic marker for severe sepsis, and EndoS, an antibody-modulating bacterial enzyme in pre-clinical development. Hansa Medical is based in Lund, Sweden. The Company's share (HMED) is listed on Nasdaq First North in Stockholm, with Remium Nordic AB as Certified Adviser. The "**Group**" means the corporate group of which Hansa Medical AB (publ) is the parent company. Information in this annual report refers to the group, if it is not explicitly stated that the information refers to the parent company Hansa Medical AB (publ).

### About IdeS

IdeS is a bacterial enzyme that cleaves human IgG antibodies and it is a unique molecule with a novel mechanism. IdeS degrades all IgG specifically, swiftly and efficiently. IdeS has been tested for safety and efficacy in numerous in vitro and in vivo models. During 2013, a Phase I clinical trial in 29 healthy subjects demonstrated that IdeS is efficacious and well tolerated, with a favourable safety profile. During 2014 and 2015, a Phase II clinical trial was conducted in sensitized (which have HLA antibodies) patients awaiting kidney transplantation.

#### Transplantation

Preliminary data indicates that IdeS has a very good efficacy in highly sensitized patients on a waiting list for a kidney transplant. The study shows that IdeS has the capacity to make sensitized patients candidates for a transplant by lowering the HLA antibodies to levels acceptable for a transplant.

The database of the entire study will be closed at the end of April and the results will be published shortly thereafter. The results from this study are planned to be published in a renowned journal.

The Company is planning to commence a clinical phase IIb study during the second quarter of 2015 at Uppsala University Hospital and the Karolinska University Hospital in Stockholm in order to study the safety, tolerability and efficacy of IdeS in reducing HLA antibody levels in patients undergoing a kidney transplant.

On 5 February 2015, Hansa Medical began a cooperation with the US transplant expert, Dr. Stanley Jordan. Dr. Jordan is the head of Kidney Transplantation and Transplant Immunology, Kidney and Pancreas Transplant Center and head of the Division of Pediatric and Adult Nephrology at Cedars Sinai Medical Center in Los Angeles.

Dr. Jordan will be a scientific and medical advisor to the Company and will contribute to the clinical development of IdeS regarding transplants. He will also be the chairman of Hansa Medical's US scientific advisory board on transplants. An IND (Investigational New Drug) application for an investigator sponsored study of IdeS has been submitted and a Letter to Proceed has been received from the Food and Drug Administration (FDA).

#### Other indications

IdeS has other potential medical applications. These include relatively rare and serious, or even life-threatening, acute autoimmune illnesses such as Guillain-Barré syndrome and anti-GBM (Goodpasture's syndrome). IdeS can also be used to degrade IgG in order to make possible other forms of treatment which have lost their effect due to anti-drug antibody formation. IdeS is protected by a number of different patents and has been described in a number of articles which were published in peer-reviewed scientific journals.

### Second-generation IdeS molecules

On 12 February 2015, the Company announced the planned development of a new generation of molecules based on IdeS which will have the potential of repeat dosing, thereby broadening the therapeutic possibilities to also cover more chronic illnesses. Since IdeS is a bacterial protein from group A streptococci, the human immune system recognizes IdeS as foreign and reacts against the molecule. Hansa Medical's phase I study proved that anti- IdeS antibodies, including neutralizing antibodies, are developed soon after administration of a dose of IdeS. The antibodies reached maximum levels two to four weeks after administration of the dose after which the levels normalized within six to twelve months.

In addition to reducing the formation of antibodies, the new generation of molecules also has reduced immunogenicity and increased specific activity. Hansa Medical has patent protected the new molecules.

In 2015 and 2016, Hansa Medical plans to optimize a new generation of molecules and choose a lead candidate for preclinical and clinical development.

### The EndoS research project

EndoS is an enzyme which modifies glycosylation (the sugar structure) of antibodies. By modifying the sugar structure, EndoS is able to inhibit and modify the effects of the antibodies, without entirely eliminating them. This mechanism has many conceivable medical uses. Together with academic research groups, Hansa Medical is conducting research in order to find new treatment methods based on EndoS.

### The HBP-assay diagnostic method

HBP-assay is a market-launched diagnostic method for predicting severe sepsis at emergency wards. In December 2012, Hansa Medical's partner, Axis-Shield Diagnostics, launched a CE-marked version of the assay. The cooperation agreement with Axis-Shield gives Hansa Medical the right to milestone payments from Axis-Shield as well as royalty revenues from license payments to Axis-Shield and their sales of HBP-assay.

Axis-Shield has launched a first version of the assay method which is primarily appropriate for specialists and clinical studies. Axis-Shield is currently further developing the assay method with the goal of incorporating it into a faster and more available analysis platform. Axis-Shield continues to further validate and market HBP-assay globally. In February 2015, Axis-Shield entered into a sublicensing agreement for the Chinese market with Hangzhou Joinstar Biomedical Technology Co Ltd for commercialization of HBP-assay in China. Hansa Medical has the right to royalties from licensing fees paid to Axis-Shield from the licensee and the Chinese market is of great significance with an estimated 20-30 million cases of sepsis annually in China.

### Key ratio for the group

KSEK, unless otherwise stated	1 January – 31 December		
	2014	2013	2012
Net sales	4,716	1,727	2,619
Operation result	-24,709	-17,629	-16,798
Result for the year	-29,042	-17,562	-16,468
Earnings per share			
before dilution (SEK)	-1.16	-0.75	-0.75
after dilution (SEK)	-1.16	-0.75	-0.75
Shareholders' equity for the Group	49,804	45,349	60,585
Equity ratio for the Group (%)	91.7	89.6	95.6
Development expenditures	36,882	38,000	37,936
Cash flow from operating activities	-23,623	-14,830	-17,899
Cash and cash equivalents at year-end	10,152	90	18,966
Number of employees at year end	14	8	8

See definitions on page 82



Comments by the CEO

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## Comments by the CEO

The first three months gave us a good start to the year, and we took important steps – both financially and in clinical development – to build a foundation for a strong Hansa Medical. The goal for Hansa Medical is to become a pharmaceutical company with important, life-saving products on the market. We are not there yet, and as everybody who follows the life science sector knows, you need patience to take clinical projects to the market as well as committed investors who believe in the company along the way.

Our shareholders showed us this trust when they backed our MSEK 246 rights issue that was announced in February, fully guaranteed by subscription undertakings and underwriting. The proceeds will be used to further strengthen our programme around the lead product IdeS, as well as evaluating opportunities for our other enzyme EndoS. This is an important undertaking that confirms that the shareholders also share our belief in our exciting R&D strategy.

In conjunction with the rights issue, we also announced that the estate of Bo Håkansson, Farstorps Gård AB, sold shares representing about 15 percent of the total number of shares and votes outstanding in the company. The shares were acquired by a selected number of Swedish and international institutional investors, including Rhenman & Partners and Hjärt-Lungfonden.

Our primary focus is on the lead product and value driver IdeS, a bacterial enzyme that cleaves human IgG antibodies and is considered to have great potential in kidney transplantation and rare autoimmune diseases. IdeS is currently in Phase II clinical development. In January, we announced preliminary data showing that IdeS has good efficacy in highly sensitized dialysis patients awaiting kidney transplantation. The study shows that IdeS has the capacity to make these patients eligible for transplantation by decreasing HLA antibodies to acceptable levels. Results from this study will be published in a well reputable journal.

Plans are in place to start the next Phase II study of IdeS in renal transplantation at Uppsala University Hospital, and Karolinska University Hospital in Stockholm. We also believe that IdeS has other potential medical indications, including relatively rare and serious – even life-threatening – acute immune diseases, such as anti-GBM and Guillain-Barré syndrome.

At the same time, we are developing a new generation of molecules based on IdeS allowing repeat dosing and thereby broadening the therapeutic opportunities for chronic diseases. A number of promising candidates will be optimized in 2015 in order to select a lead candidate and start preclinical development in 2016.

Our development partner Axis-Shield Diagnostics continues to further validate and market HBP-assay for prediction and diagnosis of severe sepsis world wide. In February, Axis-Shield entered a sublicense agreement for the Chinese market.

Taken all together, I believe that the first quarter clearly showed that we are in a good position – and have the means – to continue the journey to reach our goals.

**Göran Arvidson**  
*CFO and acting CEO*

# Shareholder information



## The share

Hansa Medical's shares are listed on Nasdaq First North with the ticker name HMED and the ISIN code SE0002148817. The shares have been issued in accordance with Swedish law and are denominated in Swedish kronor. The shareholders' rights may only be amended in accordance with the rules prescribed in the Swedish Companies Act (2005:551).

On 31 December 2014, Hansa Medical's share capital amounted to SEK 25,929,603 divided into 25,929,603 shares. There is only one class of shares in the Company. At general meetings, each share in Hansa Medical entitles the holder to one vote and each shareholder may vote the full number of shares held by him or her. All shares carry the entitlement to share the Company's assets and profits and entitled the shareholders to participate equally in dividends and any surplus in the event of liquidation. Upon the issuance of new shares, the shareholders normally have preemptive rights. However, the shareholders' meeting may resolve to disapply preemptive rights. A resolution adopted at a shareholders' meeting is required

in order to change shareholders' rights. The shares are freely transferable. There are no outstanding warrants, convertible notes or other financial instruments which may give rise to a dilution effect for existing shareholders.

Hansa Medical is affiliated to Euroclear's dematerialized securities system and therefore no physical share certificates are issued. All rights associated with the shares vest in the person who is registered in the share register maintained by Euroclear.

There have not been any public tender offers regarding the Company's shares during the current or preceding financial years. The Company's shares are not subject to any offer which has been made as a consequence of a tender obligation, redemption rights or a purchase obligation. Redemption of shares is not governed by the articles of association and is, instead, governed by the rules set forth in the Swedish Companies Act.

## Share capital and changes in share capital

Hansa Medical's share capital amounts after the rights issue 2015 to SEK 32,412,003 divided into 32,412,003 shares and, according to the articles of association, may amount to a maximum of SEK 80 million divided into 80 million shares. All outstanding shares are fully paid up. The Company's share capital is denominated in Swedish kronor and divided amongst the Company's outstanding shares with a quotient value of SEK 1 per share.

Year	Event	Increase in share capital (SEK)	Total share capital (SEK)	Change in number of shares	Total number of shares	Quotient value (SEK)
2007	Company formation	500,000	500,000	5,000	5,000	100
2007	Split (1:9)	-	500,000	45,000	50,000	10
2007	Split (1:2)	-	500,000	50,000	100,000	5
2007	Rights issue	18,815,920	19,315,920	3,763,184	3,863,184	5
2010	Rights issue	19,315,920	38,631,840	3,863,184	7,726,368	5
2011	Rights issue	28,973,880	67,605,720	5,794,776	13,521,144	5
2012	Rights issue	25,000,005	92,605,725	5,000,001	18,521,145	5
2012	Rights issue	18,521,145	111,126,870	3,704,229	22,225,374	5
2012	Reduction in share capital <sup>1)</sup>	-88,901,496	22,225,374	-	22,225,374	1
2014	Rights issue	3,704,229	25,929,603	3,704,229	25,929,603	1
2015	Rights issue	6,482,400	32,412,003	6,482,400	32,412,003	1

<sup>1)</sup> Reduction of share capital without redemption of shares for coverage of losses and allocation to unreserved fund.

### Changes in the share price

Hansa Medical's share was admitted to trading on Nasdaq First North on 17 October 2007. The closing price for Hansa Medical's shares on 31 March 2015 of SEK 38.70 per share yields a market capitalization of approximately MSEK 1,003. The closing price for Hansa Medical on 31 December 2014 of SEK 28.60 per share yielded a market capitalization of approximately MSEK 742.

The graph below indicates the change in share price during 2014



### Shareholders on 31 December 2014

Name	Number of shares	Percentage (%)
Farstorps Gård AB	11,070,320	42.69
Nexttobe AB	7,555,009	29.14
Försäkringsaktiebolaget, Avanza Pension	2,605,002	10.05
Sven Sandberg	345,000	1.33
Anja Ellesson Ljunggren	269,097	1.04
Aktiebolaget Protiga	233,333	0.90
Strategic Wisdom Nordic AB	138,630	0.53
Nordnet Pensionsförsäkring AB	133,658	0.52
Wigzellproduktion AB	91,269	0.35
Tobias Ekman	90,000	0.35
Other	3,398,285	13.10
<b>Total</b>	<b>25,929,603</b>	<b>100.00</b>

### Shareholders on 31 March 2015

Name	Number of shares	Percentage (%)
Nexttobe AB	7,555,009	29.14
Farstorps Gård AB	7,122,952	27.47
Försäkringsaktiebolaget, Avanza Pension	2,329,744	8.97
Handelsbanken Fonder AB RE JP MEL	960,526	3.70
Rhenman Healthcare Equity L/S	657,894	2.53
JP Morgan Clearing Corp	634,230	2.44
Sven Sandberg	459,578	1.77
JP Morgan Bank	423,305	1.63
BWG Holding SARL	305,000	1.17
Anja Ellesson Ljunggren	254,070	0.98
Other	5,179,249	19.97
<b>Total</b>	<b>25,929,603</b>	<b>100.00</b>

### Authorization

On 3 June 2014, the annual general meeting resolved to authorize the Board of Directors, on one or more occasions up to the next annual general meeting, applying or disapplying shareholders' preemptive rights, to resolve to carry out new issues of shares or issues of convertible debentures or warrants. An issue may be made in exchange for payment in cash, non-cash consideration or as a debt/equity swap or otherwise pursuant to the terms and conditions set forth in Chapter 2, section 5, second paragraph, subsections 1 – 3 and 5 of the Swedish Companies Act. The number of shares, convertible debentures or warrants which may be issued pursuant to the authorization would not be limited other than as prescribed in the limits applicable from time to time for the share capital and the number of shares as set forth in the articles of association. Any share issue disapplying shareholder preemptive rights would for the purpose of expanding the circle of owners, acquire or render possible the acquisition of working capital, increase liquidity in the share, carry out corporate acquisitions, or acquire or render possible the acquisition of capital for corporate acquisitions. In conjunction with resolutions regarding share issues disapplying shareholder preemptive rights, the subscription price shall be on market terms at the time of the adoption of the issue resolution.

Pursuant to the authorization, the board of directors carried out a new issue from March to April 2015 to the Company's existing shareholders. The new share issue covered a total of 6,482,400 shares which generated MSEK 246 for the company prior to issue costs.

### Market maker

The Company has entered into a market maker agreement with Erik Penser Bankaktiebolag regarding Hansa Medical's shares on Nasdaq First North. The market maker agreement entered into force on 25 March 2013 and is intended to promote liquidity and reduce the spread between the ask and bid prices in trading in the Company's shares. For this purpose, Erik Penser Bankaktiebolag has received a stock loan of 40,000 shares from Farstörps Gård AB.

### Dividends and dividend policy

Resolutions regarding the payment of dividends are taken by the general meeting. Dividends are normally paid out as a cash amount per share but can also involve payments other than cash. Payment of cash dividends is made through the auspices of Euroclear. The Company does not withhold tax at source on dividends and, instead, this is done by Euroclear in respect of natural persons domiciled in Sweden for tax purposes who are directly-registered owners and by the nominee in respect of natural persons domiciled in Sweden for tax purposes whose shares are nominee-registered. The withholding tax is 30%. No tax is withheld for legal entities. The record date for the right to receive a dividend may not be later than the day prior to the next annual general meeting. In the event a shareholder cannot be reached, the shareholder's claim for the dividend remains outstanding against the Company and is only limited through the rules governing statutes of limitation. Upon application of the statute of limitations, the dividend vests in the Company. For shareholders who reside outside of Sweden, dividends are paid in the same manner as for shareholders residing in Sweden. For shareholders not domiciled in Sweden for tax purposes, however, Swedish withholding tax is normally withheld.

The Company's dividend policy is to not pay a dividend until the Company is reporting sustainable profits. Future dividends will take into consideration the Company's cash flow and financing of future expansion. Hansa Medical has thus far never paid a dividend and does not intend to pay a dividend over the next few years.

A close-up photograph of five clear plastic pipettes arranged in a row within a multi-well plate. The pipettes are filled with a clear liquid, and the liquid level is visible in each. The background is dark, and the lighting highlights the transparency of the pipettes and the liquid. The text "Management report" is overlaid in a light blue, sans-serif font across the middle of the image.

# Management report

Hansa Medical AB (publ) (the “**Company**”) was formed in June 2007 and registered by the Swedish Companies Registration Office the same month. The Company is a public limited company governed by the Swedish Companies Act (2005:551). The Company’s registered address is Box 785, 220 07 Lund, Sweden. The Board of Directors and the CEO of Hansa Medical AB (publ), company registration number 556734-5359, with its registered office in Lund hereby submits the annual report for the business conducted by the Group and the parent company for the financial year 1 January to 31 December 2014. As used in this annual report, “**Group**” means the corporate group for which the Company is the parent company.

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## Risk factors

Hansa Medical’s business is influenced by a number of factors, the effects of which on the Company’s earnings and financial position, in certain respects, cannot be controlled by the Company at all or in part. In an assessment of the Company’s future development, it is important, alongside the possibilities for growth in earnings, to also consider these risks. Set forth below is a description, without any internal order of priority, of the risks which are considered to have greatest significance for the Company’s future development. For natural reasons, not all of the risk factors can be described. Instead, the risks which are specific to the Company or the industry are set forth here. An overall assessment must also include other information contained in the annual report as well as an overall assessment of extraneous factors in general.

### Financial risks

Hansa Medical carries out capital-intensive and value-generating pharmaceuticals and diagnostics development. Future financing of the operations is expected to take place through new issues of shares, loans, licensing revenues, cooperation with other parties, and the sales of rights or patents. Hansa Medical has financed its business operations thus far partially with the help of milestone compensation and one-time compensation amounts from the Company’s current and previous cooperating partners and with royalty revenues from licensing agreements. However, the operations have mostly been financed with shareholders’ equity through new issues of shares, primarily rights issues to the shareholders. Debt financing is not considered to be an appropriate form of financing, other than temporarily, until the Company has achieved profitability and positive cash flow. For further description of the company’s financial risks, see note 23.

### Scope of the report

This annual report covers the 2014 financial year with comparison figures for 2013 and 2012. All information contained in the annual report relates to the entire group unless expressly stated that the information relates to the parent company, Hansa Medical AB (publ). Events occurring after the balance sheet date are set forth in note 29.

### Accounting principles – transition to IFRS

The Group and the parent company have changed accounting principles. The annual report for 2013 was prepared both for the Group as well as the parent company in accordance with the general guidelines issued by the Swedish Accounting Standards Board. The annual report for 2014 for the Group has, instead, been prepared according to International Financial Reporting Standards (IFRS), as these have been adopted for application by the EU. The parent company applies RFR 2 “Reporting for legal entities” which is published by the Swedish Financial Reporting Board. The comparison figures for 2013 and 2012 has been recalculated. A description of the effects of the transition to IFRS is set forth in note 32.

### Company-specific risks

#### Clinical trials and regulatory approvals

All pharmaceuticals which are developed in order to be marketed must undergo an extensive registration procedure before the relevant governmental agency on the particular market, for example the Swedish Medical Products Agency, the US Food and Drug Administration (“**FDA**”) or the European Medicines Agency (“**EMA**”). The registration procedure includes, where appropriate, requirements regarding preclinical development, clinical testing, registration, approval, marketing, manufacturing and distribution of new pharmaceuticals and medical and biological products. The failure to fulfill such current or future requirements can lead to the recall of products, stopped import, denial of registration, the withdrawal of previously approved applications, or criminal charges. Even if a pharmaceutical manufactured by Hansa Medical, or a third party under an agreement with the Company, were to be registered for commercialization, there is a risk that Hansa Medical will not be able to comply with new rules or be able to maintain the registration or receive corresponding authorization for additional pharmaceuticals. There is also a risk that the rules currently applicable to registration, or the interpretation of these rules, will be changed in a way disadvantageous to the Company.

Before a pharmaceutical is approved for marketing, it must undergo clinical trialing on people. There is a risk that Hansa Medical will not achieve sufficient results in such trialing and thus that the necessary approvals will not be obtained. There may be requirements of additional studies or trials in order to obtain approval which may delay and increase the costs of a new product. Even after approval has been obtained, the Company and the products it markets will be under the supervision of national regulatory authorities in the countries where these products are marketed. In the event previo-

usly unknown problems are discovered, this can lead to restrictions on the use of a particular product, or the withdrawal of the product from the market. Problems associated with obtaining and maintaining approval may materially impact Hansa Medical's business operations, earnings and financial position.

#### Intellectual property issues

The value of Hansa Medical is largely dependent on its ability to obtain and defend patents and its ability to protect specific know-how. Patent protection for biomedical and biotech companies may be uncertain and involve complicated legal and technical questions. There is a risk that a patent sought will not be granted for an invention, that the patent granted will not provide sufficient protection, or that the patent granted will be circumvented or revoked. Pursuing litigation involving the validity of a patent is normally associated with significant costs. By having access to greater economic resources, competitors may be better positioned than Hansa Medical to handle such costs. In certain legal systems, these costs may be imposed on Hansa Medical even where the outcome of the case for the Company is otherwise positive. If the Company does not succeed in obtaining or defending patent protection for its inventions, competitors may be afforded an opportunity to freely use the Group's pharmaceutical candidates or diagnostic methods, which may prejudice the Company's ability to commercialize its business. In addition, this might negatively affect the possibility for the Company to enter into important cooperation agreements. Future patents may be granted to parties other than Hansa Medical which, in turn, may limit the Group's possibility of commercializing its intangible assets. If such patents are granted, it may negatively affect the Group's business, earnings and financial position. There is a risk that the Company may infringe the intellectual property rights of third parties and may be exposed to claims for compensation for this. In such cases, the Company may also be enjoined from using such rights in the future.

#### Dependence on cooperation

Hansa Medical is involved in the research and development of pharmaceuticals and, for many years, has cooperated with well-established researchers with whom the Company has had long-term relationships. However, some of these cooperation projects are governed by agreements with terms of only one year each time. Were these agreements to terminate or not be renewed, it might have negative consequences both for the Company's business operations as well as its earnings and financial position.

The Company has an exclusive licensing agreement with Axis-Shield Diagnostics Ltd. and is dependent on this cooperation functioning properly for the sale and further development of HBP-assay. If the Company is unable to maintain this, it might prejudice the Company's business and earnings.

#### Concentration of products

The value of the Company is primarily dependent on success in the Company's leading development project, IdeS, but also to a certain extent on the future sales of HBP-assay under the management of the licensee Axis-Shields. The market value of the Company, and thus the Company's share price, would be prejudiced by setbacks for IdeS and HBP-assay.

#### Market and competition

The industry for the development of new pharmaceuticals and

diagnostic methods is heavily exposed to competition. Developing a new pharmaceutical from invention to finished product requires a great deal of time. Not the least for this reason, when development is underway it is uncertain whether there will be any market for the product when it is finally developed and, in such case, how large this market will be, as well as which competing products the Company's products will encounter when they reach the market. To the extent competition consists of existing preparations or methods, Hansa Medical's success is dependent on its ability to induce potential customers to replace known products or methods with those of Hansa Medical. Another risk is that competitors, who in many cases have greater resources than the Company, will develop alternative preparations which are more effective, more secure, or cheaper than those offered by Hansa Medical. This may lead to the Company not being able to sell its products which may negatively affect the Company's earnings.

#### Purchasing and pricing

On many markets, purchases of pharmaceuticals of the type being developed by the Company are financed, in whole or in part, by a party other than the patient, for example caregivers, insurance companies or governmental authorities subsidizing pharmaceuticals. If the Company does not achieve acceptance for its products and the pricing of the products by such financiers, this may make it more difficult for the products to reach the market and may prejudice their commercial potential, which may negatively affect the Group's earnings and financial position.

#### Dependence on key persons

Hansa Medical is, to a high degree, dependent on key persons, both employees as well as directors. The Company's future earnings are affected by its ability to attract and retain qualified key persons. In cases where one or more key persons leave the Company and the Company is not successful in replacing such person, this might have a negative effect on the Company's business, financial position and earnings.

The Company's CEO is currently on leave of absence. In the event the CEO does not return to service within the near future or at all, this might have negative effect on the Company's business.

#### Trade secrets

The Company is dependent on ensuring that trade secrets which are not covered by patents or other intellectual property rights can also be protected, including among other things information regarding inventions for which patent applications have not yet been filed. The employees of the Group and its cooperating partners are normally subject to confidentiality undertakings but there is always a risk that someone who has access to information of great value to the Group disseminates or uses the information in a way which renders it impossible for the Company to obtain a patent, or otherwise damages the Group from a competition perspective, which may have a negative effect on the Company's business and financial position.

#### Dependence on development financing and working capital

The development of pharmaceuticals of the types being developed by Hansa Medical is extremely costly. At the same time, the Group has thus far only generated small revenues, which means that Hansa Medical may require access to capital in the future before its cash flow turns positive. Access to such capital varies over time.

Access to capital may be limited at times when it is needed by the Group which may prejudice the Company's financial position and its possibility to commercialize its innovations.

#### Legislation

The pharmaceuticals industry is affected to a large degree by legislation and other regulations. These regulations include, among other things, licensing procedures, quality controls, and requirements for documentation. Over time, legislation is drafted and introduced which may significantly change the regulatory scheme governing trialing, regulatory approval, manufacturing and marketing of the regulated product in question. In addition, the supervisory authorities' regulations, and their advisory comments, can be revised or reinterpreted in a manner which might significantly affect the Company's business. Such changes may, among other things, entail a request for additional results or studies, changes in the manufacturing method, revocation, replacement, or termination of a license for certain products or increased documentation obligations. Extensive changes in legislation and regulations regarding pharmaceuticals, both in Europe as well as in other parts of the world, may entail increased costs which might have a negative impact on the Company's business, financial position and earnings. In addition, changes in legislation and regulations may affect the conditions for the Company's business operations.

#### Product liability

The clinical trialing and marketing as well as sales of pharmaceuticals products entail a significant risk of product liability claims. There is a risk that the product liability insurance which the Company has purchased will not cover any claims regarding product liability which may be brought. Disputes regarding product liability may be very costly and can lead to extensive negative publicity for the Group which may negatively affect the Company's financial position.

The Company has supplier agreements which contain extensive liability disclaimers for the suppliers. In the event the Company incurs a loss as a consequence of a defect in a product supplied to it, there is a risk that compensation for this loss cannot be obtained from the supplier, which may affect the Company's business and earnings.

#### Dependence on subcontractors

Hansa Medical currently has no plans to carry out its own manufacturing of products and will, instead, be dependent on subcontractors. If Hansa Medical is unable to secure reliable subcontractors that can deliver at competitive prices, this may negatively affect its business operations and earnings. The same applies where a contracted subcontractor is unable to supply a sufficient quantity at the right quality and at the right time.

#### Dependence on distributors

Hansa Medical may be dependent upon distributors to get its products to market. If Hansa Medical is unable to establish a distribution organization which can distribute the Group's products to the end customers on terms and conditions advantageous to Hansa Medical, this may have a negative effect on Hansa Medical's business and earnings. The same distributors if retailers with whom Hansa Medical has established cooperation decide to discontinue cooperation.

## Securities-related risks

#### Changes in the share price

Trading in securities is always associated with risks and risk-taking. Since an investment in equities can both increase and decrease in value, it is not certain that an investor will recoup all or even a part of the capital invested. In addition, it should be noted that the pricing of the Company's shares is dependent on factors beyond the control of Hansa Medical including, among other things, the stock market expectations and its development as well as the economy in general. Investments in Hansa Medical's shares should therefore be made following a thorough analysis of the Company, its competitors, and extraneous factors in general as well as general information regarding the industry. An investment in shares should never be viewed as a quick way of generating a return, but rather as a long-term investment which is made with capital one can afford to do without. The price of shares may be subject to fluctuations as a consequence of changes in opinions on the capital market regarding the shares or similar securities, due to various circumstances and events such as changes in applicable legislation and other rules which affect the Company's business, or changes in the Company's earnings and business development. Stock markets may experience significant fluctuations from time to time regarding prices and volumes which need not be related to the Company's business or future prospects. In addition, the Company's earnings and future prospects may, from time to time, be lower than the expectations of capital markets, analysts or investors. One or more of these factors may result in a drop in the price of the share.

#### Unregulated market

The Company's shares are admitted for trading on Nasdaq First North which, according to the Securities Markets Act, is deemed to be a multilateral trading facility, but not a regulated market. An investment in shares traded on a multilateral trading facility is typically regarded as more risk-filled than an investment in shares on a regulated market.

The Company has submitted a preliminary application for admission to trading on Nasdaq Stockholm. There is a risk that the application for admission to trading will not be granted, or that approval will be delayed, which may negatively affect the share price.

#### Liquidity in the Company's shares

The Company is unable to predict to what extent investor interest will lead to the development and maintenance of active and liquid trading in the Company's shares. If it is not possible to maintain active and liquid trading, this may entail difficulties in selling the shares.

#### Effect of sales by major shareholders

The Company's two largest shareholders currently own approximately 57 percent of the shares. Were any major shareholder to decide to sell its holdings on the market, or if the market were to believe that such a sale may be relevant, this might negatively affect the share price.

#### The possibility for major shareholders to influence matters at general meetings

The Company's largest shareholders own approximately 57 percent of the shares. The interests of these shareholders may differ significantly from, or compete with, the interests of the Company or other shareholders and these shareholders may exercise influence over

the Company in a manner which is not in the interests of the other shareholders. For example, there may be a conflict between the interests of the largest shareholders, on the one hand, and the interests of the Company or its other shareholders, on the other, with respect to decisions concerning the payment of dividends. Such conflicts may have a significant negative effect on the Company's business, earnings and financial position.

#### Offering of shares in the future

Hansa Medical may issue shares or other securities in the future in order, for example, to be able to carry out acquisitions or make other investments. Any future share issue or issue of other securi-

ties may negatively affect the share price.

#### Dividends

Hansa Medical has never paid a dividend and does not intend to pay any dividend over the next few years. The Company's dividend policy is to not pay a dividend until the Company is reporting sustainable profits. The payment of dividends will take into consideration the Company's cash flow and financing of future expansion. In addition, the terms and conditions for future loans or credit facilities may prevent Hansa Medical from paying a dividend. As a consequence, any increase in value in Hansa Medical's stock will be the only possibility for a return for shareholders of the Company within the foreseeable future.

## The business

### Introduction

Hansa Medical is a biopharmaceutical company focused on novel immunomodulatory enzymes. Its lead project IdeS is an antibody-degrading enzyme in clinical development, with potential use in transplantation and rare autoimmune diseases. Other projects include HBP, a market-launched diagnostic marker for severe sepsis, and EndoS, an antibody-modulating bacterial enzyme in pre-clinical development. The business is based in Lund.

The Company's shares (HMED) are listed for trading on Nasdaq First North in Stockholm with Remium Nordic as the Certified Adviser.

IdeS is a bacterial enzyme which cleaves human IgG antibodies and it is a unique molecule with a novel mechanism. IdeS degrades all IgG specifically, swiftly and efficiently. IdeS has been tested for safety and efficacy in numerous in vitro and in vivo models. During 2013, a Phase I clinical trial in 29 healthy subjects demonstrated that IdeS is efficacious and well tolerated, with a favourable safety profile. During 2014 and 2015, a Phase II clinical trial was conducted in sensitized (which have HLA antibodies) patients awaiting kidney transplantation. Preliminary data indicates that IdeS has a very positive effect in highly sensitized patients who are on the waiting list for a kidney transplant. The study shows that IdeS has the capacity to make sensitized patients candidates for a transplant by lowering the HLA antibodies to levels appropriate for a transplant. IdeS has treatment potential in transplants and a large number of autoimmune diseases where effective treatment methods are currently lacking. IdeS is protected by a number of different patents and has been described in a number of articles which were published in peer-reviewed scientific journals.

### History

**2001:** Hansa Medical Utvecklings AB is founded based upon many years of cooperation between Professor Lars Björck and Hansa Medical's chairman for many years Bo Håkansson. The IdeS enzyme is discovered at Professor Lars Björck's research laboratory, and patented shortly thereafter by Hansa Medical Utvecklings AB.

**2004:** Hansa Medical Utvecklings AB is acquired by Biolin Scientific AB, becoming a wholly-owned subsidiary.

**2005:** The first preclinical model studies with IdeS are carried out. The medical use of IdeS is patented.

**2006:** The first preclinical model studies with EndoS are carried out. The medical use of EndoS is patented.

**2007:** Hansa Medical AB (publ) is formed and acquires Hansa Medical Utvecklings AB in July for a purchase price of MSEK 33.6. Hansa Medical is spun off from Biolin Scientific AB. The Company is listed on Nasdaq First North. Hansa Medical patents quantification of HBP for prediction of severe sepsis. A new share issue brings the Company MSEK 33 prior to issue costs.

**2008:** The Company acquires the rights to the alpha-11 project, a pharmaceutical target for treatment of rheumatoid arthritis and the rights to the alpha-10 project with related biological material.

**2009:** The Company enters into a cooperation agreement with Alere Inc. for joint development of a new biological pharmaceutical for the treatment of rheumatoid arthritis based on antibodies against the alpha-11 integrin. The Company sells all assets related to the potential pharmaceutical target and the biomarker alpha-10 integrin to Xintela AB. The Company receives SEK 500,000 in financing from the Forska&Väx (Research & Grow) VINNOVA program in order to carry out a pre-study of EndoS. The Company enters

into an exclusive licensing agreement with Axis-Shield Diagnostics Ltd regarding HBP-assay. The Company is merged with the wholly-owned subsidiaries Hansa Medical Utvecklings AB and Cartela i Malmö AB.

**2010:** A new share issue brings the Company MSEK 27 prior to issue costs. Hansa Medical enters into a licensing agreement with Human Genome Sciences Inc. regarding patents and patent applications concerning the alpha-11 pharmaceutical. Hansa Medical receives milestone compensation in the amount of USD 500,000 from Alere Inc. after obtaining advantageous licenses for significant patents and patent applications regarding the alpha-11 pharmaceutical.

**2011:** Hansa Medical and Axis-Shield begin clinical multi-center studies in Sweden and the United States with HBP-assay for the prediction of severe sepsis at emergency clinics. A new share issue brings the Company MSEK 29 prior to issue costs. Hansa Medical and Alere Inc. discontinue the alpha-11 project for the treatment of rheumatoid arthritis since sufficient effects are not achieved in preclinical models for the treatment of rheumatoid arthritis. The development of the GMP process for the production of IdeS is completed.

**2012:** The Company makes a private placement of shares to Nexttobe AB which brings the Company MSEK 27.5. Hansa Medical is granted a patent in Europe for the HBP-assay diagnostic method. Hansa Medical is granted patents in the United States and Europe for medical use of IdeS. The Company carries out a preferential rights issue which brings the Company MSEK 18.5 prior to issue costs. Hansa Medical's cooperating partner Axis-Shield launches a CE-marked version of the HBP-assay.

**2013:** The Company commences phase I studies with IdeS. Hansa Medical and Axis-Shield report very positive results from crucial clinical studies with the HBP-assay. The Company receives financing in the amount of MSEK 3.4 from the Forska&Väx VINNOVA program in order to carry out a phase II study with IdeS, of which MSEK 3.1 was paid out in 2014 and MSEK 300 in 2015.

**2014:** The Company reports successful implementation of a phase I study with IdeS. The study shows that IdeS inactivates antibodies safely, quickly and effectively. The Company carries out a preferential rights issue which brings the Company MSEK 37.0 million prior to issue costs. The Company is commencing a phase II study with IdeS after having received approval by the Swedish Medical Products Agency. Birgit Stattin Norinder is appointed chairman of the Board of Directors after the death of the previous chairman Bo Håkansson. Fredrik Lindgren is appointed the new CEO.

## Vision

Hansa Medical's vision is to create a pharmaceuticals company which develops innovative pharmaceuticals with a good level of profitability.

## Targets

The most important operational targets over the next few years are to:

- › develop IdeS through necessary studies to market approval
- › develop a second-generation IdeS for repeated dosage to clinical development phase
- › develop an additional product candidate to the clinical development phase

The longer-term financial targets are to:

- › generate significant revenues from products developed in-house
- › achieve a good level of profitability
- › create a strong cash flow

## Business model

Hansa Medical develops new pharmaceuticals and medical diagnostic products for introduction on the international market. The Company carries out innovation focusing on immune-modulating enzymes. Innovative substances, production processes or medical uses are regularly patented in order to secure fundamental commercial rights. Research takes place through an in-house research organization and through long-term cooperation with academic research groups. Product development in the form of preclinical experiments and preclinical and clinical studies takes place in-house, in cooperation with research and practicing physicians and physician groups, and by retaining external contract research organizations. Analysis of the medical and regulatory conditions for product candidates is carried out on a regular basis by the Company's own personnel and by external consultants and scientific advisors with specific expertise. Production on a small scale for use in preclinical experiments is carried out in-house or by academic research partners, while production on a larger and quality-secured scale for use in preclinical and clinical studies and for sales is carried out by the contracting manufacturers. Commercialization may take place through market introduction by the Company itself on certain markets and on other markets through various types of distribution partners. Industrial cooperation and sublicensing of rights is evaluated on a regular basis and may involve global or territorial commercialization rights in exchange for either product development work and production capacity or monetary compensation in the form of advance payments, milestone compensation and royalties.

## Strategies

### Strategy for intellectual property rights

Hansa Medical routinely applies for patent protection for innovations for the purpose of securing fundamental commercial rights. Patents are obtained for entirely new innovations, and for innovations which support or strengthen an earlier innovation or patent. The patent application may relate to the substances per se, production processes, or medical uses. Since the innovations in certain cases involve naturally occurring substances, it is not always possible to patent the substance per se. Consequently, patents are instead focused on the production process or use of the substances, medicinal or otherwise. Patent applications regularly cover the United States, the European Union and Japan, but also other international markets where the possibilities for success with a patent application are considered to be good at the same time as the commercial

potential is considered to be sufficiently great in order to justify the cost of the patent application. The documentation for the patent applications is prepared by the Company's in-house research organization and, to a certain extent, in cooperation with academic research groups and other inventors or rights holders. The formalization and registration of patent applications is carried out through international patent agents. For some time, the Company has had solid cooperation with a leading international patent agency headquartered in London. After a patent application is filed, there is extensive work in answering questions from various patent agencies and rebutting challenges from other possible rights holders. After the patent has been granted, regular monitoring of the validity of the patent is carried out as well as any possible infringement of the patent protection and monitoring of possible competing patent applications from other parties.

In addition to its own patent applications, the Company analyzes the possibilities to license or acquire rights to other parties' patents. Other parties may hold patents which either limit the possibilities for the Company to utilize the rights within the scope of its own patent protection or which entail a new use of rights for the Company. Licensing and acquisition are only carried out where believed to be of sufficient commercial value.

In addition to patent protection, the Company applies for other types of rights protection. In the pharmaceuticals industry, there is what is commonly referred to as market exclusivity, in part for orphan drugs, and in part for biologics. In the United States, the Food and Drug Administration (FDA) grants market exclusivity for orphan drugs for up to 7 years for a particular indication and market exclusivity for biologics for up to 12 years for a particular indication. The Company is of the opinion that both of these types of market exclusivity may be relevant for its product candidates and will, from time to time, actively apply for such market exclusivity where appropriate. In Europe, the European Medicines Agency (EMA) may grant market exclusivity for orphan drugs for a period of up to 10 years for a particular indication, and market exclusivity for innovative substances for a period of up to 11 years for a particular indication.

#### Research strategy

Research by the Company takes place through the Company's own research organization and through long-term cooperation with academic research groups. The Company's own research organization carries out its own preclinical experiments, as well as ongoing studies of leading research in the academic fields of interest to the Company's business.

Cooperation with academic research groups is of a long-term nature. In exchange for providing monetary support to the academic research, the Company obtains commercialization rights for interesting research results. The Company primarily cooperates in research with:

- › Professor Lars Björck, University of Lund
- › Associate Professor Mattias Collin, University of Lund
- › Professor Heiko Herwald, University of Lund
- › Professor Rikard Holmdahl, Karolinska Institute in Stockholm

Interesting research results are analyzed and evaluated in several stages. Successfully implemented research normally leads to a patent application and is documented either in the form of internal

research reports or a scientific articles for publication in peer-reviewed journals.

#### General comments about the development of pharmaceuticals

A completely new pharmaceutical is typically developed through the identification of an interesting medical mechanism (disease factor) and the production of a potential pharmaceutical candidate (molecule) for the purpose of affecting the medical mechanism. The production of potential pharmaceutical candidates entails that a molecule is modified in several stages, including preliminary trialing in various stages with cell models and animal models. One or more potential pharmaceutical candidates are trialed for effects in animal models which are representative of the disease mechanism. A preliminary toxicological study in animals may also be carried out. The nominated pharmaceutical candidate is then produced on a limited, preliminary quality-ensured scale for toxicological studies in one or more types of animals in order to assess the safety of repeated and escalating dosages in a number of groups of animals, normally compared with a placebo. If the pharmaceutical candidate demonstrates acceptable safety in toxicological studies, and if a medicinal effect can be rendered credible, authorization can be obtained from the Medical Products Agency and ethical testing boards to test the safety of the pharmaceutical candidate in healthy test persons, normally younger men, through what is commonly referred to as a phase I study. For completely new pharmaceuticals, normally only one dose is given. For biological pharmaceuticals, normally several different dosage levels are tested in a number of groups of test persons. In order to test the effects of the pharmaceutical candidate, authorization can then be given to trial in a limited, relevant group of patients who have the relevant illness, through a so-called phase II study. In order to obtain approval to market a pharmaceutical, necessary clinical studies must be carried out in patients in order to study the long-term effects and safety of the pharmaceutical candidate. These studies normally cover a sufficient number of patients to create a statistical basis for analysis. Additional, smaller studies can also be required in order to study any carcinogenic effects (animals) or any cross-reactions with other pharmaceuticals (people). A pharmaceutical can then receive approval to be marketed for the specific purpose (the disease). Such approval can be given with or without conditions for certain follow-up to take place over time, possibly through so-called phase IV studies. When a pharmaceutical is approved for marketing, there is nothing which prevents additional studies from being carried out in order to study the effects of the pharmaceutical in diseases other than the disease initially studied.

#### Development strategy

The Company's product development consists of preclinical experiments and preclinical and clinical studies which are ultimately aimed at demonstrating that the Company's pharmaceutical candidates are effective and safe enough to obtain approval to be marketed.

Preclinical experiments primarily involve experiments in various cell and animal models which are carried out in order to study the mechanisms, effects and safety of the pharmaceutical candidate. These experiments can be carried out in-house by the Company's own research organization, in cooperation with academic research groups, or on a contractual basis by preclinical contract research organizations. Preclinical toxicological studies are regularly carried out on a contract basis by specialized contract research organiza-

tions which specialize in these types of activities and which possess all the necessary licenses to carry out the activities. The project management of clinical studies is often handled by the Company's own personnel, while the actual trialing is carried out by research physicians and practicing physicians and physician groups which have access to, and which are treating, the patients. Other physicians and scientific experts monitor the implementation of the study on a regular basis as well as any questions which arise regarding the safety of the pharmaceutical candidate. Analysis of the medical and regulatory conditions for product candidates is carried out on a regular basis by the Company's own personnel as well as external consultants and scientific advisers with specific expertise.

#### Production strategy

The production of the Company's pharmaceutical candidates is a complex process which involves recombinant production and purification in many stages along the way to the final product. The risk of contaminants is always present and can give rise to serious consequences. For a properly functioning product, not only a pure pharmaceutical substance is required but also a pharmacologically functioning and medically practical formulation.

Production of the pharmaceuticals candidate takes place in various ways depending on the stage of the development of the pharmaceuticals candidate. For preclinical experiments, production takes place on a small and experimental scale in-house or by academic research partners.

Production for toxicological studies and for clinical phase I and phase II studies normally takes place on a limited scale and with preliminary quality-assurance by a contracting manufacturer. Production for clinical studies and for subsequent marketing and sales takes place on a larger and ultimately quality-assured scale by contract manufacturers. This production can involve several different contract manufacturers and it may involve other contract manufacturers than those which were retained for the initial clinical studies. Provided that the pharmaceutical is approved for marketing and achieves sufficient sales volumes, the Company may build up its own production.

#### Commercialization

The Company's fundamental strategy for commercialization is to develop pharmaceutical candidates through necessary studies to approval for marketing and then to introduce pharmaceuticals on the international market. In order to achieve good distribution, various types of geographic or therapeutically limited distribution partnerships will be required. Appropriate distribution partners may consist of pharmaceuticals companies focusing on orphan drugs in a particular geographical area or focusing on a particular area of therapy. Such distribution partnerships can be achieved either through sub-licensing of rights, distributorships, or agency agreements.

However, the Company also evaluates other types of industrial partnerships with various types of pharmaceutical companies on a regular basis. Possible partnerships include, among others, manufacturing partnerships and product development partnerships. A manufacturing partnership is conceivable through a company with production capacity for biological pharmaceuticals receiving production rights, and possibly other rights, in exchange for investments in process development. A product development partnership

may entail another pharmaceutical company taking over the responsibility for pharmaceutical development, in whole or in part, and at least large portions of the commercialization rights, probably in exchange for monetary compensation in the form of advance payments, milestone payments or royalties.

#### Financing strategy

The Company's capital requirements have historically been satisfied primarily through new issues of shares subject to preemptive rights for the shareholders. On one occasion, a new issue was directed to a new investor on market terms and conditions. As the Company's pharmaceutical candidates achieve success in development, additional possibilities are opened up for financing. As a Swedish limited company, the first choice for the Company is issuing new shares subject to preemptive rights for its shareholders. Secondary possibilities include sublicensing rights to pharmaceutical candidates and a new issue of shares to new investors, provided this can take place on terms and conditions favorable to the current shareholders. Debt financing is not considered an appropriate form of financing other than on a temporary basis before the Company has achieved profitability and positive cash flow.

#### Products and projects

Hansa Medical's main project is the development of the IdeS pharmaceutical candidate. In addition, the Company has developed HBP, a biomarker for the diagnosis and prediction of severe sepsis which has been launched on market, and the Company is conducting preclinical research surrounding EndoS, a bacterial antibody-modulating enzyme.

#### The IdeS pharmaceutical candidate

IdeS was characterized and discovered in 2001 by a research group established around Lars Björck. The characterization of IdeS was first published in 2002 and, since then, a number of articles about IdeS have been published in peer-reviewed journals, including:

- › von Pawel-Rammingen, U., B.P. Johansson, and L. Björck. 2002a. IdeS, a novel streptococcal cysteine proteinase with unique specificity for immunoglobulin G. *EMBO J* 21:1607-1615.
- › von Pawel-Rammingen, U., B.P. Johansson, H. Tapper, and L. Björck. 2002b. *Streptococcus pyogenes* and phagocytic killing. *Nat Med* 8:1044-1045; author reply 1045-1046.
- › Wenig, K., L. Chatwell, U. von Pawel-Rammingen, L. Björck, R. Huber, and P. Sondermann. 2004. Structure of the streptococcal endopeptidase IdeS, a cysteine proteinase with strict specificity for IgG. *Proc Natl Acad Sci U S A* 101:17371-17376.
- › Vincents, B., U. von Pawel-Rammingen, L. Björck, and M. Abrahamson. 2004. Enzymatic characterization of the streptococcal endopeptidase, IdeS, reveals that it is a cysteine protease with strict specificity for IgG cleavage due to exosite binding. *Biochemistry* 43:15540-15549.
- › Agniswamy, J., B. Lei, J.M. Musser, and P.D. Sun. 2004. Insight of host immune evasion mediated by two variants of group A *Streptococcus Mac* protein. *J Biol Chem* 279:52789-52796.
- › Nandakumar, K.S., B.P. Johansson, L. Björck, and R. Holmdahl. 2007. Blocking of experimental arthritis by cleavage of IgG antibodies in vivo. *Arthritis Rheum* 56:3253-3260.
- › Johansson, B.P., O. Shannon, and L. Björck. 2008. IdeS: a bacterial proteolytic enzyme with therapeutic potential. *PLoS One* 3:e1692.
- › Ryan, M.H., D. Petrone, J.F. Nemeth, E. Barnathan, L. Björck,

and R.E. Jordan. 2008. Proteolysis of purified IgGs by human and bacterial enzymes in vitro and the detection of specific proteolytic fragments of endogenous IgG in rheumatoid synovial fluid. *Mol Immunol* 45:1837-1846.

- › Yang, R., M.A. Otten, T. Hellmark, M. Collin, L. Björck, M.H. Zhao, M.R. Daha, and M. Segelmark. 2010. Successful treatment of experimental glomerulonephritis with IdeS and EndoS, IgG-degrading streptococcal enzymes. *Nephrol Dial Transplant* 25:2479-2486.
- › Tradtrantip, L., N. Asavapanumas, and A.S. Verkman. 2013. Therapeutic cleavage of anti-aquaporin-4 autoantibody in neuromyelitis optica by an IgG-selective proteinase. *Mol Pharmacol* 83:1268-1275.

Hansa Medical's first patent application regarding IdeS was filed in 2001 and related to IdeS as a molecule per se. In addition, a further four rounds of patent applications have been filed regarding IdeS. In 2015, a patent application was also filed for second-generation IdeS molecule. In 2000, another company applied for a patent for IdeS' ability to induce an immune response. Hansa Medical has subsequently obtained a license for this patent application. In 2005 and 2006, patent protection was sought for medical use of IdeS. In 2014, a patent application was filed for use of IdeS in combination with other therapies.

IdeS is a bacterial enzyme which occurs naturally in group A streptococcus (*Streptococcus pyogenes*). Group A streptococci are highly disease-inducing in humans and cause, among other things, strep throat and skin infections, but can also be life-threatening in their form as "killer bacteria".

Through evolution, the human immune system has developed various types of mechanisms and molecules to protect the body against bacterial infections, among other things antibodies of the IgG type. IgG is the most commonly occurring antibody type in blood and lymph and makes up a large majority of all antibodies in human beings. IgG is thus a central part of the humoral immune response. The immune system has the ability to develop specific antibodies against, in principle, all substances which are experienced as foreign, so called antigens. When IgG binds to an antigen many different immunological reactions are triggered, which have the ultimate purpose of defending the body against the foreign substance. IgG is thus a central component of the adaptive immune response, the part of the immune system which has the ability to "learn" over time.

Group A streptococci have, in turn, developed various types of protection against the human immune system, among other things IdeS. Consequently, IdeS comprises a part of group A streptococci protection against the human immune system and, through the cleaving of IgG by IdeS, the ability of bacteria to survive increases.

IdeS is a proteolytic enzyme which means that it is a protein which degrades other proteins through cleavage. The protein which IdeS cleaves is IgG. IdeS always cleaves IgG in the same way, by binding to IgG at a specific location and then cleaving IgG in two parts at a different specific location. The residual product is two fragments of the antibody, designated F(ab')<sub>2</sub> and Fc fragment.

IdeS only cleaves human IgG of all subclasses. This means that IdeS in animals only cleaves such IgG which are very similar to

those of humans. Of the various families of animals, rabbits are a class unto themselves since rabbits only have one type of IgG, and it is similar to human IgG. In other animals such as mice, rats and dogs, IdeS only cleaves some of the IgG subclasses.

Based upon what we currently know, IdeS does not cleave any other antibodies, for example IgA, IgD, IgE or IgM. It is also not known that IdeS cleaves any other proteins found in human beings. IdeS is thus very specific.

IdeS cleaves human IgG irrespective of in what form it is found. IgG can be freely circulating in the bloodstream or be found outside of the bloodstream, it can be bound to an antigen or to receptors on a cell's surface. IdeS thus cleaves IgG irrespective of whether it is free or bound, and irrespective of how it is bound.

An IdeS molecule has the ability to cleave many IgG molecules. It is estimated that one (1) IdeS molecule can cleave approximately 2,500 IgG molecules. IdeS is thus very potent, or effective.

In dosages for human beings, IdeS has proven to cleave IgG rapidly in the human body. Within the scope of only a few minutes, a partial cleaving of IgG can be studied and, given a sufficient dose, in principle all IgG in the body has been cleaved within the span of a few hours. IdeS thus acts quickly.

IdeS and its byproducts, fragments of the cleaved antibodies, are broken down in the body and eliminated. IdeS is eliminated within 24 hours. The antibody fragments, Fc and F(ab')<sub>2</sub>, are eliminated during the span of a few days up to a week. Within the span of weeks, the body forms new IgG. During the time in which the body lacks IgG, it is more vulnerable to infections.

A particular circumstance is the fact that the immune system forms antibodies against IdeS. Since most people have at some time been infected by group A streptococci, they also have antibodies against IdeS to some extent. When a person has received a dose of Hansa Medical's IdeS, one consequence is that high levels of antibodies are formed directed against IdeS. This means that there is a risk of severe side effects if IdeS is given repeatedly to individuals with existing antibodies against IdeS as well as that IdeS' mechanism of action can be blocked since the antibodies against IdeS have the ability to inactivate IdeS. This phenomenon is referred to as immunogenicity.

In summary, IdeS has a mechanism of action which specifically, effectively and rapidly inactivates human IgG through cleavage.

The production of IdeS takes place through a bio-technical process. The process is referred to as recombinant and, simplified, entails that the genetic material for producing IdeS in group A streptococci is transferred to another bacterium, *E. Coli*, which in turn becomes very effective in producing IdeS. *E. Coli* bacteria are then cultivated through a process called fermentation. IdeS is thereafter "harvested" from the culture and the highest possible purity of IdeS is obtained through a number of stages of mechanical, chemical and biotechnical purification. During the time up to 2011, Hansa Medical invested extensive capital and resources in producing a quality-assured manufacturing practice, GMP, for IdeS. Production according to this process is currently carried out by a contract manufacturer in Finland.

IdeS and its effects have been the subject of extensive trialing of various types. Among other things, IdeS' general cleavage effects have been studied in blood samples from humans and rabbits. In addition, IdeS' specific cleavage effects have been studied in blood tests from HLA sensitized patients with chronic kidney disease and with Guillain-Barrés syndrome, a rare and serious acute autoimmune disease.

IdeS has also been tested in a number of animal models (in vivo), after receiving the necessary animal ethical licenses. General testing of cleavage effects and appropriate doses has been carried out in rabbits and dogs. Tests of various induced disease conditions in mice have been made, among other things, with respect to RA (rheumatoid arthritis, a common autoimmune disease), ITP (Idiopathic Thrombocytopenic Purpura, an autoimmune blood disease) and Anti-GBM (also called Goodpastures disease, a very rare autoimmune kidney disease).

During 2012 and 2013, two toxicological studies were carried out in rabbits (New Zealand White) and dogs (HsdRcc:DOBE Beagle) in accordance with Good Laboratory Practice (GLP). The purpose of the studies was to study the safety and tolerance profile of IdeS in repeated dosages in various dosage groups with various dosage levels. Through these studies, certain side effects could be studied and a highest tolerated dose (no observed adverse effect level, NOAEL) could be identified. Based on the results of the study, the highest tolerated dose could be established at 2.0 mg IdeS per kilogram of body weight.

During 2013 and 2014, a phase I study comprising 29 healthy test persons was carried out. The study was a so-called "first-in-man" study using double-blind randomization with gradually increasing single doses of IdeS. The primary purpose of the study was to study the safety and tolerability profile of IdeS. Amongst the secondary purposes was the study of IdeS' ability to cleave IgG in humans at various dosage levels, to study the degradation of IdeS and its residual products, and to study the immune response to IdeS. The test persons were broken down into groups which were administered IdeS in increasing dosage levels (20 test persons) with a placebo as the control group (9 test persons). No serious side effects (serious adverse events, SAE) arose as a consequence of dosages of IdeS or the placebo. A number of side effects (adverse events, AE) arose in both dosage groups which received IdeS and a placebo, including headaches and fatigue. With respect to IdeS' ability to cleave IgG, the conclusion could be drawn that IdeS at an effective dose (from 0.12 mg IdeS per kilogram of body weight) begins to inactivate IgG as early as within the span of a few minutes and that all IgG is fully cleaved within the span of a few hours. With respect to the degradation of IgG and its residual products, the conclusion to be drawn was that IdeS is degraded within the span of less than 24 hours and that the residual products in the form of antibody fragments are degraded within the span of several days up to a week. With respect to the immune response to IdeS, the conclusion could be drawn that antibodies against IdeS are formed and reach their highest level within the span of a few weeks, and that the level is normalized within six months. Taken as a whole, on the basis of the results of the study, it was concluded that IdeS is safe and tolerable. This phase I study is the proof-of-concept study for IdeS and constitutes the basis for further development of IdeS in various IgG mediated illnesses.

A phase II study was carried out in 2014 and 2015 on patients on a waiting list for a kidney transplant but who have high levels of Human Leucocyte Antigen (HLA) antibodies, also referred to as HLA sensitized patients. Antibodies against HLA constitute an impediment to carrying out a kidney transplant. The main purposes of the study were to study whether IdeS can reduce the levels of HLA antibodies to such an extent that the patients qualify for a kidney transplant and to study the safety and tolerance profiles of IdeS in a relevant group of patients. In total, eight patients were included in the study. The patients received one or two doses of IdeS, of which one group received 0.12 mg IdeS per kilogram body weight and the other group received 0.24 mg of IdeS per kilogram of body weight. The patients were not administered dosages of IdeS for the purpose of carrying out a kidney transplant, but there was the possibility in the study to allow for a kidney transplant if a suitable organ became available for a patient participating in the study. Preliminary results from this study indicate that IdeS quickly and effectively inactivates IgG to such an extent that patients qualify for a kidney transplant. Among the side effects, one could note anticipated side effects in the form of infections and muscle aches (which commonly occurs when using biological pharmaceuticals). A complete report from the study is expected during the first half of 2015.

The potential medical use for IdeS is multifaceted. It is believed that it will be possible to use IdeS to cure or alleviate autoimmune diseases which, to varying degrees, are caused by pathogenic IgG and to inactivate IgG which constitutes an obstruction to other therapy, for example kidney transplants.

Pathogenic IgG means antibodies harmful to the body which arise in particular situations, typically within autoimmune diseases and in conjunction with hypersensitivity reactions. Many autoimmune diseases are caused, to varying degrees by the pathogenic IgG. This is true of both chronic autoimmune diseases such as Lupus (systemic lupus erythematosus, SLE), and a number of acute monophasic (nonrecurring) diseases. Since IdeS is currently being developed to be used on one occasion or on a few occasions during the life of the patient (since the body also forms antibodies against IdeS), it is primarily the monophasic autoimmune diseases that are relevant. Guillain Barrés syndrome and anti-GBM disease (also called Goodpastures disease) are two examples of autoimmune diseases which span the course of a few weeks and then seldom recur. In both of these diseases, the disease is serious with antibody attacks on vital organs. Guillain Barré syndrome, which affects approximately one in 100,000 people, can lead to death or lifelong impairment of functions. Anti-GBM disease, which affects approximately 1 person in 1 million, can lead to the loss of pulmonary or kidney functions, or death. Examples of other acute monophasic diseases where IgG plays (or is suspected of playing) an important role include Neuromyelitis optica, anti-NMDA receptor encephalitis, catastrophic Antiphospholipid Syndrome (within Antiphospholipid Syndrome), myasthenic crisis (within Myasthenia Gravis) and ANCA-associated vasculitis. Even if IdeS is not assumed to be able to play important role in chronic autoimmune diseases, unless it can be administered several times during the patient's life, the possibilities of treating crises within chronic autoimmune diseases, for example "flares" in SLE, are also being studied.

"Obstructive IgG" refers to antibodies which per se are not harmful to the body but which entail an impediment to other treatment.

One example of such obstructive treatment is transplantation, for example of organs such as the kidney or the heart, but also transfusions and cell therapy. Another example of obstructed treatments is the administration of biological pharmaceuticals generally, and certain blood factors, vaccines and genetic therapeutic pharmaceuticals in particular. A common feature of all of these situations is that the body has formed IgG which inhibits or reduces the possibilities for success for the subsequent treatment. In transplants, there is a risk that IgG will attack and destroy the transplanted organ. In conjunction with subsequent treatments with biological pharmaceuticals, the risk scenario is typically that IgG will neutralize the biological pharmaceutical which thereby suffers a loss or reduction of effect. The situation which has been studied most closely with respect to IdeS is kidney transplants. A kidney transplant is a successful method of curing chronic kidney disease which requires dialysis. Of all of the patients on a waiting list for a kidney transplant, approximately 30% are deemed to have such levels of anti-HLA antibodies (of the IgG type) that the possibility of finding an appropriate organ is reduced. These patients must therefore wait a very long time for a kidney transplant which results in a seriously deteriorated state of health and loss of quality of life, and a large share of the patients die while on the waiting list. It has been shown that even these patients can receive access to organs and successfully undergo a kidney transplant if the levels of anti-HLA antibodies can be reduced sufficiently prior to the transplant. The treatment concept for IdeS within kidney transplants is therefore to inactivate anti-HLA antibodies in a safe, speedy, effective and noninvasive manner and render possible a transplant from both deceased as well as living donors.

There are a number of methods and pharmaceuticals designed to reduce the levels of IgG in the body. There are pharmaceuticals which seek to inhibit the creation of new IgG and there are medical-technical methods to purify the blood from IgG. The pharmaceuticals which are used to inhibit the creation of new IgG work in different ways, and normally work slowly and with limited effect. The most commonly used therapy is IVIG (intravenous gammaglobulin) which consists of IgG which has been extracted from human blood. The mechanisms behind IVIG are not fully known but the therapy is considered to have an effect in a number of the clinical conditions which are relevant for IdeS. Of the medical-technical methods used to purify the blood from IgG, plasmapheresis is the most widely used. This method entails the blood being led outside of the body (extracorporeal) and cleaned mechanically by large molecules such as IgG being separated from small molecules with the larger molecules then being filtered away. Plasmapheresis cleans out not only IgG, but also other types of antibodies and other large molecules. It is believed that plasmapheresis can eliminate no more than 80% of all IgG, given repeated sessions which take weeks or months to carry out. Plasmapheresis is used in many of the indications which are relevant to IdeS, including desensitizing kidney transplant patients, and in conjunction with Guillain Barrés syndrome and anti-GBM disease. The costs of carrying out a maximum elimination of IgG through plasmapheresis are deemed to be in the tens of thousands of US dollars per patient.

In order to be able to market IdeS, there must be continued structured development of IdeS into a finished pharmaceutical. The first task is to establish commercial production of IdeS which is quality-assured for the market. This is a time-consuming and costly

process which is anticipated to continue during 2015 and 2016. A second important task is to ensure that IdeS receives optimal treatment by regulatory authorities such as the US FDA and European EMA. This requires that both advisory as well as formal contacts be prepared carefully and implemented at an appropriate place. The Company is of the opinion that IdeS has the potential of obtaining the status of orphan drug. It is also believed that it is possible to receive treatment during other advantageous governmental protocols such as the Breakthrough Therapy Designation. This can give us a faster processing of the application for market approval, and market exclusivity for biological pharmaceuticals which can provide market exclusivity for up to 12 years from the time of registration. The third task is to implement additional clinical studies in order to document the safety and effectiveness of IdeS. The Company's current plans call for carrying out further clinical studies in several indications during 2015 – 2016. The Company will continue its clinical studies regarding kidney transplants. There indications being evaluated are anti-GBM disease and Guillain Barrés syndrome. The studies being planned will have the goal of contributing to results which will form the basis for registration. Extensions of these studies may be required or additional clinical studies with different approaches (protocols) or a greater number of patients.

The work in finally developing IdeS is being carried out as a project with the head of clinical development as the project manager. In addition to internal personnel, contract research organizations and contract manufacturers, there are physicians and clinical researchers in the organization working with the project. In addition, the Company has appointed medical advisory committees for various indications. For kidney transplants in Europe, professors Gunnar Tuvesson, Kathryn Wood and Christoph Legendre are participating. For kidney transplants in the United States, Professor Stanley Jordan has been appointed as an advisor. For anti-GBM, Professor Mårten Segelmark and Dr. David Jayne and Dr. Vladimir Szpirt have been appointed to the medical advisory committee.

A special project being conducted by the Company is designed to produce new molecules with the same activity as IdeS regarding cleavage of antibodies, but which are less immunogenic. The goal is to produce molecules which can be administered repeatedly or chronically. If this is successful, the potential use will be expanded to cover a larger number of autoimmune diseases, resulting also in a significant increase in the commercial potential. An important milestone was reached in the beginning of 2015 when a patent was applied for regarding certain results from the development work.

Final development of IdeS and developing the second-generation IdeS molecules will require capital and expertise. In March and April 2015, the Company carried out a preferential rights issue which provided the Company with approximately MSEK 246 prior to deduction for costs. As a supplement to this, the Company can investigate the possibilities of industrial cooperation with other pharmaceutical companies. Such cooperation might either cover the development of IdeS for particular medical indications, or the future distribution of IdeS in specific geographic markets, or a more fundamental global cooperation. The Company is of the opinion that there are many potential cooperating partners that have demonstrated great interest in IdeS as a pharmaceutical candidate.

### The HBP-assay diagnostic method

HBP-assay is a method of analysis which has been launched on the market and which is used to predict severe sepsis in emergency clinics. In December 2012, Hansa Medical's partner Axis-Shield Diagnostics Ltd launched a CE-marked version of the analysis method. The cooperation agreement with Axis-Shield gives Hansa Medical the right to milestone payments from Axis-Shield as well as royalty income on licensing payments made to Axis-Shield and their sales of the HBP-assay.

Axis-Shield has launched a first version of the analysis method which is primarily appropriate for research use and for particularly interested specialists. Axis-Shield is currently further developing the analysis method with the goal of incorporating it in a faster and more accessible analysis platform. A number of clinical studies are being conducted as well. The goal is to implement commercial launch of the analysis method in 2015.

### The EndoS research project

EndoS is an enzyme which modifies glycosylation (the glucose structure) of antibodies. By modifying the glucose structure, EndoS can inhibit and modify the effects of the antibodies without entirely eliminating them. This mechanism has many conceivable medical uses.

Together with academic research groups, Hansa Medical is conducting research to find new treatment methods based on EndoS for rare but serious autoimmune diseases.

## Equality and diversity

Hansa Medical believes in an open and inclusive place of work where human rights are respected and colleagues treat each other with integrity, respect, humility and dignity. Diversity and equality are prioritized issues at Hansa Medical. Diversity helps Hansa Medical attract, recruit and retain personnel with the right expertise.

## Resources

The Company's business is dependent upon access to certain important resources. Most important of these is access to patents and other intellectual property rights which are described in more detail under the section "*Patents, trademarks and other intellectual property rights*", the personnel resources described in the section "*Organization and employees*" (p. 25) and the financial resources set forth in the section "*Financial development*" (p. 24). The Company also has laboratories and laboratory equipment in its own premises in Lund, primarily for molecular biological and biochemical analyses and experiments.

## Patents, trademarks and other intellectual property rights

Hansa Medical is partially dependent on patents for its business operations. The Company's intellectual property rights are primarily protected through patents and patent applications. Filed patent applications provide protection corresponding to the patent, provided that the patent is ultimately granted. Development work

at Hansa Medical and the research work which is carried out by cooperating researchers, continuously generate new patent opportunities for Hansa Medical, both within existing projects as well as in entirely new areas. These opportunities are carefully evaluated by Hansa Medical and by patent attorneys retained by the Company. Whether a particular invention will be the subject of a patent application is determined from case to case.

Hansa Medical currently holds a total of ten patent families and holds exclusive licenses on two other patent families. The IdeS project is protected by four patent families which include both granted patents as well as pending patent applications. These families cover the enzyme as such and its ability to cleave IgG antibodies and the medical use of IdeS in conjunction with IgG mediated medical conditions including autoimmune diseases and transplants. Geographically, these patent families cover a large number of countries including the United States, Europe and Japan. The various IdeS patent families expire between 2021 and 2040, provided that the Company applies for, and is granted, supplemental protection.

The HBP project is protected by three different patent families which include pending patent applications. These families cover the prediction of severe sepsis and the diagnosis of bacterial meningitis and urinary tract infections. Geographically, these patent families cover a large number of countries and they expire between 2028 and 2036, provided the Company applies for, and is granted, supplemental protection.

Various applications for EndoS are protected by three different patent families which include both existing patents and pending patent applications. Geographically, these patent families cover a large number of countries and they expire between 2027 and 2039, provided the Company applies for, and is granted, supplemental protection.

## Environmental work

Hansa Medical works actively with environmental issues and consistently endeavors to reduce the use of environmentally hazardous substances and to ensure that the environmental impact is as little as possible. The Company makes limited discharges from laboratories and development facilities. Discharges consist of common salts and easily decomposable organic substances. Waste is sorted and special routines are applied for the handling of environmentally hazardous waste. Hansa Medical uses genetically modified microorganisms (GMM) in its research and development work (research activities). The Company's operations are subject to a notification obligation under the Swedish Environmental Code with a reporting obligation to the municipality of Lund.

## Customers

Hansa Medical currently does not have any actual customers. A quasi-customer relationship does, however, exist since the Company's HBP-assay method has been licensed to Axis-Shield Diagnostics. Axis-Shield sells the analysis method to clinics throughout the world. Among other things, Hansa Medical is entitled to royalties from Axis-Shield's sales of the HBP-assay.

## Market and factors in general

### IdeS

There are a number of general factors which influence the future possible commercialization of IdeS. In an initial stage, the Company is dependent on the interest of physicians groups and academic researchers in carrying out or participating in clinical studies, and on government pharmaceutical agencies and ethics committees providing approval for the implementation of clinical studies. The Company is then dependent on regulatory authorities providing their approval for marketing and sales of IdeS. Finally, insurance companies and other payers must approve the pricing of IdeS and customers and users (clinics) must purchase the product. Cooperation with other pharmaceutical companies participating in the distribution of IdeS on various markets around the world may also be required.

For the indications which are initially relevant, kidney transplants and anti-GBM, IdeS should command a large value from a health-economic perspective. The sales potential for IdeS could possibly reach hundreds of millions of US dollars per year<sup>1)</sup>. The potential is even greater if IdeS can play a role in crises within chronic autoimmune diseases.

### HBP-assay

Through improved prediction and diagnostics, lives are saved and healthcare costs can be lowered dramatically. In the autumn of 2013, the U.S. Department of Health and Human Services published the report "National Inpatient Hospital Costs: The Most Expensive Conditions by Payer, 2011". The report identifies sepsis as the single most costly disease condition in the American healthcare system. In total, sepsis cost USD 20.3 billion, corresponding to 5.2% of the total costs of the US healthcare system. 1.1 million patients were treated at hospitals for sepsis in 2011. The market for predicting severe sepsis at emergency clinics is estimated at 3 million analyses per year in the United States and Europe alone. Hansa Medical's licensee, Axis-Shield Diagnostics Ltd, has entered into a sublicense with the Chinese diagnostics company, Hangzhou Joinstar Biomedical Technology Co. Ltd., for commercialization of the HBP-assay in China.

<sup>1)</sup> The Company's assessment based upon the number of treatable patients, the pricing of other biological pharmaceuticals for the treatment of rare diseases, and the cost of dialysis.

## Financial developments

### Sales and earnings

Net sales during the 2014 financial year amounted to KSEK 4,716 as compared with KSEK 1,727 for the corresponding period in 2013 and KSEK 2,619 for 2012. For 2014 and 2013, net sales consisted of licensing revenues from Axis-Shield Diagnostics, and compensation for patent costs from Axis-Shield Diagnostics. For 2014, net sales also consisted of contributions from VINNOVA. For 2012, net sales primarily consisted of licensing revenues from Genovis AB and Axis-Shield Diagnostics and compensation for patent costs from Axis-Shield Diagnostics and Alere Inc. Operating earnings for the 2014 financial year amounted to KSEK -24,709, as compared with KSEK -17,629 for 2013 and KSEK -16,798 for 2012.

The result for the year for 2014 amounted to KSEK -29,042, as compared with KSEK -17,562 for 2013 and KSEK -16,468 for 2012. The 2014 result included a write-down of MSEK 4,252 regarding shares in Genovis AB.

### Cash flow and financial position

Cash flow from current operations amounted to KSEK -23,522 for the 2014 financial year, as compared with KSEK -17,520 for the corresponding period in 2013 and KSEK -16,278 for 2012. Cash and equivalents amounted to KSEK 10,152 at the end of the 2014 financial year, as compared with SEK 90,000 at the corresponding time in 2013 and KSEK 18,966 for 2012. At the end of the 2014 financial year, shareholders' equity amounted to KSEK 49,804 as compared with KSEK 45,349 at the end of the 2013 financial year and KSEK 60,585 at the corresponding time in 2012.

### Investments

Investments during the 2014 financial year amounted to KSEK 1,319, as compared with KSEK 4,529 for 2013 and KSEK 6,559 for 2012. The investments during 2014 related primarily to purchases of laboratory equipment and office fixtures in the amount of KSEK 1,204 and the acquisition of 29,000 shares in Genovis AB with an acquisition value of SEK 115,000.

In 2013, the Company acquired an additional 1,122,265 shares in Genovis AB through Genovis AB's rights issue and on Nasdaq First North for the total amount of KSEK 4,465. Investments in intangible assets were made in an amount less than SEK 64,000 which consists of capitalized development costs for the establishment of a GMP process for IdeS.

In 2012, the Company acquired 1,025,800 shares in Genovis AB on Nasdaq First North for the total amount of KSEK 3,852. Investments in intangible assets were made in the amount of KSEK 2,707 which consisted entirely of capitalized development costs for the establishment of a GMP process for IdeS.

In total, the Company's holdings in Genovis AB amount to 2,177,065 shares with an acquisition value of KSEK 8,432. Genovis AB is a biotechnology company focused on antibody modification

with the help of the IdeS and EndoS enzymes. Genovis AB's applications of IdeS and EndoS are marketed under the trademarks FabRICATOR and IgGZERO. These products simplify the development and quality control of pharmaceutical products. Hansa Medical and Genovis entered into a licensing agreement in 2007 which grants Genovis the right to commercialize the IdeS enzyme as a non-therapeutic research tool. Hansa Medical's investment in Genovis is a strategic investment in a biotechnology company which develops new and promising non-therapeutic applications of assets which are central to Hansa Medical's operations: the IdeS and EndoS enzymes.

### The parent company

The parent company's net sales for the 2014 financial year amounted to KSEK 4,716 as compared with KSEK 1,727 for the 2013 financial year and KSEK 2,618 for the 2012 financial year. Earnings after net financial items for the parent company amounted to KSEK -31,438 for the 2014 financial year, as compared with KSEK -17,560 for 2013 and KSEK -16,466 for 2012. Liquidity at the end of 2014 amounted to KSEK 10,152 as compared with SEK 90,000 at the end of 2013 and KSEK 18,965 at the end of 2012.

### Shareholders' equity

On 31 December 2014, shareholders' equity for the parent company amounted to KSEK 49,806 as compared with KSEK 45,683 at the end of the 2013 financial year and KSEK 63,243 at the corresponding time in 2012.

### Future capital requirements

Hansa Medical carries out capital-intensive and value-generating pharmaceuticals and diagnostics development. Future financing of the operations is expected to take place through new issues of shares, loans, licensing revenues, cooperation with other parties, and the sales of rights or patents.

In March and April 2015, the Company carried out a preferential rights issue which provided the Company with approximately MSEK 246 prior to deductions for costs.

Hansa Medical endeavors to eventually achieve a position where the Group's revenues are significantly better matched to its costs. Hansa Medical's development projects have the potential of generating significant revenues in the form of one-time compensation, milestone payments or licensing revenues if the Company is successful in entering into attractive cooperation agreements. Debt financing is not considered to be an appropriate form of financing, other than temporarily, until the Company has achieved profitability and positive cash flow.

## Financing

Hansa Medical has financed its business operations thus far partially with the help of milestone compensation and one-time compensation amounts from the Company's current and previous cooperating partners and with royalty revenues from licensing agreements. However, the operations have mostly been financed with shareholders' equity through new issues of shares, primarily rights issues to the shareholders.

## Capitalization

On 31 December 2014, shareholders' equity amounted to KSEK 49,806 as compared with KSEK 45,349 at the end of the 2013 financial year and KSEK 60,585 the corresponding time in 2012. On 31 December 2014, Hansa Medical had interest-bearing current liabilities in the amount of KSEK 39. For the corresponding period in 2013, interest-bearing current liabilities amounted to KSEK 556 and for 2012 KSEK 36. On 31 December 2014, Hansa Medical had a long-term liabilities totaling KSEK 91. For the corresponding period in 2013, interest-bearing current liabilities amounted to KSEK 131 and for 2012 KSEK 168.

## Financing arrangement

After the expiration of the 2014 financial year, the Company secured a bridge loan from Nexttobe AB in the amount of MSEK 20, and subsequent to that carried out a new share issue which provided the Company with approximately MSEK 246 prior to deduction for costs. The bridge loan was repaid in conjunction with the new share issue. For more information, please see note 29.

## Financial risk management

Through its business activities, the Group is exposed to various financial risks. The most significant financial risk is the financing risk, i.e. the risk that the Group will not be able to obtain sufficient financing for the business, or that financing cannot be obtained at a reasonable cost. In addition to the financing risk, the Group is also exposed, among other things, to currency risks and to risks associated with the management of cash and equivalents. For more information, please see note 23.

## Organization and employees

The Group consists of the Company and the subsidiary Cartela R & D AB, in which no business is currently conducted.

At the close of 2014, the Board of Directors consisted of the chairman Birgit Stattin Norinder and directors Anders Blom, Stina Gestrelus, Per-Olof Wallström and Cindy Wong. The board's audit committee consisted of Anders Blom (chairman), Birgit Stattin Norinder and Per-Olof Wallström and the remuneration committee consisted of Birgit Stattin Norinder (chairman), Stina Gestrelus and Per-Olof Wallström.

Corporate management consists of the CEO Fredrik Lindgren (on leave of absence), CFO and Executive Vice President Göran Arvidson, vice president for research Christian Kjellman, vice president for clinical development Lena Winstedt and vice president for business development Emanuel Björne.

There were 14 employees at the end of 2014 as compared with 8 employees at the end of 2013 and 2012.

## Share

On 31 December 2014, Hansa Medical's share capital amounted to SEK 25,929,603 divided into 25,929,603 shares. The Company has only issued one class of shares. At general meeting, each share in Hansa Medical entitles the holder to one vote and each shareholder may vote the full number of shares held by him or her. All shares carry the same rights to share in the Company's assets and profits and provide the same entitlement to dividends. Upon the issuance of new shares, the shareholders normally have preemptive rights. However, the shareholders' meeting may resolve to disapply preemptive rights. A resolution adopted at a shareholders' meeting is required in order to change shareholders' rights. The terms and conditions for changing shareholders' rights correspond to the provisions set forth in law. The shares are freely transferable. There are no outstanding warrants, convertible debentures or other financial instruments which might give rise to a dilution effect for existing shareholders.

## Shareholdings

According to the share register maintained by Euroclear Sweden AB, on 31 December 2015 Hansa Medical had 1,198 shareholders. Information regarding shareholders and share ownership is updated every quarter on the Company's website at [www.hansamedical.com](http://www.hansamedical.com).

### Shareholders on 31 December 2014

Name	Number of shares	Percentage (%)
Farstorps Gård AB	11,070,320	42.69
Nexttobe AB	7,555,009	29.14
Försäkringsaktiebolaget, Avanza Pension	2,605,002	10.05
Sven Sandberg	345,000	1.33
Anja Ellesson Ljunggren	269,097	1.04
Aktiebolaget Protiga	233,333	0.90
Strategic Wisdom Nordic AB	138,630	0.53
Nordnet Pensionsförsäkring AB	133,658	0.52
Wigzellproduktion AB	91,269	0.35
Tobias Ekman	90,000	0.35
Other	3,398,285	13.10
<b>Total</b>	<b>25,929,603</b>	<b>100.00</b>

## Annual general meeting

The annual general meeting of Hansa Medical AB (publ) will take place on 2 June 2015 in the auditorium at the Company's offices on Scheelevägen 22 in Lund. Notice to attend the annual general meeting will be published on Hansa Medical's website at [www.hansamedical.com](http://www.hansamedical.com).

### Guidelines for remuneration to senior management

The Board of Directors of Hansa Medical proposes that the annual general meeting to be held on 2 June 2015 adopt a resolution regarding the following guidelines for determination of salaries and other compensation to be paid to senior management of Hansa Medical, to be applicable until the annual general meeting held in 2016.

The guidelines entail that senior management will be offered remuneration which is competitive and on market terms. The level of the remuneration for the individual manager shall be based on factors such as position, expertise, experience and performance. The remuneration consists of a fixed salary and pension benefits and, in addition, may consist of variable salary, severance compensation and non-monetary benefits. The variable salary shall be based on the achievement of quantitative and qualitative targets. Salary during the notice of termination period and severance compensation shall be possible in a total maximum amount of 24 monthly salaries. It is proposed that the Board of Directors be authorized to disapply the guidelines where special cause exists in an individual case.

## Proposal for dividend

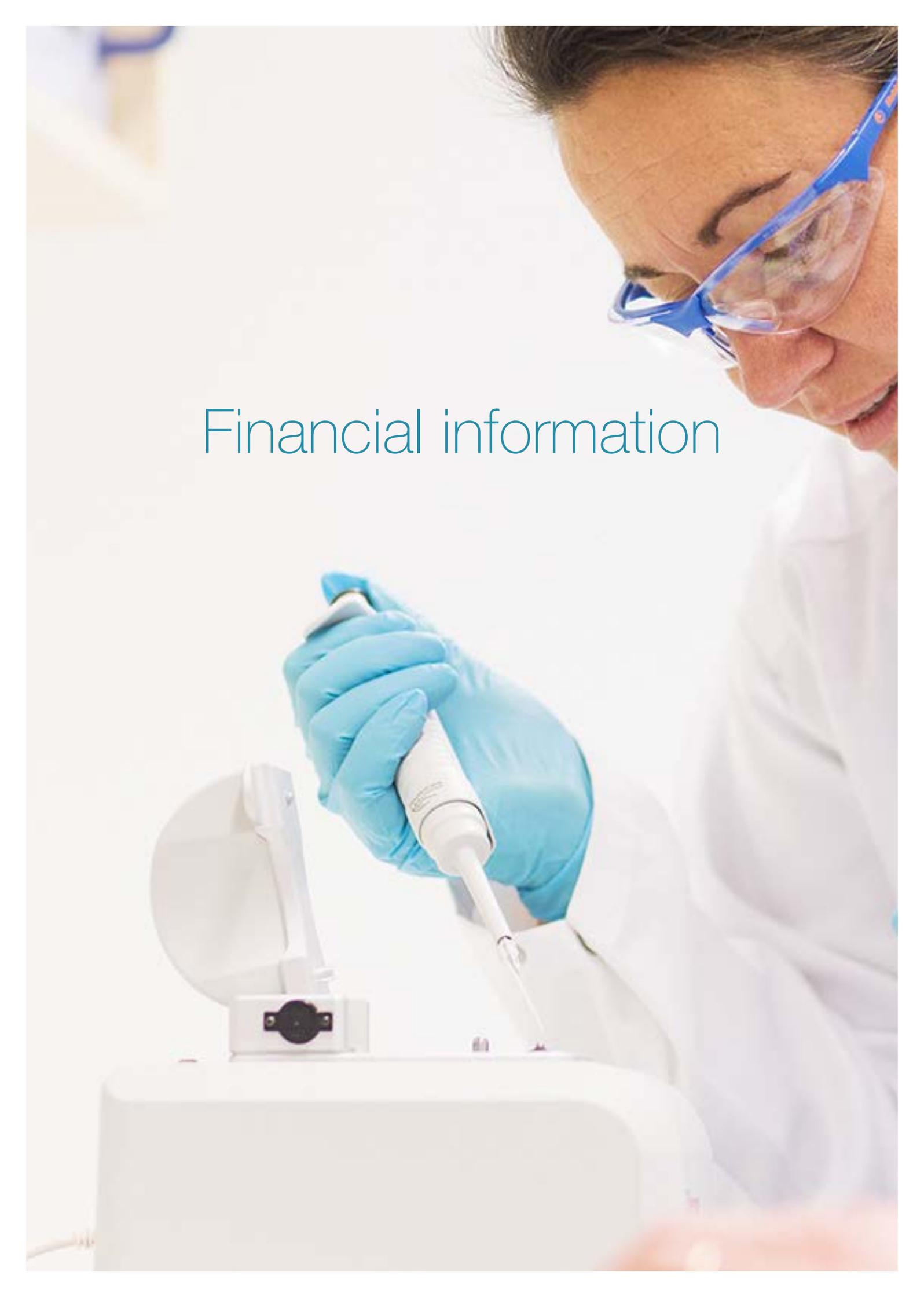
Unrestricted shareholders' equity in the parent company

Share premium reserve	33,336,410
Profit carried forward	21,978,367
Result for the year	-31,438,207
<b>Total</b>	<b>23,876,570</b>

The Board of Directors proposes that the profits available for distribution and unrestricted reserves be allocated as follows

Share premium reserve	23,876,570
Profit carried forward	0
<b>Total</b>	<b>23,876,570</b>

The group's and the company's results and financial position are shown in the following income statements, balance sheets, cash flow statements and statements of shareholders' equity and accompanying notes and supplementary information, which are an integral part of these financial statements.

A close-up photograph of a female scientist in a white lab coat, wearing blue safety glasses and blue nitrile gloves. She is focused on using a white pipette to transfer liquid into a small vial. The pipette is held in her right hand, and the tip is positioned over the vial. The background is a bright, clean laboratory setting. The text "Financial information" is overlaid in a teal color on the left side of the image.

Financial information

## The group

### Consolidated income statement

KSEK	Note	1 January – 31 December		
		2014	2013	2012
Net sales	2, 3	4,716	1,727	2,619
Capitalized work on own account			64	2,706
Other operating income		59		
<b>Total operating income, stock changes, etc.</b>		<b>4,775</b>	<b>1,791</b>	<b>5,325</b>
Raw materials and consumables		-245	-382	-220
Other external costs		-17,422	-11,190	-14,073
Personnel expenses		-10,468	-7,696	-7,647
Amortization, depreciation and write-down of tangible and intangible fixed assets		-1,349	-152	-183
<b>Operating result</b>	4, 5, 24	<b>-24,709</b>	<b>-17,629</b>	<b>-16,798</b>
Financial income		42	93	347
Financial expenses		-4,375	-26	-17
<b>Net financial income/expenses</b>	6	<b>-4,333</b>	<b>67</b>	<b>330</b>
Result before tax		-29,042	-17,562	-16,468
Tax	7			
<b>Result for the year</b>		<b>-29,042</b>	<b>-17,562</b>	<b>-16,468</b>
Attributable to				
Parent company shareholders		-29,042	-17,562	-16,468
		<b>-29,042</b>	<b>-17,562</b>	<b>-16,468</b>
Earnings per share	8			
before dilution (SEK)		-1.16	-0.75	-0.75
after dilution (SEK)		-1.16	-0.75	-0.75

### Consolidated statement of comprehensive income

KSEK	Note	1 January – 31 December		
		2014	2013	2012
<b>Result for the year</b>		<b>-29,042</b>	<b>-17,562</b>	<b>-16,468</b>
<b>Other comprehensive income</b>				
Items that have been, or may be reclassified to profit or loss for the year				
Fair value changes for the year on realizable financial assets		-2,064	2,326	-262
<b>Other comprehensive income for the year</b>		<b>-2,064</b>	<b>2,326</b>	<b>-262</b>
<b>Total net comprehensive income</b>		<b>-31,106</b>	<b>-15,236</b>	<b>-16,730</b>
Total net comprehensive income attributable to				
The parent company's owners		-31,106	-15,236	-16,730
		<b>-31,106</b>	<b>-15,236</b>	<b>-16,730</b>

## Consolidated balance sheet

KSEK	Note	As of 31 December			2012-01-01
		2014	2013	2012	
<b>ASSETS</b>					
<b>Fixed assets</b>					
Intangible fixed assets	9	36,898	38,028	37,976	35,282
Tangible fixed assets	10	1,283	298	438	608
Financial fixed assets	12	4,180	10,381	3,590	
<b>Total fixed assets</b>		<b>42,361</b>	<b>48,707</b>	<b>42,004</b>	<b>35,890</b>
<b>Current assets</b>					
Tax receivable		292	211	101	108
Accounts receivable	15	59		672	381
Prepaid expenses and accrued income	16	373	953	1,119	502
Other receivables	14	1,074	653	483	703
Cash and cash equivalents	17	10,152	90	18,966	1,157
<b>Total current assets</b>		<b>11,950</b>	<b>1,907</b>	<b>21,341</b>	<b>2,851</b>
<b>TOTAL ASSETS</b>		<b>54,311</b>	<b>50,614</b>	<b>63,345</b>	<b>38,741</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>					
<b>Shareholders' equity</b>					
Share capital	18	25,930	22,225	22,225	67,605
Other paid in capital		33,336	1,480	1,480	19,806
Reserves			2,064	-262	
Retained earnings including result for the year		-9,462	19,580	37,142	-55,097
<b>Shareholders' equity attributable to parent company shareholders</b>		<b>49,804</b>	<b>45,349</b>	<b>60,585</b>	<b>32,314</b>
<b>Total shareholders' equity</b>		<b>49,804</b>	<b>45,349</b>	<b>60,585</b>	<b>32,314</b>
<b>Liabilities</b>					
Long-term interest bearing liabilities	19	91	131	168	204
<b>Total long-term liabilities</b>		<b>91</b>	<b>131</b>	<b>168</b>	<b>204</b>
Current interest-bearing liabilities	19	39	556	36	2,734
Accounts payable		1,795	710	840	634
Other liabilities	21	1,039	804	617	477
Accrued expenses and deferred income	22	1,543	3,064	1,099	2,378
<b>Total current liabilities</b>		<b>4,416</b>	<b>5,134</b>	<b>2,592</b>	<b>6,223</b>
<b>Total liabilities</b>		<b>4,507</b>	<b>5,265</b>	<b>2,760</b>	<b>6,427</b>
<b>TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES</b>		<b>54,311</b>	<b>50,614</b>	<b>63,345</b>	<b>38,741</b>

Information regarding the group's pledged assets and contingent liabilities, see note 25.

## Consolidated statement of changes in equity

KSEK	Note	Equity attributable to the parent company's shareholders					Total	Total shareholders' equity
		Share capital	Additional paid in capital	Fair value reserve	Retained earnings incl. profit or loss for the year			
<b>Opening shareholders' equity, 1 Jan 2012</b>	18	67,605	19,806		-55,097	32,314	32,314	
<b>Net comprehensive income</b>								
Result for the year					-16,468	-16,468	-16,468	
Other comprehensive income for the year				-262		-262	-262	
<b>Net comprehensive income</b>		<b>0</b>	<b>0</b>	<b>-262</b>	<b>-16,468</b>	<b>-16,730</b>	<b>-16,730</b>	
Reduction of the share capital		-88,901	-19,806		108,707	0	0	
<b>Transactions with the group's owner</b>								
New share issue		43,521	2,500			46,021	46,021	
Expenses attributable to new share issue			-1,020			-1,020	-1,020	
<b>Total transactions with the group's owner</b>		<b>43,521</b>	<b>1,480</b>	<b>0</b>	<b>0</b>	<b>45,001</b>	<b>45,001</b>	
<b>Closing shareholders' equity, 31 Dec 2012</b>		<b>22,225</b>	<b>1,480</b>	<b>-262</b>	<b>37,142</b>	<b>60,585</b>	<b>60,585</b>	

KSEK	Note	Equity attributable to the parent company's shareholders					Total	Total shareholders' equity
		Share capital	Additional paid in capital	Fair value reserve	Retained earnings incl. profit or loss for the year			
<b>Opening shareholders' equity, 1 Jan 2013</b>	18	22,225	1,480	-262	37,142	60,585	60,585	
<b>Net comprehensive income</b>								
Result for the year					-17,562	-17,562	-17,562	
Other comprehensive income for the year				2,326		2,326	2,326	
<b>Net comprehensive income</b>		<b>0</b>	<b>0</b>	<b>2,326</b>	<b>-17,562</b>	<b>-15,236</b>	<b>-15,236</b>	
<b>Total transactions with the group's owners</b>		<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	
<b>Closing shareholders' equity, 31 Dec 2013</b>		<b>22,225</b>	<b>1,480</b>	<b>2,064</b>	<b>19,580</b>	<b>45,349</b>	<b>45,349</b>	

KSEK	Note	Equity attributable to the parent company's shareholders					Total	Total shareholders' equity
		Share capital	Additional paid in capital	Fair value reserve	Retained earnings incl. profit or loss for the year			
<b>Opening shareholders' equity, 1 Jan 2014</b>	18	22,225	1,480	2,064	19,580	45,349	45,349	
<b>Net comprehensive income</b>								
Result for the year					-29,042	-29,042	-29,042	
Other comprehensive income for the year				-2,064		-2,064	-2,064	
<b>Net comprehensive income</b>		<b>0</b>	<b>0</b>	<b>-2,064</b>	<b>-29,042</b>	<b>-31,106</b>	<b>-31,106</b>	
<b>Transactions with the group's owner</b>								
New share issue		3,705	33,337			37,042	37,042	
Expenses attributable to new share issue			-1,481			-1,481	-1,481	
<b>Total transactions with the group's owners</b>		<b>3,705</b>	<b>31,856</b>	<b>0</b>	<b>0</b>	<b>35,561</b>	<b>35,561</b>	
<b>Closing shareholders' equity, 31 Dec 2014</b>		<b>25,930</b>	<b>33,336</b>	<b>0</b>	<b>-9,462</b>	<b>49,804</b>	<b>49,804</b>	

## Consolidated statement of cash flows

KSEK	Note	1 January – 31 December		
		2014	2013	2012
<b>Operating activities</b>	28			
Operating income		-24,709	-17,629	-16,798
Adjustment for items not included in cash flow		1,349	152	183
Interest received		42	93	347
Interest paid		-123	-26	-17
Income tax paid		-81	-110	7
<b>Cash flow from operating activities before changes in working capital</b>		<b>-23,522</b>	<b>-17,520</b>	<b>-16,278</b>
<b>Cash flow from changes in working capital</b>				
Increase (-)/Decrease (+) of accounts receivable		-59	672	-291
Increase (-)/Decrease (+) of other operating receivables		159	-4	-397
Increase (+)/Decrease (-) of accounts payable		1,085	-130	206
Increase (+)/Decrease (-) of other operating liabilities		-1,286	2,152	-1,139
<b>Cash flow from operating activities</b>		<b>-23,623</b>	<b>-14,830</b>	<b>-17,899</b>
<b>Investing activities</b>				
Acquisition of tangible fixed assets		-1,204		
Investments in capitalized development expenditures			-64	-2,707
Acquisition of financial assets		-115	-4,465	-3,852
<b>Cash flow from investing activities</b>		<b>-1,319</b>	<b>-4,529</b>	<b>-6,559</b>
<b>Financing activities</b>				
New share issue		37,042		46,021
Issue expenses		-1,481		-1,020
Loans raised			519	
Repayment of loans		-519		-2,700
Repayment of leasing liabilities		-38	-36	-34
<b>Cash flow from financing activities</b>		<b>35,004</b>	<b>483</b>	<b>42,267</b>
Net cash flow		10,062	-18,876	17,809
Cash and cash equivalents, beginning of year		90	18,966	1,157
<b>Cash and cash equivalents, year-end</b>		<b>10,152</b>	<b>90</b>	<b>18,966</b>

## The parent company

### Parent company income statement

KSEK	Note	1 January – 31 December		
		2014	2013	2012
Net sales	2, 3	4,716	1,727	2,618
Capitalized work on own account			64	2,706
Other operating income		59		
<b>Total operating income, stock changes, etc.</b>		<b>4,775</b>	<b>1,791</b>	<b>5,324</b>
Raw materials and consumables		-245	-382	-220
Other external costs		-17,483	-11,254	-14,138
Personnel expenses		-10,468	-7,696	-7,647
Amortization, depreciation and write-down of tangible and intangible fixed assets		-1,294	-96	-127
<b>Operating result</b>	4, 5, 24	<b>-24,715</b>	<b>-17,637</b>	<b>-16,808</b>
Result from financial items:				
Result from participating interests in group companies		-2,398		
Result from other securities and receivables which are fixed assets		-4,252		
Other interest income and similar profit/loss items		42	93	347
Interest expenses and similar profit/loss items		-115	-16	-5
<b>Result after financial items</b>	6	<b>-31,438</b>	<b>-17,560</b>	<b>-16,466</b>
Result before tax		-31,438	-17,560	-16,466
Tax	7			
<b>Net result</b>		<b>-31,438</b>	<b>-17,560</b>	<b>-16,466</b>

### Consolidated statement of parent company's comprehensive income

KSEK	Note	1 January – 31 December		
		2014	2013	2012
<b>Net result</b>		<b>-31,438</b>	<b>-17,560</b>	<b>-16,466</b>
<b>Other comprehensive income</b>				
Other net comprehensive income		0	0	0
<b>Net comprehensive income</b>		<b>-31,438</b>	<b>-17,560</b>	<b>-16,466</b>

## Parent company balance sheet

KSEK	Note	As of 31 December		
		2014	2013	2012
<b>ASSETS</b>				
<b>Fixed assets</b>				
Intangible fixed assets	9	36,898	38,028	37,976
Tangible fixed assets	10	1,155	115	199
Financial fixed assets				
Interests in group companies	27	100	100	100
Receivables from group companies	11		2,296	2,295
Other long-term holdings of securities	13	4,180	8,317	3,852
Total financial fixed assets		4,280	10,713	6,247
<b>Total fixed assets</b>		<b>42,333</b>	<b>48,856</b>	<b>44,422</b>
<b>Current assets</b>				
Current receivables				
Accounts receivable	15	59		672
Tax receivable		292	211	101
Other receivables	14	1,074	653	483
Prepaid expenses and accrued income	16	373	970	1,156
Total current receivables		1,798	1,834	2,412
Cash and cash equivalents		10,152	90	18,965
<b>Total current assets</b>		<b>11,950</b>	<b>1,924</b>	<b>21,377</b>
<b>TOTAL ASSETS</b>		<b>54,283</b>	<b>50,780</b>	<b>65,799</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>				
<b>Shareholders' equity</b>				
Restricted equity				
Share capital		25,930	22,225	22,225
Unrestricted shareholders' equity				
Share premium reserve		33,336	1,480	1,480
Retained earnings		21,978	39,538	56,004
Net result		-31,438	-17,560	-16,466
<b>Total shareholders' equity</b>		<b>49,806</b>	<b>45,683</b>	<b>63,243</b>
<b>Current liabilities</b>				
Liabilities to credit institutions	20		519	
Trade payables		1,795	710	840
Liabilities to group companies		100		
Other liabilities	21	1,039	804	617
Accrued expenses and deferred income	22	1,543	3,064	1,099
<b>Total current liabilities</b>		<b>4,477</b>	<b>5,097</b>	<b>2,556</b>
<b>TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES</b>		<b>54,283</b>	<b>50,780</b>	<b>65,799</b>

## Pledged assets and contingent liabilities of the parent company

KSEK	Note	As of 31 December		
		2014	2013	2012
Pledged assets		Inga	Inga	Inga
Contingent liabilities		Inga	Inga	Inga

## Parent company statement of changes in shareholders' equity

KSEK	Restricted equity		Unrestricted equity		Total shareholders' equity
	Share capital	Share premium reserve	Retained earnings	Result for the year	
<b>Opening shareholders' equity, 1 Jan 2012</b>	67,605	19,806	-28,131	-24,572	34,708
<b>Net comprehensive income</b>					
Result for the year				-16,466	-16,466
Other comprehensive income for the year					
<b>Net comprehensive income</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>-16,466</b>	<b>-16,466</b>
Appropriation of profits			-24,572	24,572	
New share issue	43,521	2,500			46,021
Costs attributable to new share issue		-1,020			-1,020
Reduction of the share capital	-88,901	-19,806	108,707		
<b>Closing shareholders' equity, 31 Dec 2012</b>	<b>22,225</b>	<b>1,480</b>	<b>56,004</b>	<b>-16,466</b>	<b>63,243</b>

KSEK	Restricted equity		Unrestricted equity		Total shareholders' equity
	Share capital	Share premium reserve	Retained earnings	Result for the year	
<b>Opening shareholders' equity, 1 Jan 2013</b>	22,225	1,480	56,004	-16,466	63,243
<b>Net comprehensive income</b>					
Result for the year				-17,560	-17,560
Other comprehensive income for the year					
<b>Net comprehensive income</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>-17,560</b>	<b>-17,560</b>
Appropriation of profits			-16,466	16,466	
<b>Closing shareholders' equity, 31 Dec 2013</b>	<b>22,225</b>	<b>1,480</b>	<b>39,538</b>	<b>-17,560</b>	<b>45,683</b>

KSEK	Restricted equity		Unrestricted equity		Total shareholders' equity
	Share capital	Share premium reserve	Retained earnings	Result for the year	
<b>Opening shareholders' equity, 1 Jan 2014</b>	22,225	1,480	39,538	-17,560	45,683
<b>Net comprehensive income</b>					
Result for the year				-31,438	-31,438
Other comprehensive income for the year					
<b>Net comprehensive income</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>-31,438</b>	<b>-31,438</b>
Appropriation of profits			-17,560	17,560	
New share issue	3,705	33,337			37,042
Costs attributable to new share issue		-1,481			-1,481
<b>Closing shareholders' equity, 31 Dec 2014</b>	<b>25,930</b>	<b>33,336</b>	<b>21,978</b>	<b>-31,438</b>	<b>49,806</b>

## Parent company statement of cash flows

KSEK	Note	1 January – 31 December		
		2014	2013	2012
<b>Operating activities</b>	28			
Operating income		-24,715	-17,637	-16,808
Adjustment for items not included in cash flow		1,294	96	127
Interest received		42	93	347
Interest paid		-115	-16	-5
Income tax paid		-81	-110	7
<b>Cash flow from operating activities before changes in working capital</b>		<b>-23,575</b>	<b>-17,574</b>	<b>-16,332</b>
<b>Cash flow from changes to working capital</b>				
Increase (-)/Decrease (+) of accounts receivable		-59	672	-291
Increase (-)/Decrease (+) of other operating receivables		176	16	-377
Increase (+)/Decrease (-) of accounts payable		1,085	-130	206
Increase (+)/Decrease (-) of other operating liabilities		-1,286	2,152	-1,130
<b>Cash flow from operating activities</b>		<b>-23,659</b>	<b>-14,864</b>	<b>-17,924</b>
<b>Investing activities</b>				
Acquisition of tangible fixed assets		-1,204		
Capitalized development expenditures			-64	-2,707
Acquisition of financial assets		-117	-4,466	-3,861
<b>Cash flow from investing activities</b>		<b>-1,321</b>	<b>-4,530</b>	<b>-6,568</b>
<b>Financing activities</b>				
New share issue		37,042		46,021
Issue expenses		-1,481		-1,020
Loans raised			519	
Repayment of loans		-519		-2,700
<b>Cash flow from financing activities</b>		<b>35,042</b>	<b>519</b>	<b>42,301</b>
Net cash flow		10,062	-18,875	17,809
Cash and cash equivalents, beginning of year		90	18,965	1,156
<b>Cash and cash equivalents, year-end</b>		<b>10,152</b>	<b>90</b>	<b>18,965</b>

# Notes

## Note 1 Material accounting principles

### (a) Compliance with norms and legislation

The consolidated financial statements have been prepared in accordance with the International Financial Reporting Standards (IFRS) issued by the International Accounting Standards Board (IASB) as adopted by the EU. In addition, recommendation RFR 1 issued by the Swedish Financial Reporting Board (Supplemental Accounting Rules for Corporate Groups) has been applied. The parent company applies the same accounting principles as the group with the exception of those cases set forth below under the section entitled "The parent company's accounting principles".

### (b) Valuation grounds applied in the preparation of the financial reports

Assets and liabilities are reported at the historical acquisition values, with the exception of certain financial assets and liabilities which are valued at net realizable value. Financial assets and liabilities valued at net realizable value consist of shares listed on an exchange.

### (c) Functional currency and reporting currency

The functional currency of the parent company is Swedish kronor, which is also the reporting currency for the parent company and for the group. This means that the financial reports are presented in Swedish kronor. Unless otherwise stated, all amounts are rounded off to the nearest thousand.

### (d) Assessments and estimates in the financial reports

Preparing the financial reports in accordance with IFRS requires that corporate management make assessments, estimates and assumptions which impact the application of the accounting principles and the reported amounts of assets, liabilities, revenues and costs. Actual results may deviate from these estimates and assessments.

The estimates and assumptions are reviewed regularly. Changes to estimates are reported in the period in which the changes are made, provided the change only affects this period, or in the period in which the changes were made and future periods, if the change affects both the current period and future periods.

### (e) Changes in accounting principles

#### (i) Transition to IFRS

The press release of unaudited earnings for 2014 published on 13 February 2015 was Hansa Medical's first financial report prepared in accordance with IFRS. Reports published prior to that date were prepared in accordance with the Swedish Annual Accounts Act and the general guidelines issued by the Swedish Accounting Standards Board.

The date for transition to IFRS is 1 January 2012. A description of the effects of the transition to IFRS is set forth in note 32.

#### (ii) New IFRS which have not yet begun to be applied

A number of new or amended standards and interpretations in the IFRS do not enter into force until the next financial year and have

not been applied prematurely in conjunction with the preparation of these financial statements. New items or changes with a future application are not planned to be implemented prematurely. No changes in the IFRS with a future application are considered to have any material effect on the group's reporting.

### (f) Classification

Fixed assets and long-term liabilities consist, in all material respects, of amounts expected to be recovered or paid after more than 12 months calculated from the balance sheet date. Current assets and current liabilities consist, in all material respects, of amounts expected to be recovered or paid within 12 months calculated from the balance sheet date.

### (g) Operating division reporting

An operating division is a part of the group which conducts operations from which it can generate revenues and incur costs and for which independent financial information is available. The earnings of an operating division are monitored by the company's most senior executive officer in order to evaluate the earnings and to be able to allocate resources to the operating division. Since the group's business is organized as a cohesive business with similar risks and opportunities for the goods and services produced, the group's entire business constitutes a single operating division. The entire business is conducted in Sweden.

### (h) Consolidation principles

Subsidiaries are companies under the controlling influence of Hansa Medical AB. Intra-group receivables and liabilities, revenues or costs and unrealized profits or losses which arise from intra-group transactions between group companies are eliminated in their entirety in the preparation of the consolidated financial statements.

### (i) Transactions in foreign currencies

Transactions in foreign currencies are translated to the functional currency at the currency exchange rate in effect on the transaction date. The functional currency is the currency in the primary financial environments in which the companies conduct their business operations. Monetary assets and liabilities in foreign currency are translated to the functional currency at the currency exchange rate in effect on the balance sheet date. Currency rate differences which arise in the translations are reported in the earnings for the year. Non-monetary assets and liabilities which are reported at their historical acquisition values are translated to the currency exchange rate at the time of the transaction. Non-monetary assets and liabilities which are reported at net realizable values are translated to the functional currency at the exchange rate in effect at the time of the net realizable value valuation.

### (j) Net sales

The group's reported net sales derive primarily from licensing and royalty revenues. Revenues are reported at the net realizable value of what has been, or will be, received. Revenues are reported to the

extent it is probable that the economic advantages will be realized by the company and the revenues can be calculated in a reliable manner. Licensing compensation is reported as revenue when all contractual undertakings incumbent upon the group have been fulfilled.

#### (k) Leasing

##### *(i) Operational leasing agreements*

Costs regarding operational leasing agreements are reported in the earnings for the year using a straight line method over the leasing term. Benefits obtained in conjunction with the execution of an agreement are reported in the earnings for the year as a reduction in the leasing fees using a straight line method over the term of the leasing agreement. Variable fees are booked as expenses in the periods in which they arise.

##### *(ii) Financial leasing agreements*

Minimum leasing fees are allocated between interest expenses and amortization on the outstanding debt. The interest expense is allocated over the leasing term so that an amount is booked in each reporting period which corresponds to a fixed rate of interest for the debt reported in each respective period. Variable fees are booked as expenses in the periods in which they arise.

#### (l) Financial income and expenses

Financial income consists of interest income and other financial income. Financial expenses consist of interest expenses on loans, write-downs of financial assets, and other financial expenses.

#### (m) Taxes

Income tax consists of current taxes and deferred taxes. Income tax is reported in the earnings for the year with the exception of cases where the underlying transaction has been reported in other comprehensive income or in shareholders' equity in which case the associated tax effect is reported in other comprehensive income or shareholders' equity.

Current tax is tax to be paid or received for the current year upon application of the tax rates in effect, or in effect in practice, on the balance sheet date. Current tax also includes adjustments of current tax related to earlier periods.

Deferred tax is calculated in accordance with the balance sheet method based upon temporary differences between reported values and tax values for assets and liabilities. Temporary differences are not taken into consideration in group goodwill, nor is the difference which arises upon the first reporting of assets and liabilities which are not business acquisitions and which, at the time of the transaction, do not affect either reported or taxable earnings. In addition, temporary differences related to shares in subsidiaries and affiliated companies which are not expected to be reversed within the foreseeable future are not taken into consideration. The valuation of deferred tax is based on how the underlying assets or liabilities are expected to be realized or settled. Deferred tax is calculated applying the tax rates and tax rules in effect, or in effect in practice, on the balance sheet date.

Deferred tax claims regarding deductible temporary differences and loss carry forwards are reported only to the extent it is probable that these can be utilized. The value of deferred tax claims is reduced when it is no longer considered probable that they can be utilized.

#### (n) Financial instruments

Financial instruments which are reported in the statement of financial position include, on the assets side, cash and equivalents, accounts receivable, other financial claims and listed shares. On the liability side, accounts payable, interest-bearing liabilities and other financial liabilities are reported.

##### *(i) Reporting in, and deletion from, the statement of financial position*

A financial asset or financial liability is reported in the balance sheet when the company becomes a party according to the contract terms and conditions of the instrument. A receivable is reported when the company has performed and a contractual obligation exists for the counterparty to make payment, notwithstanding that an invoice has not yet been issued. Accounts receivable are reported in the statement of financial position when an invoice has been issued. Liabilities are reported when the counterparty has performed and a contractual obligation exists to make payment, notwithstanding that an invoice has not yet been received. Accounts payable are reported when an invoice has been received.

A financial asset is deleted from the balance sheet when the rights in the agreement have been realized, lapsed, or the company loses control over them. This also applies for part of a financial asset. A financial liability is deleted from the balance sheet when the obligation set forth in the agreement has been performed or otherwise extinguished. This also applies to a part of a financial liability.

A financial asset and a financial liability are set off and reported at a net amount in the statement of financial position only when there is a legal right to set off the sums and there is an intent to settle the items with a net amount, or to simultaneously realize the asset and settle the liability.

Acquisitions and sales of financial assets are reported on the transaction date. The transaction date is the date on which the company undertakes to acquire or sell the asset.

##### *(ii) Classification and valuation*

Financial instruments are initially reported at an acquisition value corresponding to the instrument's net realizable value plus any transaction costs for all financial instruments. A financial instrument is classified in the first reporting on the basis, among other things, of the purpose behind the acquisition of the instrument. The classification determines how the financial instrument is valued after the first reporting occasion as described below.

Cash and equivalents consist of cash and immediately available funds deposited with banks and corresponding institutions as well as short-term liquid investments with terms from the date of acquisition of less than three months which are only exposed to an insignificant risk of fluctuation in value.

##### *Loan claims and accounts receivable*

Loan claims and accounts receivable are financial assets which are not derivatives, and which have fixed or fixable payments, and are not listed on an active market. These assets are valued at the accrued acquisition value. The accrued acquisition value is determined based on the effective rate of interest which is calculated at the

time of acquisition. Accounts receivable are reported at the sums at which they are anticipated to be collected, i.e. after deductions for doubtful receivables.

#### *Realizable financial assets*

The category "realizable financial assets" includes financial instruments which have not been classified in any other category or financial assets which the company initially chose to classify in this category. Only the group's holdings of listed shares are reported in this category.

#### **Financial liabilities valued at accrued acquisition value**

Loans as well as other financial liabilities, for example accounts payable, are included in this category. The liabilities are valued at the accrued acquisition value.

#### **(o) Tangible fixed assets**

Tangible fixed assets are reported by the group at acquisition value after deductions for accumulated depreciation and any write-downs. The acquisition value includes the purchase price and is utilized in accordance with the purpose of the acquisition. The accounting principles for write-downs are set forth below.

The reported value for a tangible fixed asset is deleted from the balance sheet upon disposal or sale or where no future economic advantages are anticipated from the use or disposal/sale of the asset. Profits or losses which arise upon the sale or disposal of asset consist of the difference between the sales price and the reported value of the asset less any direct sales costs. Profits and losses are reported as other operating income/expenses.

Depreciation is carried out using the straight line method over the anticipated life of the asset. Real property is not depreciated.

Anticipated useful life:

Office equipment, tools and fixtures and fittings	5 years
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#### **(p) Intangible fixed assets**

##### *Acquired intangible assets*

Acquired intangible assets held by the group consists of patents and capitalized development expenses. These intangible assets are reported at the acquisition value minus accumulated depreciation and any impairment (see accounting principle (q)).

Accrued expenses for internally-generated goodwill and internally-generated trademarks are reported in the profit/loss for the year at the time at which the cost arises.

##### *Capitalized development expenditures*

Costs for research are immediately booked as an expense. Development costs directly related to the development of production processes which will probably be used for production of a pharmaceutical candidate for clinical studies and for market introduction of an approved pharmaceutical are booked as an asset. Costs regarding development projects (related to the design and testing of new or improved products) are booked as an intangible asset of the group to the extent these costs are anticipated to a high degree of certainty to generate future economic advantages. Other development costs are booked as expenses as they arise. Development costs which were previously booked as expenses are not booked as assets in subsequent periods.

Depreciation of capitalized development costs begins when the project is deemed completed, which either takes place by the group in-house or in conjunction with the licensing of patents or preparations in exchange for compensation, where continued development work is carried out by an independent party. Depreciation is carried out using the straight line method over the anticipated economic life cycle; however, for patents not longer than the remaining patent protection.

#### **(q) Impairment**

The group's reported assets are assessed on each balance sheet date in order to determine whether there is an indication of a need for a write-down. IAS 36 is applied regarding impairment of assets other than financial assets which are reported according to IAS 39.

##### *(i) Impairment of intangible assets*

För immateriella tillgångar med obestämd nyttjandeperiod och im-  
For intangible assets with an indeterminate useful life and intangible assets which are not yet subject to depreciation according to plan, an annual assessment is carried out of the recovery value, which is the net realizable value or the use value, whichever is higher. Upon calculation of the use value, future assessed cash flow is discounted at a rate of interest which takes into consideration the market's assessment of risk-free interest rate and the risk associated with the specific asset.

##### *(ii) Impairment of financial assets*

On each reporting occasion, the company evaluates whether there is objective evidence that a financial asset or group of assets should be written down. Objective evidence consists of observable circumstances which have occurred and which have a negative impact on the possibility of recovering the acquisition value, as well as significant or extended reductions in the net realizable value of an investment in a financial investment classified as a realizable financial asset.

##### *(iii) Reversal of impairment losses*

Impairment of assets included in the area of application for IAS 36 is reversed if there is both an indication that the need for the impairment the longer exists and that there has been a change in the assumptions which formed the basis for the calculation of the recovery value. Impairment of goodwill are never reversed, however. A reversal is only made to the extent the reported value of the asset after reversal does not exceed the reported value which would have been reported, following a deduction for depreciation where relevant, if no write-down had been made. Impairment of loan claims and accounts receivable which are reported at the accrued acquisition value are reversed if the earlier reasons for the impairment no longer exist and where full payment by the customer is expected.

Impairment of the company's own capital instruments which are classified as realizable financial assets, and which were previously reported in the income statement, are not reversed in the income statement but in other comprehensive income instead. The written down value is the value from which subsequent re-evaluations are made, which is reported in other comprehensive income.

#### **(r) Dividends**

Dividends are reported as a liability after the annual general meeting has approved the dividend.

**(s) Earnings per share**

The calculation of earnings per share is based on the group's earnings for the year attributable to the parent company's owner and on the weighted average number of shares outstanding during the year. There are no potential diluting common shares either for the current financial year or for the comparison years. There is thus no dilution effect.

**(t) Remuneration to employees****(i) Short-term remuneration**

Short-term remuneration to employees is calculated without any discounting and reported as an expense when the relevant services are received.

**(ii) Defined contribution pension plans**

Plans where the company's obligations are limited to the fees the company has undertaken to pay are classified as "defined contribution pension plans". In such cases, the size of the employee's pension is dependent upon the fees which the company pays into the plan, or to an insurance company, and the return on capital which the fees generate. Consequently, it is the employee who bears the actuarial risk (that the benefits will be lower than anticipated) and the investment risk (that the invested assets will be insufficient to generate the anticipated benefits). The company's obligations regarding fees paid to defined contribution plans are reported as an expense in the income statement as they are earned by the employees performing their services on behalf of the company during a given period of time.

**(u) Contingent liabilities**

A contingent liability is reported when there is a possible undertaking derived from past events, the existence of which is confirmed only by one or more uncertain future events beyond the control of the group, or when there is an undertaking which is not reported as a liability or provision on the grounds that it is not probable that an

outflow of resources will be required or cannot be calculated with sufficient reliability.

**The parent company's accounting principles**

The parent company has prepared its annual report in accordance with the Swedish Annual Accounts Act (SFS 1995:1554) and Recommendation RFR 2 issued by the Swedish Financial Reporting Board, Reporting for legal entities. The statements issued by the Swedish Financial Reporting Board applicable to listed companies have also been applied. RFR 2 entails that in the annual report for the legal entity the parent company must apply all of IFRS and the statements adopted by the EU to the extent possible within the scope of the Swedish Annual Accounts Act, the Securing of Pension Obligations Act, and taking into consideration the connection between reporting and taxation. The Recommendation sets forth which exceptions from, and additions to, IFRS are to be made.

**Differences between the group's and the parent company's accounting principles**

The differences between the group's and the parent company's accounting principles are set forth below. The accounting principles set forth below for the parent company have been applied consistently to all periods presented in the parent company's financial statements.

**Classification and layout**

The differences apparent in the parent company's income statements and balance sheets as compared with the group's statements consist primarily of the reporting of financial income and expenses, fixed assets and shareholders' equity.

**Financial instruments**

Due to the connection between reporting and taxation, the rules governing financial instruments and hedge reporting set forth in IAS 39 are not applied in the parent company as a legal entity.

**Note 2 Breakdown of income****Income per significant category of income**

KSEK	1 January – 31 December		
	2014	2013	2012
<b>Group</b>			
Net sales			
Royalty and licensing revenue	1,641	1,712	1,143
Other	3,075	15	1,476
	<b>4,716</b>	<b>1,727</b>	<b>2,619</b>
<b>Parent company</b>			
Net sales			
Royalty and licensing revenue	1,641	1,712	1,143
Other	3,075	15	1,475
	<b>4,716</b>	<b>1,727</b>	<b>2,618</b>

**Note 3 Operating segments**

To a significant extent, Hansa Medical's business currently consists of research and development for the production of pharmaceuticals. The company is of the opinion that this business, in its entirety, constitutes a single operating segment. All operations are conducted in Sweden and income is derived from Sweden and fixed assets are allocated to Sweden.

## Note 4 Employees and personnel costs

## Costs for employee remuneration

KSEK	1 January – 31 December		
	2014	2013	2012
<b>Group</b>			
Salaries and remuneration, etc.	7,232	5,077	5,066
Pension costs, fee-based plans	1,025	724	743
Employer payroll tax	1,518	1,728	1,648
	<b>9,775</b>	<b>7,529</b>	<b>7,457</b>

## Average number of employees

	2014		2013		2012	
	Number	of whom men	Number	of whom men	Number	of whom men
<b>Parent company</b>						
Sweden	10	50%	8	63%	8	63%
Parent company total	10		8		8	
Group total	10	50%	8	63%	8	63%

## Breakdown of corporate management according to gender

	Share of women		
	2014-12-31	2013-12-31	2012-12-31
<b>Parent company</b>			
Board of Directors	60%	50%	50%
Other senior management	33%	33%	33%
<b>Group total</b>			
Board of Directors	60%	50%	50%
Other senior management	33%	33%	33%

## Salaries, other remuneration and employer payroll taxes

KSEK	2014	2013	2012
<b>Parent company</b>			
Salaries and remuneration	7,232	5,077	5,066
Employer payroll tax	2,543	2,452	2,391
(of which, pension costs)	<sup>1)</sup> (1,025)	<sup>1)</sup> (724)	<sup>1)</sup> (743)

<sup>1)</sup> Of the parent company's pension costs, 484 (363, 278) KSEK relates to the Board of Directors and CEO. There are no outstanding pension obligations for the Board of Directors and CEO.

## Salaries and other remuneration broken down between directors, etc. and other employees

KSEK	2014		2013		2012	
	Senior management	Other employees	Senior management	Other employees	Senior management	Other employees
<b>Parent company</b>						
Sweden	3,534	3,698	2,903	2,174	3,012	2,054
(of which commissions and similar remuneration)	(0)	(0)	(0)	(0)	(0)	(0)
Parent company total	3,534	3,698	2,903	2,174	3,012	2,054
(of which commissions and similar remuneration)			(0)	(0)	(0)	(0)
Group total	3,534		2,903		3,012	
(of which commissions and similar remuneration)	(0)		(0)		(0)	

**Benefits for senior management****Remuneration to Board of Directors**

Fees are payable to the chairman of the Board of Directors and other directors pursuant to a resolution adopted by the annual general meeting. The 2014 annual general meeting resolved that the fees paid to the directors for work during 2014 will be SEK 300,000 to the chairman of the Board of Directors and SEK 100,000 to each of the other directors, however no fee is payable to Anders Blom. There are no contracts regarding severance compensation or other benefits for the chairman of the Board of Directors or other directors.

**Remuneration to CEO****Remuneration**

Remuneration is payable to the CEO in the form of a fixed salary and pension. The current CEO assumed office on 24 November 14. During 2014, the basic salary per month was SEK 150,000 for the current CEO and SEK 75,000 for the previous CEO. In addition to this, remuneration may be paid in the form of variable salary, severance compensation and non-monetary benefits. The variable salary shall be based on the achievement of quantitative and qualitative goals. In 2014, the remuneration paid to the CEO was KSEK 1,069 which covers compensation to the previous CEO up to and including 25 November 14 and the current CEO for the period thereafter.

**Notice of termination periods and severance compensation**

Upon termination by the company or the CEO, a six month notice of termination period applies. Upon termination by the company, the CEO shall be entitled to severance compensation corresponding to 12 times his/her fixed monthly salary at the end of his/her employment. The above-stated also applies upon termination by the CEO where the grounds for termination are gross breach of contract by the company.

**Pension remuneration**

The employment contract for the CEO terminates without prior notice of termination at the time of the CEO's age of retirement. The company sets aside 25% of the CEO's monthly salary on a monthly basis for the occupational pension insurance indicated by the CEO. In 2014, the cost of premiums for the CEO was KSEK 168.

**Remuneration paid to other members of group management  
Remuneration**

Remuneration is determined by the CEO following the approval of the chairman of the Board of Directors. Remuneration in 2014 to members of group management other than the CEO amounted to KSEK 1,737.

**Notice of termination period and severance compensation**

Other members of group management have three months' notice of termination upon termination by them or the company. The company has a consulting agreement with the CFO, Göran Arvidson. The consulting agreement is valid up to 26 July 2015. In the event the agreement is not terminated not later than one month prior to the expiration of the contract term, the agreement will be extended by terms of six months subject to one month's notice of termination. Where applicable, the company shall observe the longer notice of termination period set forth in the Employment Protection Act. During their notice period, other members of group management are entitled to full salary and other employment benefits. None of the other members of group management are entitled to severance compensation.

**Pension compensation**

Other members of group management are entitled to retire as follows. Lena Winstedt's and Christian Kjellman's employments terminate at the age of 67 without any requirement of notice. Emanuel Björne's employment terminates at the age of 65 without any requirement of notice. However, he is entitled to continue working until 67 years of age. Other members of group management, with the exception of the CEO, are entitled to pension benefits in accordance with the company's insurance and pension policy.

**Salaries and other remuneration, and other benefits paid to senior management, parent company 2014**

KSEK	Base salary Directors' fees	Variable compensation	Other benefits	Pension costs	Total
Chairman of the Board of Directors Bo Håkansson	168				168
Director Stina Gestrelus	94				94
Director Per-Olof Wallström	115				115
Director Fredrik Lindgren	113				113
Director Cindy Wong	94				94
Director Birgit Stattin Norinder	144				144
CEO	1,069			168	1,237
Other senior management (3 persons)	1,737			316	2,053
<b>Total</b>	<b>3,534</b>	<b>0</b>	<b>0</b>	<b>484</b>	<b>4,018</b>

**Salaries and other remuneration paid to senior management, parent company 2013**

KSEK	Base salary Directors' fees	Variable compensation	Other benefits	Pension costs	Total
Chairman of the Board of Directors Bo Håkansson	169				169
Director Stina Gestrelus	85				85
Director Per-Olof Wallström	102				102
Director Fredrik Lindgren	71				71
Director Cindy Wong	84				84
Director Birgit Stattin Norinder	138				138
CEO	740			115	855
Other senior management (3 persons)	1,514			248	1,762
<b>Total</b>	<b>2,903</b>	<b>0</b>	<b>0</b>	<b>363</b>	<b>3,266</b>

**Salaries and other remuneration paid to senior management, parent company 2012**

KSEK	Base salary Directors' fees	Variable compensation	Other benefits	Pension costs	Total
Chairman of the Board of Directors Bo Håkansson	144				144
Director Per Belfrage	27				27
Director Stina Gestrelus	81				81
Director Paula Zeilon	27				27
Director Per-Olof Wallström	81				81
Director Fredrik Lindgren	54				54
Director Cindy Wong	54				54
Director Birgit Stattin Norinder	54				54
CEO	792			126	918
Other senior management (3 persons)	1,698			152	1,850
<b>Total</b>	<b>3,012</b>	<b>0</b>	<b>0</b>	<b>278</b>	<b>3,290</b>

## Note 5 Fees and competition for costs, auditors

KSEK	2014	2013	2012
<b>Group</b>			
KPMG			
Auditing services	145		
Grant Thornton Sweden AB			
Auditing services	168	235	273
Other services	17		
<b>Parent company</b>			
KPMG			
Auditing services	145		
Grant Thornton Sweden AB			
Auditing services	168	235	273
Other services	17		

"Auditing services" means statutory audit of the annual report and group accounts and bookkeeping, and the management by the Board of Directors and CEO, as well as the audit and other reviews carried out as agreed. The above-stated includes other duties incumbent upon the company's auditor as well as advice or other assistance necessitated by observations in conjunction with such reviews or the performance of such other duties.

## Note 6 Net financial items

### Group

KSEK	2014	2013	2012
Interest income on bank deposits	42	90	
Other interest income		3	347
<b>Financial income</b>	<b>42</b>	<b>93</b>	<b>347</b>
Interest expenses, credit institutions	-75	-15	
Interest expenses, other	-48	-11	-17
Impairment of realizable financial assets <sup>1)</sup>	-4,252		
<b>Financial expenses</b>	<b>-4,375</b>	<b>-26</b>	<b>-17</b>
<b>Net financial items</b>	<b>-4,333</b>	<b>67</b>	<b>330</b>

<sup>1)</sup> Relates to impairment of shares in Genovis AB due to significant decrease in value.

### Parent company

KSEK	2014	2013	2012
<b>Profit/loss from shares in group companies</b>			
Impairment of shareholder contribution	-2,398		
	<b>-2,398</b>	<b>0</b>	<b>0</b>
<b>Results from other securities and claims which are fixed assets</b>			
Impairment of shares in Genovis AB	-4,252		
	<b>-4,252</b>	<b>0</b>	<b>0</b>
<b>Interest income and similar income statement items</b>			
Interest income on bank deposits	42	90	
Interest income, other		3	347
	<b>42</b>	<b>93</b>	<b>347</b>
<b>Interest expenses and similar income statement items</b>			
Interest expenses, credit institutions	-75	-15	
Interest expenses, other	-40	-1	-5
	<b>-115</b>	<b>-16</b>	<b>-5</b>

## Note 7 Taxes

### Unreported deferred tax claims

Deferred tax claims have not been reported regarding temporary differences and losses carried forward since it is not probable that such can be set off against future taxable profits. The group's losses carried forward in 2014 amounted to KSEK 139,912 (KSEK 112,840 KSEK 95,329).

## Note 8 Earnings per share

### Earnings per share

SEK	2014	2013	2012
Earnings per share prior to and after dilution	-1.16	-0.75	-0.75

There were no outstanding potential shares on the balance sheet date which might give rise to a dilution effect. The earnings per share prior to, and after, dilution are therefore the same.

The calculation of the numerator and denominator used in the above-stated calculations of earnings per share are stated below.

### Profit/loss attributable to the parent company's shareholders prior to and after dilution

KSEK	2014	2013	2012
Profit/loss for the year related to the parent company's shareholders	-29,042	-17,562	-16,468
Earnings attributable to the parent company's shareholders prior to and after dilution	<b>-29,042</b>	<b>-17,562</b>	<b>-16,468</b>

### Weighted average number of outstanding shares prior to and after dilution

Number of shares	2014	2013	2012
Total number of shares on 1 January	22,225,374	22,225,374	13,521,144
Effect of the new share issues in January and March 2012			7,524,639
Effect of new share issue in April 2014	2,916,319	1,079,775	1,022,467
Weighted average number of shares during the year prior to and after dilution	<b>25,141,693</b>	<b>23,305,149</b>	<b>22,068,250</b>

The weighted average number of shares is affected by new share issues carried out in 2012 and 2014. The weighted number of shares for 2012 and 2013 has been recalculated taking into consideration the new share issue carried out in 2014.

## Note 9 Intangible fixed assets

## Group

KSEK	Developed in-house	Acquired intangible assets		Total
	Development fees	Patents	Development fees	
Accumulated acquisition value				
Opening balance 1 Jan 2012	1,715	125	33,515	35,355
Assets developed in-house	2,706			2,706
Closing balance 31 Dec 2012	4,421	125	33,515	38,061
Accumulated write-offs and impairment				
Opening balance 1 Jan 2012	0	-72	0	-72
Write-offs for the year		-13		-13
Closing balance 31 Dec 2012	0	-85	0	-85
Reported values				
As of 1 Jan 2012	1,715	53	33,515	35,283
As of 31 Dec 2012	4,421	40	33,515	37,976

KSEK	Developed in-house	Acquired intangible assets		Total
	Development fees	Patents	Development fees	
Accumulated acquisition value				
Opening balance 1 Jan 2013	4,421	125	33,515	38,061
Assets developed in-house	64			64
Closing balance 31 Dec 2013	4,485	125	33,515	38,125
Accumulated write-offs and impairment				
Opening balance 1 Jan 2013	0	-85	0	-85
Write-offs for the year		-12		-12
Closing balance 31 Dec 2013	0	-97	0	-97
Reported values				
As of 1 Jan 2013	4,421	40	33,515	37,976
As of 31 Dec 2013	4,485	28	33,515	38,028

KSEK	Developed in-house	Acquired intangible assets		Total
	Development fees	Patents	Development fees	
Accumulated acquisition value				
Opening balance 1 Jan 2014	4,485	125	33,515	38,125
Closing balance 31 Dec 2014	4,485	125	33,515	38,125
Accumulated write-offs and impairment				
Opening balance 1 Jan 2014	0	-97	0	-97
Impairment for the year			-559	-559
Write-offs for the year		-12	-559	-571
Closing balance 31 Dec 2014	0	-109	-1,118	-1,227
Reported values				
As of 1 Jan 2014	4,485	28	33,515	38,028
As of 31 Dec 2014	4,485	16	32,397	36,898

**Parent company**

KSEK	Developed in-house	Acquired intangible assets		Total
	Development fees	Patents	Development fees	
<b>Accumulated acquisition value</b>				
Opening balance 1 Jan 2012	1,715	125	33,515	35,355
Assets developed in-house	2,706			2,706
Closing balance 31 Dec 2012	4,421	125	33,515	38,061
<b>Accumulated write-offs and impairment</b>				
Opening balance 1 Jan 2012	0	-72	0	-72
Write-offs for the year		-13		-13
Closing balance 31 Dec 2012	0	-85	0	-85
<b>Reported values</b>				
As of 1 Jan 2012	1,715	53	33,515	35,283
As of 31 Dec 2012	4,421	40	33,515	37,976

KSEK	Developed in-house	Acquired intangible assets		Total
	Development fees	Patents	Development fees	
<b>Accumulated acquisition value</b>				
Opening balance 1 Jan 2013	4,421	125	33,515	38,061
Assets developed in-house	64			64
Closing balance 31 Dec 2013	4,485	125	33,515	38,125
<b>Accumulated write-offs and impairment</b>				
Opening balance 1 Jan 2013	0	-85	0	-85
Write-offs for the year		-12		-12
Closing balance 31 Dec 2013	0	-97	0	-97
<b>Reported values</b>				
As of 1 Jan 2013	4,421	40	33,515	37,976
As of 31 Dec 2013	4,485	28	33,515	38,028

KSEK	Developed in-house	Acquired intangible assets		Total
	Development fees	Patents	Development fees	
<b>Accumulated acquisition value</b>				
Opening balance 1 Jan 2014	4,485	125	33,515	38,125
Closing balance 31 Dec 2014	4,485	125	33,515	38,125
<b>Accumulated write-offs and impairment</b>				
Opening balance 1 Jan 2014	0	-97	0	-97
Impairment for the year			-559	-559
Write-offs for the year		-12	-559	-571
Closing balance 31 Dec 2014	0	-109	-1,118	-1,227
<b>Reported values</b>				
As of 1 Jan 2014	4,485	28	33,515	38,028
As of 31 Dec 2014	4,485	16	32,397	36,898

The projects pending in the group are combination of acquired development projects and continued activities in these projects. Of the total fees for product development, 75% relates to IdeS and 25% relates to HBP-assay.

Project overview	Indication/Purpose	Status
IdeS	IdeS is a pharmaceutical candidate the primary goal of which is to make possible transplants by counteracting antibody mediated rejection. Additional goals include treating acute antibody mediated illnesses.	In 2013 and 2014, IdeS underwent phase I studies in healthy trialing individuals with good results. Phase II studies on kidney patients were commenced during the latter part of 2014 and the results are expected during the first half of 2015.
HBP-assay	HBP-assay is a method of analysis used to predict severe sepsis in emergency clinics. A first version has been launched, primarily intended for research purposes and interested specialists.	The product has been licensed to a cooperating partner, Axis-Shield Diagnostics, which is currently developing a fully commercial product. Hansa Medical receives milestone compensation and additional royalty revenues upon the sale of the sublicensed technology.

Write-offs of capitalized fees for product development of IdeS have not yet commenced since the intangible asset cannot be used yet as intended by corporate management, i.e. it cannot yet begin to generate revenues. The company will begin to write off the capitalized fees for product development of IdeS when these begin to generate revenues.

Capitalized fees for product development is assessed for possible impairment needs at least on an annual basis. In conjunction with this assessment, the recovery value is calculated based upon the beneficial value of the asset which is then compared with the reported value.

The impairment assessment on 31 December 2014, 2013 and 2012 demonstrated that there was no need for impairment. The discount rates of interest before tax were 19.4 percent, 21.4 percent, and 22.6 percent respectively.

Capitalized development expenses regarding HBP are written off over the term of the underlying patent in the amount of KSEK 559 per year.

## Note 10 Tangible fixed assets

**Group**

KSEK	Equipment, tools and facilities		
	2014-12-31	2013-12-31	2012-12-31
<b>Accumulated acquisition values</b>			
Opening balance on 1 January	1,173	1,173	1,173
Investments during the year	1,204		
Closing balance on 31 December	2,377	1,173	1,173
<b>Accumulated write-offs and impairment</b>			
Opening balance on 1 January	-875	-735	-565
Write-offs during the year	-219	-140	-170
Closing balance on 31 December	-1,094	-875	-735
<b>Reported values</b>			
As of 1 January	298	438	608
As of 31 December	1,283	298	438

**Financial leasing – the group**

KSEK	2014-12-31	2013-12-31	2012-12-31
<b>Group</b>			
Reported value for assets in financial leasing agreements	128	183	239

The group leases automobiles under financial leasing agreements. The leased asset constitutes security for the leasing obligations. See also note 19 and note 25.

**Parent company**

KSEK	Equipment, tools and facilities		
	2014-12-31	2013-12-31	2012-12-31
<b>Accumulated acquisition values</b>			
Opening balance on 1 January	869	869	869
Investments during the year	1,204		
Closing balance on 31 December	2,073	869	869
<b>Accumulated write-offs and impairment</b>			
Opening balance on 1 January	-754	-670	-556
Write-offs during the year	-164	-84	-114
Closing balance on 31 December	-918	-754	-670
<b>Reported values</b>			
As of 1 January	115	199	313
As of 31 December	1,155	115	199

## Note 11 Receivables from group companies

**Parent company**

KSEK	2014-12-31	2013-12-31	2012-12-31
<b>Accumulated acquisition values</b>			
1 January	2,296	2,295	2,286
Additional receivables	2	1	9
Settled through shareholder contribution	-2,298		
<b>Reported value on 31 December</b>	<b>0</b>	<b>2,296</b>	<b>2,295</b>

## Note 12 Financial fixed assets

### Group

KSEK	2014-12-31	2013-12-31	2012-12-31
<b>Financial investments which are fixed assets</b>			
Realizable financial assets			
Shares and participating interests	4,180	10,381	3,590
	<b>4,180</b>	<b>10,381</b>	<b>3,590</b>

The holdings related to shares in Genovis AB which is listed on First North. These are valued at market value.

In 2014, an impairment of the shareholdings in the amount of KSEK 4,252 (0, 0) was reported in the group's income statement since corporate management concluded that the decrease in value during the year had been significant.

## Note 13 Other long-term securities holdings

### Parent company

KSEK	2014-12-31	2013-12-31	2012-12-31
<b>Accumulated acquisition values</b>			
1 January	8,317	3,852	
Purchases	115	4,465	3,852
Closing balance 31 December	8,432	8,317	3,852
<b>Accumulated impairment</b>			
1 January			
Impairment during the year	-4,252		
Closing balance 31 December	-4,252	0	0
Reported value on 31 December	4,180	8,317	3,852

## Note 14 Other receivables

### Group

KSEK	2014-12-31	2013-12-31	2012-12-31
<b>Other receivables which are current assets</b>			
VAT receivables	796	328	483
Other receivables	278	325	
	<b>1,074</b>	<b>653</b>	<b>483</b>

### Parent company

KSEK	2014-12-31	2013-12-31	2012-12-31
<b>Other receivables (current)</b>			
VAT receivables	796	328	483
Other receivables	278	325	
	<b>1,074</b>	<b>653</b>	<b>483</b>

## Note 15 Accounts Receivable

Accounts Receivable are reported after consideration of bad debt losses during the year which amounted to KSEK 0 for the group and parent company.

## Note 16 Prepaid expenses and accrued income

**Group**

KSEK	2014-12-31	2013-12-31	2012-12-31
Interest	41		
Accrued royalties and licensing revenues	170	808	1,071
Other	162	145	48
	<b>373</b>	<b>953</b>	<b>1,119</b>

**Parent company**

KSEK	2014-12-31	2013-12-31	2012-12-31
Rent/leasing		17	37
Interest	41		
Accrued royalties and licensing revenues	170	808	1,071
Other	162	145	48
	<b>373</b>	<b>970</b>	<b>1,156</b>

## Note 17 Cash and cash equivalents

**Group**

KSEK	2014-12-31	2013-12-31	2012-12-31
<b>The following subcomponents are included in cash and cash equivalents</b>			
Cash and bank deposits	10,152	90	18,966
Total according to balance sheet	10,152	90	18,966
Total according to cash flow analysis	<b>10,152</b>	<b>90</b>	<b>18,966</b>

## Note 18 Shareholders' equity

### Share capital and number of shares

Number of shares	2014	2013	2012
Issued as of 1 January	22,225,374	22,225,374	13,521,144
New share issue January 2012			5,000,001
New share issue March 2012			3,704,229
New share issue April 2014	3,704,229		
Issued as of 31 December – paid up	<b>25,929,603</b>	<b>22,225,374</b>	<b>22,225,374</b>

The company's shares have a quotient value of SEK 1. Shareholders are entitled to dividends which are determined after they become shareholders and the shareholdings entitle the shareholders to one vote per share at general meetings.

#### Other contributed capital

Refers to shareholders' equity contributed by the shareholders. This includes premiums paid in conjunction with share issues.

#### Reserves

##### Actual value of reserves

The reserve for the net realizable value includes the accumulated net change in the net realizable value of realizable financial assets until the asset can be deleted from the balance sheet.

##### Retained earnings, including profit/loss for the year

Retained earnings, including profit/loss for the year, includes profits earned in the parent company and its subsidiaries. Previous allocations to statutory reserves, excluding transferred share premium reserves, are included in this shareholders' equity item.

#### Dividends

After the balance sheet date, the Board of Directors proposed that no dividend be paid. The dividend proposal will be submitted to the annual general meeting on 2 June 2015.

No dividend was paid in 2012 or 2013.

#### Parent company

##### Unrestricted shareholders' equity

Together with the profit/loss for the year, the following reserves constitute unrestricted shareholders' equity, i.e. the amount available for payment of a dividend to the shareholders.

##### Retained earnings

Retained earnings consists of last year's retained earnings plus the profit/loss after deductions for dividends paid during the year.

##### Management of capital

The group endeavors to maintain a sound financial position which contributes to retaining the confidence of creditors and the market and which constitutes the foundation for the continued development of the business. The group defines "management of capital" as total reported shareholders' equity.

## Note 19 Interest-bearing liabilities

This note contains information regarding the company's contractual terms and conditions regarding interest-bearing liabilities. For more information regarding the company's exposure to interest risks and the risk of changes in currency exchange rates, reference is made to note 23.

### Group

KSEK	2014	2013	2012
<b>Long-term liabilities</b>			
Financial leasing liabilities	91	131	168
	<b>91</b>	<b>131</b>	<b>168</b>
<b>Current liabilities</b>			
Bank overdraft facilities		519	
Current portion of financial leasing liabilities	39	37	36
	<b>39</b>	<b>556</b>	<b>36</b>

### Financial leasing liabilities

Financial leasing liabilities due and payable as follows:

### Group

#### 2014

KSEK	Minimum leasing fees	Interest	Principal amount
Within one year	46	7	39
Between one and five years	96	5	91
Later than five years			
	<b>142</b>	<b>12</b>	<b>130</b>

#### 2013

KSEK	Minimum leasing fees	Interest	Principal amount
Within one year	46	9	37
Between one and five years	142	11	131
Later than five years			
	<b>188</b>	<b>20</b>	<b>168</b>

#### 2012

KSEK	Minimum leasing fees	Interest	Principal amount
Within one year	46	10	36
Between one and five years	188	20	168
Later than five years			
	<b>234</b>	<b>30</b>	<b>204</b>

## Note 20 Liabilities to credit institutions

### Parent company

KSEK	2014	2013	2012
<b>Current liabilities</b>			
Bank overdraft facilities		519	
	<b>0</b>	<b>519</b>	<b>0</b>

## Note 21 Other liabilities

**Group**

KSEK	2014-12-31	2013-12-31	2012-12-31
<b>Other current liabilities</b>			
Personnel-related liabilities	1,039	804	617
	<b>1,039</b>	<b>804</b>	<b>617</b>

**Parent company**

KSEK	2014-12-31	2013-12-31	2012-12-31
Personnel-related liabilities	1,039	804	617
	<b>1,039</b>	<b>804</b>	<b>617</b>

## Note 22 Accrued costs and prepaid income

**Group**

KSEK	2014-12-31	2013-12-31	2012-12-31
Personnel-related costs	1,067	735	639
Directors' fees	181	140	161
Prepaid income		2,000	
Other	295	189	299
	<b>1,543</b>	<b>3,064</b>	<b>1,099</b>

**Parent company**

KSEK	2014-12-31	2013-12-31	2012-12-31
Personnel-related costs	1,067	735	639
Directors' fees	181	140	161
Prepaid income		2,000	
Other	295	189	299
	<b>1,543</b>	<b>3,064</b>	<b>1,099</b>

## Note 23 Financial risk management and financial instruments

Through its activities, the group is exposed to the following financial risks. Hansa Medical is exposed to a liquidity and refinancing risk, currency risk, interest rate risk, share price risk, and credit risk.

The Board of Directors has adopted a policy for managing financial risks within the group. The Board of Directors is responsible for the group's long-term financing strategy as well as any acquisition of capital. The management of financial risks in the day-to-day operations is handled by the CFO together with the CEO.

### Liquidity and financing risk

The liquidity and financing risk is the risk that the group will not have access to the financing needed to meet its contractual obligations or can only obtain such financing at significantly increased costs.

The Board of Directors is responsible for the long term financing strategy and for the acquisition of capital. All financing must be managed or approved centrally.

In order to secure short-term liquidity, Hansa Medical's financial policy prescribes that at least 80% of the anticipated costs for the upcoming month be available in the form of cash and cash equivalents. On the balance sheet date, this goal was fulfilled. Cash and cash equivalents on 31 December 2014 amounted to KSEK 10,152 (90, 18,966).

According to Hansa Medical's financial policy, any surplus liquidity can be broken down into two portfolios (A and B) based on the forecasted cash flow. Investments in portfolio A may only be made in very liquid commercial paper or a similarly liquid funds with a satisfactory credit rating. Investments in portfolio B must primarily be made in liquid bonds. However, cash and cash equivalents consisted on the balance sheet date only of bank deposits. For further information on future capital requirements see section "Further capital requirements" on page 25.

### Set forth below is a term-based analysis of the group's financial liabilities

#### 2014

KSEK	Nominal amount	0–3 months	3–12 months	1–5 years
Long-term interest-bearing liabilities	91			91
Current interest-bearing liabilities	39	10	29	
Accounts payable	1,795	1,795		
<b>Total</b>	<b>1,925</b>	<b>1,805</b>	<b>29</b>	<b>91</b>

#### 2013

KSEK	Nominella belopp	0–3 mån	3–12 mån	1–5 år
Long-term interest-bearing liabilities	131			131
Current interest-bearing liabilities	556	9	547	
Accounts payable	710	710		
<b>Total</b>	<b>1,397</b>	<b>719</b>	<b>547</b>	<b>131</b>

#### 2012

KSEK	Nominella belopp	0–3 mån	3–12 mån	1–5 år
Long-term interest-bearing liabilities	168			168
Current interest-bearing liabilities	36	9	27	
Accounts payable	840	840		
<b>Total</b>	<b>1,044</b>	<b>849</b>	<b>27</b>	<b>168</b>

### Currency risk

Hansa Medical purchases research-related services in USD, GBP and EUR. A weakening of the Swedish krona in relation to these currencies therefore leads to increased costs for the group, all else remaining the same. In addition, the group receives licensing revenues which are paid in USD and GBP. A strengthening of the Swedish krona in relation to USD and GBP therefore leads to reduced revenues for the company expressed in SEK, all else remaining the same.

A strengthening of SEK in relation to EUR by an average of 10% would affect the group's earnings before tax by approximately KSEK +162 (+150, +349). Correspondingly, a strengthening of SEK

in relation to GBP by an average of 10% would affect the group's earnings before tax by approximately KSEK +87 (+78, +149), while a 10% strengthening of SEK in relation to USD would affect earnings before tax by approximately KSEK -46 (-43, -70). The sensitivity analysis has been prepared from the point of departure that revenues and costs in each currency remain unchanged as compared with what is actually reported during each financial year.

Currency risks may also arise in conjunction with the management of the surplus liquidity. According to the group's policy, surplus liquidity may only be invested in foreign currencies where such investment can be used for known payments within six months in

the same currency. However, there were no investments in foreign currencies on the balance sheet date.

#### Interest rate risk

The interest rate risk consists of the risk that a change in market interest rates will have a negative effect on earnings. The group's exposure to interest rate risks is considered to be small since the group only has very limited interest-bearing liabilities. There is certain exposure to interest rate risks in cash and cash equivalents in the form of bank deposits. However, this risk is also considered to be small.

In conjunction with investments in interest-bearing securities, Hansa Medical shall endeavor to maximize its profit within the scope of the financial policy. Hansa Medical endeavors to maintain a sound allocation in a fixed-income portfolio by making investments with varying terms and conditions. However, the underlying principle is that investments shall be made in securities with a low risk.

#### Share price risk

Hansa Medical is exposed to a share price risk through its holdings of shares in Genovis AB which is listed on First North. In 2014, the group reported an impairment of the holdings in the amount of KSEK -4,252 (2013: 0, 2012: 0).

#### Credit risk

The group's credit risk is primarily related to bank deposits. However, this risk is considered to be low since the bank deposits are held in Swedish banks with good credit ratings.

According to the group's financial policy, Hansa Medical may only hold bank deposits with, or initiate payments through, Swedish and foreign banks under the supervision of the Swedish Financial Supervisory Authority or similar foreign agency.

#### The net realizable value of financial assets and financial liabilities

The reported values of financial assets and financial liabilities are deemed to be the reasonable estimates of the actual value of each class of financial assets and financial liabilities. The net realizable value of shareholdings in Genovis has been established based upon the closing price on the balance sheet date. The valuation of the holdings in Genovis is thus at Level I in the evaluation hierarchy.

#### The reported value for financial assets and financial liabilities per valuation category

The table below shows the reported value for financial assets and financial liabilities broken down by valuation category in IAS 39.

#### Group

KSEK	Loan claims and accounts receivable			Realizable financial assets		
	2014	2013	2012	2014	2013	2012
<b>Financial assets valued at net realizable value</b>						
Financial fixed assets						
Listed shares				4,180	10,381	3,590
<b>Financial assets not valued at net realizable value</b>						
Accounts receivable	59		672			
Accrued income	211	808	1,071			
Other receivables	278	325				
Cash and cash equivalents	10,152	90	18,966			
<b>Total financial assets</b>	<b>10,700</b>	<b>1,223</b>	<b>20,709</b>	<b>4,180</b>	<b>10,381</b>	<b>3,590</b>
	Financial liabilities valued at accrued acquisition value					
KSEK	2014	2013	2012			
Long-term interest-bearing liabilities	91	131	168			
Current interest-bearing liabilities	39	556	36			
Accounts payable	1,795	710	840			
<b>Total financial liabilities</b>	<b>1,925</b>	<b>1,397</b>	<b>1,044</b>			

## Note 24 Operational leasing

### Leasing agreements under which the company is the lessee

Future payments for leasing agreements which cannot be terminated amount to:

#### Group

KSEK	2014-12-31	2013-12-31	2012-12-31
Within one year	1,065	963	935
Between one and five years	2,133		
Later than five years			
	<b>3,198</b>	<b>963</b>	<b>935</b>

#### Parent company

KSEK	2014-12-31	2013-12-31	2012-12-31
Within one year	1,111	1,009	981
Between one and five years	2,133	46	92
Later than five years			
	<b>3,244</b>	<b>1,055</b>	<b>1,073</b>

Most of the group's operational leasing agreements involve leases of real property and premises on which the business operations are conducted.

Fees for operational leasing agreements booked as expenses amount to:

#### Group

KSEK	2014	2013	2012
Total leasing costs	<b>1,087</b>	<b>962</b>	<b>888</b>

#### Parent company

KSEK	2014	2013	2012
Total leasing costs	<b>1,151</b>	<b>1,029</b>	<b>954</b>

## Note 25 Collateral provided, contingent liabilities and contingent assets

#### Group

KSEK	2014-12-31	2013-12-31	2012-12-31
<b>Collateral provided</b>			
In the form of collateral for own liabilities and provisions			
Assets subject to retention of title	128	183	239
<b>Total collateral provided</b>	<b>128</b>	<b>183</b>	<b>239</b>

## Note 26 Closely-associated persons

### Relationships with closely-associated persons

The group has a closely-associated relationship with Farstorps Gård AB, the decedent's es-tate of Bo Håkansson, Nexttobe AB, and key persons in management positions. Farstorps Gård AB was wholly-owned by the former chairman of the Board of Directors Bo Håkansson. Nexttobe AB was previously the company's second largest shareholder with holdings of 29.1%.

The parent company also has a closely-associated relationship with its subsidiary; see note 27.

### Transactions with closely-associated persons

KSEK	2014	2013	2012
Bo Håkansson			
Remuneration for underwriting guarantee	418		
Active Capital AB (previously Farstorp Invest AB)			
Remuneration for underwriting guarantee			250
Consultancy fees			35
Nexttobe AB			
Remuneration for underwriting guarantee	418		250

### Transactions with key persons in a senior management position

Transactions with key persons in a senior management position are set forth in note 4.

## Note 27 Group companies

### Holdings in subsidiaries

Subsidiary	Registered office / Country	Share ownership percentage (%)		
		2014	2013	2012
Cartela R & D AB	Lund / Sweden	100.0	100.0	100.0

### Parent company

KSEK	2014-12-31	2013-12-31	2012-12-31
<b>Accumulated acquisition values</b>			
On 1 January	100	100	100
<b>Reported value on 31 December</b>	<b>100</b>	<b>100</b>	<b>100</b>

### Specification of parent company's direct holdings of shares in subsidiaries

Subsidiaries / Company reg. no. / Registered office	Number of shares	Percentage (%)	Reported value		
			2014	2013	2012
Cartela R & D AB / 556746-0083 / Lund	1,000	100.0	100	100	100
			<b>100</b>	<b>100</b>	<b>100</b>

## Note 28 Cash flow analysis

### Group

KSEK	2014	2013	2012
Write-offs	1,349	152	183
	<b>1,349</b>	<b>152</b>	<b>183</b>

### Parent company

KSEK	2014	2013	2012
Write-offs	1,294	96	127
	<b>1,294</b>	<b>96</b>	<b>127</b>

## Note 29 Events after the balance sheet date

- › The company reported preliminary results from the clinical phase II study showing that IdeS quickly and effectively reduces the levels of HLA antibodies.
- › Göran Arvidson was appointed CFO.
- › The company reported the formation of a medical advisory committee for IdeS regarding anti-GBM (Goodpastures disease).
- › Hansa Medical took up a loan in the amount of MSEK 20 from the largest shareholder Nexttobe AB. The purpose of the loan was to strengthen the company's long-term financial position. The loan carries a market rate of interest of 5% and the lender is entitled to demand repayment at the end of 2015.
- › The company announced that Dr. Stanley Jordan had been appointed as a medical advisor in the United States and that authorization has been obtained from the FDA to clinically trial IdeS in sensitized transplant patients in the United States.
- › The company announced that it is developing, and submitting a patent application regarding, a second-generation IdeS molecule which is intended to make possible repeated dosages and potentially provide IdeS with a role in the treatment of chronic autoimmune diseases.
- › The company announced that a preliminary application had been submitted for admission to trading on Nasdaq Stockholm.
- › Hansa Medical's licensee, Axis-Shield Diagnostics Ltd, has entered into a sublicensing agreement with the Chinese diagnostics company Hangzhou Joinstar Biomedical Technology Co Ltd for commercialization of HBP-assay in China.
- › The largest shareholder, Farstorps Gård AB, decreased its shareholdings from 43% to approximately 27%.
- › The Board of Directors resolved to carry out a new share issue which brings the company MSEK 246 prior to deductions for issue costs. The new share issue was entirely underwritten through subscription and underwriting guarantees. The subscription period for the issue commenced on 19 March 2015 and up to and including 2 April 2015.
- › Hansa Medical's CFO Göran Arvidson was appointed acting CEO during Fredrik Lindgren's leave of absence on medical grounds.

## Note 30 Important estimates and opinions

Certain assumptions regarding the future and certain estimates and opinions on the balance sheet date have particular significance for the valuation of the assets and liabilities set forth in the balance sheet. Set forth below is a discussion of the areas in which the risk of material changes in value, during the subsequent year, are significant due to the fact that the assumptions or the estimates may need to be changed.

### Recovery of the value of development expenses

On at least an annual basis, the group assesses whether there is any impairment need for development projects which have not yet been completed. In the calculation of the beneficial value, future cash flows are discounted at a rate of interest which takes into consideration the market's opinion of risk-free interest and risk (WACC). The group bases these calculations on estimated forecasts and business plans. The estimates and assumptions made by management in the assessment of the need for impairment may have a large effect on the group's reported earnings. Impairment is made if the calculated beneficial value is less than the reported value and affects profit/loss for the year. The group's business is entirely based on the future commercialization of the research projects being carried out and if these were to be assessed, and the assessment of their future potential to change, this would entail a material negative effect on the group's business, earnings and financial position. See also section "Riskfactors" on pages 13ff.

## Note 31 Information regarding the parent company

Hansa Medical AB (publ) is a Swedish registered public company (company reg. no. 556734-5359). The registered office is located in Lund.

The parent company's shares are registered on Nasdaq First North. The address of the headquarters is Scheelevägen 22, 223 63 Lund. The consolidated accounts for 2014 cover the parent company and its subsidiaries, jointly referred to as the group.

## Note 32 Transition to financial reporting in accordance with IFRS

The accounting principles set forth in note 1 have been applied in the preparation of the group's financial reports for the 2014 financial year and for the 2013 and 2012 comparison years, as well as for the group's opening balance on 1 January 2012. Upon preparation of the group's opening balance, amounts reported according to previously applied accounting principles have been adjusted in accordance with IFRS. Explanations regarding how the transition from previously applied accounting principles to IFRS has affected the group's financial position, financial earnings and cash flow are set forth in the following tables and the explanations for these.

Operating acquisitions prior to 1 January 2012 have not been recalculated.

### IAS 17

According to previously applied accounting principles, leasing agreements are reported as operational. The transition to IFRS has entailed that some of the agreements are classified as financial leasing agreements and consequently reported as assets and interest-bearing liabilities in the group's balance sheet. In the income statement, the leasing cost is replaced by depreciation and interest costs.

### IAS 36

A review of the book values of assets was carried out as per the date of transition to IFRS as set forth in IFRS. In conjunction with this review, intangible assets for which use had commenced were reviewed to determine if there was an indication of a need for impairment. Where the answer was "yes", an impairment assessment was carried out. For intangible assets which are not yet ready for use, there is a requirement of a mandatory impairment assessment. The results of this is led to a write-down of intangible assets as per the opening balance on 1 January 2012.

### IAS 39

The group holds listed shares and participating interests. These have been classified as realizable financial assets. In accordance with IAS 39, these have been valued at net realizable value in the balance sheet with changes in value in other comprehensive income, and which are accumulated in the net realizable value reserve in shareholders' equity.

### Effects on the income statement, balance sheet and shareholders' equity

The compilations set forth below illustrate the above-stated effects on the income statement, balance sheet and shareholders' equity if IFRS had been applied in 2012 and 2013.

## Consolidated balance sheet, 1 January 2012

KSEK	According to previous principles	Effect of IAS 17	Effect of IAS 36	Effect of IAS 39	Pursuant to IFRS
<b>ASSETS</b>					
<b>Fixed assets</b>					
Intangible fixed assets	37,675		-2,393		35,282
Tangible fixed assets	313	295			608
<b>Total fixed assets</b>	<b>37,988</b>	<b>295</b>	<b>-2,393</b>	<b>0</b>	<b>35,890</b>
<b>Fixed assets</b>					
Prepaid tax	108				108
Accounts receivable	381				381
Prepaid costs and deferred income	559	-57			502
Other receivables	703				703
Cash and cash equivalents	1,157				1,157
<b>Total fixed assets</b>	<b>2,908</b>	<b>-57</b>	<b>0</b>	<b>0</b>	<b>2,851</b>
<b>TOTAL ASSETS</b>	<b>40,896</b>	<b>238</b>	<b>-2,393</b>	<b>0</b>	<b>38,741</b>
<b>SHAREHOLDERS' EQUITY</b>					
<b>Equity</b>					
Share capital	67,605				67,605
Other contributed capital	19,806				19,806
Reserves					
Retained earnings including result for the year	-52,704		-2,393		-55,097
<b>Shareholders' equity attributable to the parent company's shareholders</b>	<b>34,707</b>	<b>0</b>	<b>-2,393</b>	<b>0</b>	<b>32,314</b>
<b>Total shareholders' equity</b>	<b>34,707</b>	<b>0</b>	<b>-2,393</b>	<b>0</b>	<b>32,314</b>
<b>Liabilities</b>					
Long-term interest-bearing liabilities		204			204
<b>Total long-term liabilities</b>	<b>0</b>	<b>204</b>	<b>0</b>	<b>0</b>	<b>204</b>
Current interest-bearing liabilities	2,700	34			2,734
Accounts payable	634				634
Other liabilities	477				477
Accrued costs and prepaid income	2,378				2,378
<b>Total current liabilities</b>	<b>6,189</b>	<b>34</b>	<b>0</b>	<b>0</b>	<b>6,223</b>
<b>Total liabilities</b>	<b>6,189</b>	<b>238</b>	<b>0</b>	<b>0</b>	<b>6,427</b>
<b>TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES</b>	<b>40,896</b>	<b>238</b>	<b>-2,393</b>	<b>0</b>	<b>38,741</b>

## Consolidated income statement, 1 January – 31 December 2012

KSEK	According to previous principles	Effect of IAS 17	Effect of IAS 36	Effect of IAS 39	Pursuant to IFRS
Net sales	2,619				2,619
Capitalized work on own account	2,706				2,706
<b>Total operating income, stock changes, etc.</b>	<b>5,325</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>5,325</b>
Raw materials and consumables	-220				-220
Other external costs	-14,139	66			-14,073
Personnel costs	-7,647				-7,647
Amortization, depreciation and write-down of tangible and intangible fixed assets	-127	-56			-183
<b>Operating result</b>	<b>-16,808</b>	<b>10</b>	<b>0</b>	<b>0</b>	<b>-16,798</b>
Financial income	347				347
Financial expenses	-5	-12			-17
<b>Net financial items</b>	<b>342</b>	<b>-12</b>	<b>0</b>	<b>0</b>	<b>330</b>
<b>Result before tax</b>	<b>-16,466</b>	<b>-2</b>	<b>0</b>	<b>0</b>	<b>-16,468</b>
Tax					
<b>Result for the year</b>	<b>-16,466</b>	<b>-2</b>	<b>0</b>	<b>0</b>	<b>-16,468</b>
Attributable to					
Parent company shareholders	-16,466	-2	0	0	-16,468
	<b>-16,466</b>	<b>-2</b>	<b>0</b>	<b>0</b>	<b>-16,468</b>
Earnings per share					
before dilution (SEK)	-0.75	0.00	0.00	0.00	-0.75
after dilution (SEK)	-0.75	0.00	0.00	0.00	-0.75

## Consolidated statement of comprehensive income

KSEK	According to previous principles	Effect of IAS 17	Effect of IAS 36	Effect of IAS 39	Pursuant to IFRS
<b>Result for the year</b>	<b>-16,466</b>	<b>-2</b>	<b>0</b>	<b>0</b>	<b>-16,468</b>
<b>Other comprehensive income</b>					
<b>Items that have been, or may be reclassified to profit or loss for the year</b>					
Fair value changes during the year for realizable financial assets				-262	-262
<b>Other comprehensive income for the year</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>-262</b>	<b>-262</b>
<b>Total comprehensive income</b>	<b>-16,466</b>	<b>-2</b>	<b>0</b>	<b>-262</b>	<b>-16,730</b>
Total comprehensive income attributable to					
Parent company's owner	-16,466	-2	0	-262	-16,730
<b>Total comprehensive income</b>	<b>-16,466</b>	<b>-2</b>	<b>0</b>	<b>-262</b>	<b>-16,730</b>

## Consolidated balance sheet, 31 December 2012

KSEK	According to previous principles	Effect of IAS 17	Effect of IAS 36	Effect of IAS 39	Pursuant to IFRS
<b>ASSETS</b>					
<b>Fixed assets</b>					
Intangible fixed assets	40,369		-2,393		37,976
Tangible fixed assets	199	239			438
Financial fixed assets	3,852			-262	3,590
<b>Total fixed assets</b>	<b>44,420</b>	<b>239</b>	<b>-2,393</b>	<b>-262</b>	<b>42,004</b>
<b>Current assets</b>					
Prepaid taxes	101				101
Accounts payable	672				672
Prepaid expenses and deferred income	1,156	-37			1,119
Other receivables	483				483
Cash and cash equivalents	18,966				18,966
<b>Total current assets</b>	<b>21,378</b>	<b>-37</b>	<b>0</b>	<b>0</b>	<b>21,341</b>
<b>TOTAL ASSETS</b>	<b>65,798</b>	<b>202</b>	<b>-2,393</b>	<b>-262</b>	<b>63,345</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>					
<b>Shareholders' equity</b>					
Share capital	22,225				22,225
Other contributed capital	1,480				1,480
Reserves				-262	-262
Retained earnings including profit or loss for the year	39,537	-2	-2,393		37,142
<b>Shareholders' equity attributable to parent company shareholders</b>	<b>63,242</b>	<b>-2</b>	<b>-2,393</b>	<b>-262</b>	<b>60,585</b>
<b>Total shareholders' equity</b>	<b>63,242</b>	<b>-2</b>	<b>-2,393</b>	<b>-262</b>	<b>60,585</b>
<b>Liabilities</b>					
Long-term interest-bearing liabilities		168			168
<b>Total long-term liabilities</b>	<b>0</b>	<b>168</b>	<b>0</b>	<b>0</b>	<b>168</b>
Current interest-bearing liabilities		36			36
Accounts payable	840				840
Other liabilities	617				617
Accrued expenses and pre-paid income	1,099				1,099
<b>Total current liabilities</b>	<b>2,556</b>	<b>36</b>	<b>0</b>	<b>0</b>	<b>2,592</b>
<b>Total liabilities</b>	<b>2,556</b>	<b>204</b>	<b>0</b>	<b>0</b>	<b>2,760</b>
<b>TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES</b>	<b>65,798</b>	<b>202</b>	<b>-2,393</b>	<b>-262</b>	<b>63,345</b>

## Consolidated income statement, 1 January – 31 December 2013

KSEK	According to previous principles	Effect of IAS 17	Effect of IAS 36	Effect of IAS 39	Pursuant to IFRS
Net sales	1,727				1,727
Capitalized work on own account	64				64
<b>Total operating income, stock changes, etc.</b>	<b>1,791</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>1,791</b>
Raw materials and consumables	-382				-382
Other external costs	-11,256	66			-11,190
Personnel costs	-7,696				-7,696
Amortization, depreciation and write-down of tangible and intangible fixed assets	-96	-56			-152
<b>Operating result</b>	<b>-17,639</b>	<b>10</b>	<b>0</b>	<b>0</b>	<b>-17,629</b>
Financial income	93				93
Financial expenses	-16	-10			-26
<b>Net financial items</b>	<b>77</b>	<b>-10</b>	<b>0</b>	<b>0</b>	<b>67</b>
<b>Result before tax</b>	<b>-17,562</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>-17,562</b>
Tax					0
<b>Result for the year</b>	<b>-17,562</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>-17,562</b>
Attributable to					
Parent company shareholders	-17,562	0	0	0	-17,562
	<b>-17,562</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>-17,562</b>
Earnings per share					
before dilution (SEK)	-0.75	0.00	0.00	0.00	-0.75
after dilution (SEK)	-0.75	0.00	0.00	0.00	-0.75

## Consolidated statement of comprehensive income

KSEK	According to previous principles	Effect of IAS 17	Effect of IAS 36	Effect of IAS 39	Pursuant to IFRS
<b>Result for the year</b>	<b>-17,562</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>-17,562</b>
<b>Other comprehensive income</b>					
<b>Items that have been, or may be reclassified to profit or loss for the year</b>					
Fair value changes during the year for realizable financial assets				2,326	2,326
<b>Other comprehensive income for the year</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>2,326</b>	<b>2,326</b>
<b>Total comprehensive income</b>	<b>-17,562</b>	<b>0</b>	<b>0</b>	<b>2,326</b>	<b>-15,236</b>
Total comprehensive income attributable to					
Parent company's owners	-17,562	0	0	2,326	-15,236
<b>Total comprehensive income</b>	<b>-17,562</b>	<b>0</b>	<b>0</b>	<b>2,326</b>	<b>-15,236</b>

## Consolidated balance sheet, 31 December 2013

KSEK	According to previous principles	Effect of IAS 17	Effect of IAS 36	Effect of IAS 39	Pursuant to IFRS
<b>ASSETS</b>					
<b>Fixed assets</b>					
Intangible fixed assets	40,421		-2,393		38,028
Tangible fixed assets	115	183			298
Financial fixed assets	8,317			2,064	10,381
<b>Total fixed assets</b>	<b>48,853</b>	<b>183</b>	<b>-2,393</b>	<b>2,064</b>	<b>48,707</b>
<b>Current assets</b>					
Prepaid taxes	211				211
Accounts payable					
Prepaid expenses and deferred income	970	-17			953
Other receivables	653				653
Cash and cash equivalents	90				90
<b>Total current assets</b>	<b>1,924</b>	<b>-17</b>	<b>0</b>	<b>0</b>	<b>1,907</b>
<b>TOTAL ASSETS</b>	<b>50,777</b>	<b>166</b>	<b>-2,393</b>	<b>2,064</b>	<b>50,614</b>
<b>SHAREHOLDERS' EQUITY AND LIABILITIES</b>					
<b>Shareholders' equity</b>					
Share capital	22,225				22,225
Other contributed capital	1,480				1,480
Reserves				2,064	2,064
Retained earnings including profit or loss for the year	21,975	-2	-2,393		19,580
<b>Shareholders' equity attributable to parent company shareholders</b>	<b>45,680</b>	<b>-2</b>	<b>-2,393</b>	<b>2,064</b>	<b>45,349</b>
<b>Total shareholders' equity</b>	<b>45,680</b>	<b>-2</b>	<b>-2,393</b>	<b>2,064</b>	<b>45,349</b>
<b>Liabilities</b>					
Long-term interest-bearing liabilities		131			131
<b>Total long-term liabilities</b>	<b>0</b>	<b>131</b>	<b>0</b>	<b>0</b>	<b>131</b>
Current interest-bearing liabilities	519	37			556
Accounts payable	710				710
Other liabilities	804				804
Accrued expenses and pre-paid income	3,064				3,064
<b>Total current liabilities</b>	<b>5,097</b>	<b>37</b>	<b>0</b>	<b>0</b>	<b>5,134</b>
<b>Total liabilities</b>	<b>5,097</b>	<b>168</b>	<b>0</b>	<b>0</b>	<b>5,265</b>
<b>TOTAL SHAREHOLDERS' EQUITY AND LIABILITIES</b>	<b>50,777</b>	<b>166</b>	<b>-2,393</b>	<b>2,064</b>	<b>50,614</b>

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## Signatures

The Board of Directors and the CEO affirm that the consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) as adopted by the EU and give a fair view of the group's financial position and results. The annual report has been prepared in accordance with generally accepted accounting principles for the group and the parent company and gives a fair overview of the development of the group's and the parent company's operations, financial positions and results, and describes material risks and uncertainties facing the parent company and the companies included in the group.

Lund den 29 April 2015

Birgit Stattin Norinder  
*Chairman*

Anders Blom  
*Director*

Stina Gestrelus  
*Director*

Per-Olof Wallström  
*Director*

Cindy Wong  
*Director*

Göran Arvidson  
*CFO and Executive Vice President*

The Board of Directors and CEO approved the annual report for publication on 29 April 2015. The consolidated income statement, report on comprehensive income and balance sheet as well as the parent company's income statement and report on comprehensive income and balance sheet will be subject to adoption at the annual general meeting to be held on 2 June 2015.

My auditor's report was submitted on 29 April 2015.

Dan Kjellqvist  
*Authorized public accountant*

# Auditor's report

To the annual meeting of the shareholders of Hansa Medical AB (publ), corp. id 556734-5359

## Report on the annual accounts and consolidated accounts

I have audited the annual accounts and consolidated accounts of Hansa Medical AB (publ) for the year 2014. The annual accounts and consolidated accounts of the company are included in the printed version of this document on pages 13–66.

### Responsibilities of the Board of Directors and the Managing Director for the annual accounts and consolidated accounts

The Board of Directors and the Managing Director are responsible for the preparation and fair presentation of these annual accounts in accordance with the Annual Accounts Act and of the consolidated accounts in accordance with International Financial Reporting Standards, as adopted by the EU, and the Annual Accounts Act, and for such internal control as the Board of Directors and the Managing Director determine is necessary to enable the preparation of annual accounts and consolidated accounts that are free from material misstatement, whether due to fraud or error.

### Auditor's responsibility

My responsibility is to express an opinion on these annual accounts and consolidated accounts based on my audit. I conducted my audit in accordance with International Standards on Auditing and generally accepted auditing standards in Sweden. Those standards require that I comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the annual accounts and consolidated accounts are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the annual accounts and consolidated accounts. The procedures selected depend on the auditor's judgment, including the assessment of the risks of material misstatement of the annual accounts and consolidated accounts, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the company's preparation and fair presentation of the annual accounts and consolidated accounts in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the company's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by the Board of Directors and the Managing Director, as well as evaluating the overall presentation of the annual accounts and consolidated accounts.

I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my audit opinions.

### Opinions

In my opinion, the annual accounts have been prepared in accordance with the Annual Accounts Act, and present fairly, in all material respects, the financial position of the parent company as of 31 December 2014 and of their financial performance and cash flows for the year then ended in accordance with the Annual Accounts Act. The consolidated accounts have been prepared in accordance with the Annual Accounts Act and present fairly, in all material respects, the financial position of the group as of 31 December 2014

and of their financial performance and cash flows for the year then ended in accordance with International Financial Reporting Standards, as adopted by the EU, and in accordance with the Annual Accounts Act. The statutory administration report is consistent with the other parts of the annual accounts and consolidated accounts.

I therefore recommend that the annual meeting of shareholders adopt the income statement and balance sheet for the parent company and the group.

## Report on other legal and regulatory requirements

In addition to my audit of the annual accounts and consolidated accounts, I have also audited the proposed appropriations of the company's profit or loss and the administration of the Board of Directors and the Managing Director of Hansa Medical AB (publ) for the year 2014.

### Responsibilities of the Board of Directors and the Managing Director

The Board of Directors is responsible for the proposal for appropriations of the company's profit or loss, and the Board of Directors and the Managing Director are responsible for administration under the Companies Act.

### Auditor's responsibility

My responsibility is to express an opinion with reasonable assurance on the proposed appropriations of the company's profit or loss and on the administration based on my audit. I conducted the audit in accordance with generally accepted auditing standards in Sweden.

As basis for my opinion on the Board of Directors proposed appropriations of the company's profit or loss I examined whether the proposal is in accordance with the Companies Act.

As basis for my opinion concerning discharge from liability, in addition to my audit of the annual accounts and consolidated accounts, I examined significant decisions, actions taken and circumstances of the company in order to determine whether any member of the Board of Directors or the Managing Director is liable to the company. I also examined whether any member of the Board of Directors or the Managing Director has, in any other way, acted in contravention of the Companies Act, the Annual Accounts Act or the Articles of Association.

I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my opinions.

### Opinions

I recommend to the annual meeting of shareholders that the profit be appropriated in accordance with the proposal in the statutory administration report and that the members of the Board of Directors and the Managing Directors be discharged from liability for the financial year.

Malmö den 29 april 2015

Dan Kjellqvist  
*Auktoriserad revisor*

# Corporate governance report



## Introduction

The Board of Directors of Hansa Medical AB (publ), company reg. no. 556734-5359 (the "Company") hereby submits the 2014 corporate governance report in accordance with the requirements of the Swedish Annual Accounts Act and the Swedish Code of Corporate Governance (the "Code"; see the Swedish Corporate Governance Board website at [www.bolagsstyrning.se](http://www.bolagsstyrning.se)). Until such time as the Company applies to Nasdaq Stockholm for admission of the Company's shares for trading on Nasdaq Stockholm's main market, the Company's corporate governance was, first and foremost, regulated by the provisions of the Swedish Companies Act (2005:551). As a step in the Company's adaptation to the exchange, the Company is already applying the Code.

There was no nominating committee in 2014 since the Company did not apply the Code at that time, but a nominating committee has been established in 2015. The nominating committee intends to produce proposals for the annual general meeting, primarily in accordance with the requirements of the Code. The principles for the appointment of the nominating committee will be proposed prior to the 2015 annual general meeting of the Company. The Company does not have the same type of guidelines for remuneration to senior executives as are required of a company whose shares are admitted for trading on a regulated marketplace. However, the board of directors will propose such guidelines prior to the Company's 2015 annual general meeting. The corporate governance report has been reviewed by the Company's auditors in accordance with the Annual Accounts Act. It does not constitute a part of the formal annual report documents.

The Group comprises the parent company, Hansa Medical AB, and its wholly-owned subsidiary Cartela R & D AB. The subsidiary does not currently conduct any operations.

## Shareholders

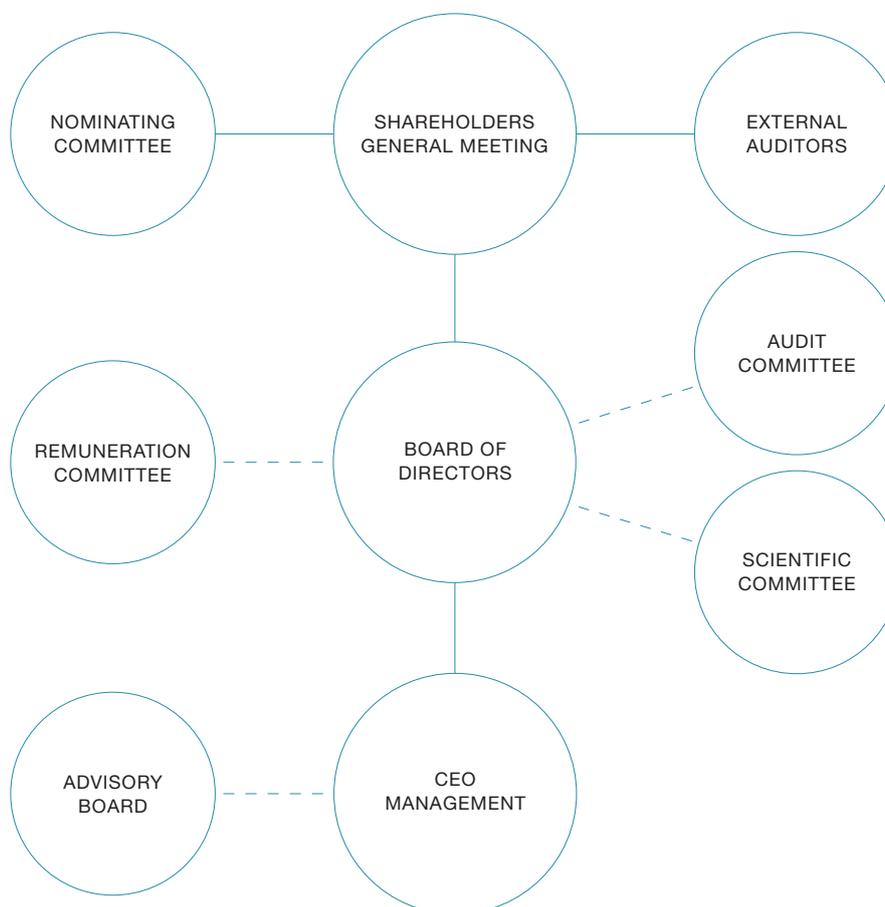
Hansa Medical AB's shares have been listed on Nasdaq First North since 2007. Information regarding the shareholders is set forth in the management report.

There are no limitations on the transferability of Hansa Medical's shares due to legal restrictions or provisions of the articles of association. To Hansa Medical's knowledge, no agreement has been entered into between any shareholders which might limit the transferability of the shares. Two shareholders, Nexttobe AB and Farstorps Gård AB, each own more than 10 percent of the Company's shares; 29.1%, and 27.5% respectively.

There was no infringement of Nasdaq First North's rules and regulations and no breach of good practice on the securities market reported by the stock exchange's disciplinary committee or the Swedish Securities Council during the financial year.

### Hansa Medical's corporate governance model

The diagram set forth below illustrates Hansa Medical's corporate governance model and the central corporate bodies at the end of February 2014. There was no nominating committee or board committees in 2014.



Significant external and internal regulations and policies which affect corporate governance:

Significant internal regulations and policies:

- › Articles of association
- › Rules of procedure for the Board of Directors
- › Instruction for the CEO, including the financial reporting instruction
- › Disclosure policy
- › Insider instruction
- › Finance policy
- › Risk management policy

Significant external regulations:

- › Swedish Companies Act
- › Swedish Accounting Act
- › Swedish Annual Accounts Act
- › International standards for audits and financial reporting (IFRS)
- › First North Rulebook
- › Swedish Code of Corporate Governance

## Information regarding Hansa Medical's shares

On 31 December 2014, the total number of shares was 25,929,603, with a quotient value of SEK 1. Each share carries one vote, and each person entitled to vote may vote for his or her full number of shares. Each share confers the right to an equally large percentage of the Company's distributable profits. On 3 June 2014, the annual general meeting resolved to authorize the board, on one or more occasions before the next annual general meeting, applying or disapplying shareholders' pre-emptive rights, to resolve upon a new issue of shares or issue of convertible instruments or warrants. Issues may take place in exchange for cash payment, payment in kind, or set off, or in other cases on terms as referred to in Chapter 2, section 5, second paragraph, points 1-3 and 5 of the Swedish Companies Act. The number of shares, convertible instruments, or warrants which may be issued on the basis of the authorization may not be limited other than as follows from the limits on share capital and number of shares as set forth in the articles of association from time to time. Acceptable reasons for the board to resolve to carry out an issue disapplying shareholders' pre-emptive rights, are to broaden the ownership base, acquire or enable acquisition of operating capital, increase liquidity of the shares, carry out corporate acquisitions, or acquire or enable acquisition of capital for corporate acquisitions. In the event of issues disapplying shareholders' pre-emptive rights, the subscription price must be on market terms as of the time of the issue resolution.

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## General meeting

The Company's highest decision-making body is the general meeting, where the shareholders' influence over the Company is exercised. Shareholders who wish to participate at a general meeting, personally or through a proxy, must be entered in the share register maintained by Euroclear Sweden AB five business days prior to the general meeting and must give the Company notice of intention to attend as described in the notice to attend the general meeting. Notices to attend general meetings are given through advertisement as well as on the Company's website ([www.hansamedical.com](http://www.hansamedical.com)). The annual general meeting must be held within six months from the close of the financial year. At the annual general meeting, the shareholders adopt resolutions regarding, among other things: the board and auditors; the procedure for appointing the nominating committee; and discharge from liability for the board and the CEO in respect of the preceding year. Resolutions are also adopted regarding: adoption of the annual report; disposition of profits or treatment of losses; fees for the directors and auditors; and guidelines for remuneration to senior executives.

The general meeting may be held in Lund or Stockholm. Shareholders who wish to have a matter considered at the general meeting shall request this in writing to the board no later than seven weeks before the meeting.

## 2014 Annual General Meeting

At the annual general meeting which was held on 3 June 2014, the annual general meeting adopted the 2013 annual accounts, adopted a resolution regarding treatment of the Company's loss, and granted the directors and CEO a discharge from liability. The general meeting resolved that no dividend would be paid. Bo Håkansson was re-elected as chairman of the board, and Stina Grestelius, Fredrik Lindgren, Birgit Stattin Norinder, Per-Olof Wallström and Cindy Wong were re-elected as directors. Anders Blom was elected as a new director. The general meeting adopted resolutions regarding election of an auditor and remuneration to the board and auditors. Bo Håkansson, chairman of the board, and directors Stina Grestelius, Fredrik Lindgren, Birgit Stattin Norinder, and Per-Olof Wallström along with the Company's auditor Ann Theander participated at the annual general meeting.

Minutes from the annual general meeting are available on Hansa Medical's website [www.hansamedical.com](http://www.hansamedical.com).

## Nominating committee

Hansa Medical had no nominating committee during 2014 since the Company was not applying the Code at that time but, in January 2015, representatives of Hansa Medical's three largest shareholders decided to organize a nominating committee. The nominating committee comprises Fredrik Bogren (representing Farstorps Gård AB, which owns approximately 27.5 percent of the shares), Anders Blom (representing Nexttobe AB, 29.1 percent of the shares), and Sven Sandberg (representing his own holding, 1.3 percent of the shares). Anders Blom is the chairman of the nominating committee.

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## External auditors

Pursuant to the articles of association, Hansa Medical must have a registered accounting firm as its external auditor. At the 2014 annual general meeting, authorized accountant Dan Kjellkvist, employed by KPMG AB in Malmö, was newly elected as auditor. Previously, Ann Theander was auditor of the Company. The auditor reviews the accounts and management of the Company and the Group as instructed by the annual general meeting. The external audit of the accounts of the parent company and the Group, as well as of the management by the board and the CEO, was carried out in accordance with generally accepted accounting standards in Sweden. The auditor participates in at least one board meeting per year, going through the accounts for the year and leading a discussion with the directors without the CEO present. The Company instructed the auditor to conduct an overall examination of an interim report during 2014 in accordance with the stipulations of the Code. The interim report for 1 January – 30 June 2014 has been audited. For information regarding fees paid to the auditors, please refer to note 5 in the 2014 annual report.

## Board of directors

The overall task of the board is to manage the affairs of the Company in the best possible manner on behalf of the shareholders. The board must continuously evaluate the Group's operations, development and financial situation, as well as the operative management. The board of directors decides upon, among other things: issues concerning the Group's strategic focus and organization; business plans; financial plans and budget; significant agreements; major investments and commitments; and finance, disclosure, and risk management policies. The board must also ensure that the Company prepares insider instructions. The board works according to rules of procedure which are adopted annually and which govern the frequency and agenda of board meetings, distribution of materials for meetings, and matters to be presented to the board for information or for a decision. The rules of procedure also govern how the board work is allocated among the board and its committees. The board has also adopted CEO instructions which governs the allocation of work among the board, the chairman, and the CEO, and which defines the CEO's authority.

The chairman must keep herself well informed about, and monitor, the Company's business. The chairman is responsible for ensuring that the board's work is carried out efficiently and that the board fulfills its obligations in accordance with applicable laws and regulations, the Code, the articles of association, resolutions of the general meeting, and the board's own rules of procedure. The chairman is also responsible for ensuring that the directors regularly update their knowledge about the Company and that new directors receive necessary introductory training.

The chairman represents the Company in ownership questions and is responsible for the day-to-day contact with the CEO and senior executives. The chairman must also approve remuneration and other employment terms and conditions for senior executives. The chairman is also responsible for the Company's archives, in which minutes from all directors meetings and general meetings must be saved.

The chairman prepares board meetings together with the CEO. The notice of the meeting and the agenda are sent to the directors only after they have been approved by the chairman of the board of directors. After this, the notice is sent together with sufficient decision-making documentation to the directors. Each and every board

meeting includes a review of the business, including development and advances within research and development, business development, consolidated earnings and financial position, financial reports, and forecasts. Pursuant to the articles of association, the board must comprise not less than three and not more than ten directors elected by the general meeting, with no alternate directors. The board is quorate when more than half of the directors are present.

The articles of association do not contain any provisions regarding appointment or dismissal of directors or regarding amendment of the articles of association.

Directors' fees were set at the Company's 2014 annual general meeting for a period up to and including the next annual general meeting. The chairman is paid SEK 300,000, and each and every other director, with the exception of Anders Blom, is paid SEK 100,000. No remuneration other than the directors' fees has been paid. No pension premiums or similar benefits were paid to directors. None of the directors are entitled to benefits after completion of their duties. During 2014, total fees of KSEK 728 were paid to the directors. Please see the management report and note 4 in the 2014 annual report for additional information regarding employment terms and conditions for the board and senior executives.

### Directors

Pursuant to the articles of association, Hansa Medical's board must comprise not less than three and not more than ten directors. The board currently comprises five individuals, including the chairman. Each director's term continues until the end of the next annual general meeting.

The following is a list of the directors, containing information regarding their years of birth and election to the board, experience, current engagements and engagements for the previous five years, holdings in other companies exceeding five percent and holdings of shares in the Company as of 29 April 2015. "Holding of shares in the Company" includes one's own holdings as well as those of closely-related persons. Other engagements within the Group are not stated.



### Birgit Stattin Norinder, born 1948

Chairman of the Board of Directors since 2014; director since 2012. Masters in pharmacology.

**Experience:** Long-term experience from international pharmaceuticals and biotechnology companies. Previously CEO and chairman of the Board of Directors of Prolifix Ltd., Senior VP Worldwide Product Development Pharmacia & Upjohn.

**Current positions:** Director of Exini Diagnostics Aktiebolag, Jettesta AB, Nicox S.A., France.

**Previous positions:** Chairman of the Board of Directors of Wingfirm Pharma AB, Partners för Utvecklingsinvesteringar inom Life Sciences, P.U.L.S. AB and Index Pharmaceutical AB. Member of the Board of Directors of Karo Bio Aktiebolag and Antisoma Plc London, Great Britain.

Owens more than 5% of the shares in: Jettesta AB.

**Number of shares:** 23,205 shares



### Stina Gestrelus, born 1949

Director since 2007. Civil engineer, med. dr. h.c., Malmö University, PhD in applied biochemistry.

**Experience:** Consultant, formerly Executive Vice President of Medicon Valley Alliance. 30 years of experience in the pharmaceuticals and biotechnology industries. Directorships in several listed life science companies. Entrepreneur and previously head of research at Biora AB.

**Current positions:** Director of BioActive Polymers in Lund AB.

**Previous positions:** Director of Lipopeptide AB, Intenz Biosciences Aktiebolag, C5 Ligno Technologies in Lund AB and Clavis Pharma ASA.

Sole proprietorship SigridScience.

**Number of shares:** 5,833 shares



### Per-Olof Wallström, born 1949

Director since 2011. Licensed pharmacist.

**Experience:** 40 years of experience in the international pharmaceuticals industry (Merck, Astra, Pharmacia and BMS) and biotechnology as well as the development and commercialization of pharmaceuticals in large and small companies. CEO of Karo Bio AB, Melacure AB and Q-Med AB.

**Current positions:** Chairman of the Board of Directors of Arosgruppen Holding AB, Arosgruppen Fastigheter Fjärdingen AB, MB Eriksson Bygg och Fastighet AB, Camurus AB, and Patients Pending Ltd. Director of Arosia Communication AB, Aggal Invest AB and MediPlast AB. Founder of Arosia Communication AB.

**Previous positions:** CEO of Karo Bio Aktiebolag, Melacure AB and Q-Med AB. Chairman of the Board of Directors of K-B Thorin Arkitektkontor AB, Aros Arkitekter AB and Chemilla AB. Director of Swedish Orphan International AB, Index Pharmaceuticals AB and Envirotainer AB.

Owens more than 5% of the shares in: Arosia Communication AB and in MB Eriksson Bygg och Fastighet AB.

**Number of shares:** 14,000 shares



### Cindy Wong, born 1959

Director since 2012. Medical degree from University of Adelaide. Specialist physician in both internal medicine and clinical immunology.

**Experience:** Broad experience in the areas of clinical medicine, clinical research and regulatory requirements for the registration of new pharmaceuticals and biotechnical products.

**Current positions:** Head of medicine at Q-Med Galderma.

**Previous positions:** None.

Does not own more than 5% of the shares in any company.

**Number of shares:** 12,503 shares



### Anders Blom, born 1969

Director since 2014. MBA.

**Experience:** Previously worked as Business Controller at Pharmacia and as Senior Director for business development and strategy at Q-Med/Galderma. He is a partner of Nexttobe AB. He is also the Executive Vice President of Oasmia Pharmaceutical AB.

**Current positions:** CEO of EQUIDx AB. Executive Vice President of Oasmia Pharmaceutical AB. Chairman of the Board of Directors of Svenska Elitskon AB and VIVALAVIDA AB. Director of Delta Projects AB, BioLamina AB, Selego AB, and EQUIDx AB. Director of Razerbourse Ltd. (dormant).

**Previous positions:** CEO of Nexttobe AB, Director of Bencar AB.

Does not own more than 5% of the shares of any company.

**Number of shares:** 0 shares

## The Board of Director's work in 2014

During 2014, the board held five ordinary meetings at which minutes were kept and five extraordinary meetings. The board was quorate at all meetings (in addition, the Board of Directors adopted resolutions per capsulum on four occasions). During 2014, the board secretary was advokat Tora Molander. Major matters addressed by the board during 2014 include the election of Fredrik Lindgren as new CEO, election of Birgit Stattin Norinder as new chairman of the board following the death of the previous chairman, Bo Håkansson,

the start of a phase II study, the election of an Advisory Board, and the Company's submission of an orphan drug application.

At the board meetings held during the 2014 financial year, the directors were present as set forth below. The number of meetings and the maximum number of directors who could have been present are stated in parentheses, given that one of the directors was newly elected during the financial year.

### The reporting period is 1 January – 31 December 2014

Director	Elected	Annual fee, KSEK	Present at ordinary meetings	Present at extra meetings	Independent in relation to the Company and corporate management	Independent in relation to the Company's largest shareholders
Bo Håkansson <sup>1)</sup>	2007	168	4 (4)	2 (2)	Ja	Nej
Birgit Stattin Norinder	2012	144	5 (5)	5 (5)	Ja	Ja
Stina Gestrelius	2007	94	5 (5)	5 (5)	Ja	Ja
Per-Olof Wallström	2011	115	5 (5)	5 (5)	Ja	Ja
Cindy Wong	2012	94	5 (5)	5 (5)	Ja	Ja
Anders Blom <sup>2)</sup>	2014	0	3 (3)	2 (3)	Ja	Nej
Fredrik Lindgren <sup>3)</sup>	2012	113	5 (5)	4 (4)	Ja	Ja

<sup>1)</sup> Passed away 28 September 2014

<sup>2)</sup> Joined the board at meeting held 6/2014

<sup>3)</sup> Resigned as a director as a consequence of employment by the Company as CEO on 25 November 2014

## Board committees

The Board of Directors did not have any committees in 2014. In January 2015, the Board of Directors formed an audit committee, a remuneration committee and a scientific committee.

### Remuneration committee

The remuneration committee which the Company formed in January 2015 consists of Birgit Stattin Norinder, chairman, Stina Gestrelus and Per-Olof Wallström. The remuneration committee is charged with performing the duties set forth in the Swedish Corporate Governance Code. The committee is obligated to keep minutes of its meetings and make the minutes available to the Board of Directors.

The primary duties of the remuneration committee are to:

- › prepare decisions for the Board of Directors regarding remuneration principles, remuneration and other employment terms and conditions for senior management, among other things by proposing to the Board of Directors the guidelines for remuneration to senior management, to be adopted at the annual general meeting;
- › monitor and evaluate any programs pending or adopted during the year for variable compensation for senior management; and
- › monitor and evaluate the application of the guidelines for remuneration adopted by the annual general meeting, as well as applicable remuneration structures and levels for the Company.

### Audit committee

The audit committee established by the Company in January 2015 consists of Anders Blom, chairman, Birgit Stattin Norinder and Per-Olof Wallström. The committee is obligated to keep minutes of its meetings and make the minutes available to the Board of Directors. The audit committee shall perform the duties incumbent upon audit committees as required by law and the Swedish Code of Corporate Governance.

The primary duties of the audit committee are to:

- › monitor the Company's financial reporting;
- › with respect to the financial reporting, monitor the effectiveness of the Company's internal control, internal audit and risk management;
- › inform itself of the audit of the annual reports and group accounts;
- › review and monitor the auditor's impartiality and independence and, in this context, particularly monitor whether the auditor is providing the Company with services other than auditing services;
- › take decisions regarding guidelines for services other than the auditing services which the external auditor can provide the Company;
- › assume responsibility for the preparation of the Board of Directors' work by ensuring that the Company's financial reporting maintains high standards;
- › assist the nomination committee in the preparation of proposals for resolutions by the shareholders' meeting regarding the choice of auditor and fees for the auditor's work;
- › meet with the Company's auditor on a regular basis in order to obtain information regarding the focus and scope of the audit

and to discuss the coordination between the external auditor and internal procedures for overview and insight into the Company's risks;

- › evaluate the auditor's work and inform the Company's nomination committee or, where applicable, special nomination committee regarding the results of the evaluation, and
- › assist the nomination committee in the preparation of proposals for nomination of the external auditor prior to the annual general meeting and proposals for fees for the external auditor's work.

### Scientific committee

The scientific committee which the Company established in January 2015 consists of Lars Björck, chairman, Hans Wigzell, Stina Gestrelus, Birgit Stattin Norinder and Cindy Wong. The committee is obligated to keep minutes of its meetings and make the minutes available the Board of Directors.

The primary duties of the scientific committee are to:

- › assist the Board of Directors with recommendations regarding the Company's research and development strategies and possibilities;
- › perform such other duties as are considered necessary and appropriate in conjunction with the work set forth above; and
- › perform such other duties as instructed by the Board of Directors from time to time.

## Executive management

The board appoints a CEO to manage the Company. The CEO is responsible for the day-to-day management of the Company in accordance with the board's instructions and guidelines. In addition to the CEO, there are four individuals who make up the executive management: the Chief Financial Officer (CFO) and Executive Vice President; the Chief Scientific Officer (CSO); the Chief Research Director (CRD); and the Chief Development Director (CDD). The management group holds meetings every month to discuss the Group's earnings and financial position, the status of research and development projects, strategic issues, and follow-up of budgets and forecasts.

### The CEO's responsibility

The CEO is responsible for managing the Company's day-to-day operations pursuant to the board's guidelines and instructions. The CEO is also responsible, in accordance with the board's written instructions, for preparing and presenting to the board issues which fall beyond the scope of day-to-day management. He must act in the Company's best interests and in accordance with the decisions of the board and the general meeting, and in the best interests of all shareholders. He must also respect the fiduciary duty and duty of confidentiality which apply to affairs and circumstances which might cause damage to the Company if disclosed, as well as the duty to report matters and circumstances which are material to the Company.

The CEO must take any and all measures which are necessary to ensure that the Company's bookkeeping is legally compliant and to ensure that funds are managed in a satisfactory manner. Accordingly, it is the CEO's responsibility to ensure that the Company has good internal management and routines to ensure application of the adopted principles for financial reporting and internal control. The CEO is responsible for preparing annual reports and interim reports and, each month (with the exception of January) to compile a report regarding the Company's financial situation. He is responsible for ensuring that the Company complies with applicable laws and guidelines, including Swedish law, the First North Rulebook, and the Code. The CEO must ensure, at a minimum, that the six-month report or the nine-month report is examined by an auditor. The CEO also has specific responsibility to ensure the competitive supply of all purchases of goods or services exceeding SEK 1 million. The CEO must provide the board with all necessary background information and documentation, both before and between board meetings. The CEO must attend board meetings unless the

chairman informs him that he need not attend. The CEO must also attend all general meetings of the Company, including both annual general meetings and extraordinary general meetings. The CEO may not have any engagements outside of the Company without the board's approval.

The CEO is also responsible for implementing the strategy approved by the board and to propose such other strategies and operational measures to the board which he deems appropriate. The CEO is responsible for the Company's internal organization, but must obtain the board's approval prior to major organizational changes. The CEO is responsible for issuing and maintaining instructions for delegation to senior executives of the Company. He is also responsible for entering into or terminating employment agreements and for other employment terms and conditions; however the chairman's approval is necessary for such issues in respect of senior executives. In a serious crisis situation, it is the CEO's responsibility to inform the board immediately and, if necessary, to form and instruct a crisis committee and to prepare a contingency plan for the business. The CEO must immediately report any event or procedure which he suspects may be significantly adverse to the business or the Company's financial position, e.g. a liquidity crisis, to the chairman.

Information regarding the CEO's age, primary education, work experience, significant engagements outside of Hansa Medical, and his and closely-related persons holdings of shares in the Company and those of closely-related persons are set forth below.

### Senior executives

Hansa Medical's senior executives currently comprise five individuals: the CEO Fredrik Lindgren (on leave of absence), the CFO and acting CEO Göran Arvidson, the Chief Scientific Officer Christian Kjellman, Chief Research Director Lena Winstedt and the Chief Development Director Emanuel Björne. Hansa Medical's current senior executives, the years when they assumed their positions, their years of birth, education, experience, shareholdings in Hansa Medical, current engagements, and engagements during the preceding five years are set forth below.

Engagements within the Group are not listed. In addition, shareholdings in the Company as of 29 April 2015 are stated. "Shareholdings in the Company" includes both one's own holdings and/or those of closely-related persons.



### Fredrik Lindgren, born 1971

CEO since 2014, on leave of absence since February 2015. Law degree from Lund University and degree and financial analysis from the Stockholm School of Economics.

**Experience:** Many years of experience from the Nordic life science industry. Previously CEO of Karo Bio Aktiebolag, Biolin Scientific AB and previously CFO of Wih. Sonesson AB (now Midsona AB), COO of Meaning Green AB and deputy CEO of Active Biotech AB.

**Current engagements:** Chairman of the board of directors of Böle Garveri AB, Sustainably Yours AB, Exini Diagnostics Aktiebolag, ProstaLund AB, Larodan AB and Larodan Holding AB. Director of West Atlantic AB, Agbaleo AB, and Image Systems AB.

**Previous engagements:** Chairman of the boards of Svenskt Integrationskapital AB, Nickel Mountain Group AB, Nickel Mountain Resources AB, Nickel Mountain AB, Q-Sense Aktiebolag and Ostell AB.

Director of Biolin Medical Aktiebolag, Biolin Scientific AB, Genovis Aktiebolag, Karo Pharma AB and Borgeby Kids & Friends AB. CEO of Karo Bio Aktiebolag.

**Number of shares:** 23,333 shares



### Göran Arvidson, born 1960

Executive vice President and Chief Financial Officer since 2015. MBA from the Stockholm School of Economics.

**Experience:** Extensive experience in the life science industry. Previously Executive Vice President and CFO of Swedish Orphan Biovitrum AB (publ) and has held a number of leading positions within Procordia AB and Pharmacia AB.

**Current engagements:** CEO of Arvidson Möller Consulting AB.

**Previous engagements:** Director of Biovitrum Treasury AB, Nya Paradiset 19 AB, Arexis AB and Fastighetsaktiebolaget Paradiset. External authorized signatory for Swedish Orphan Biovitrum AB (publ).

**Number of shares:** 3,000 shares



### Christian Kjellman, born 1967

Chief Scientific Officer since 2008. Fil. mag. in chemical biology and a doctorate in medical science with a concentration in tumour immunology from Lund University.

**Experience:** Many years of research experience in cell biology and molecular biology. He was previously Senior Scientist at BioInvent International AB focusing on the evaluation of new pharmaceutical targets and application of antibody technology. Prior to that, Kjellman was the head of research at Cartela AB.

**Number of shares:** 0 shares



### Lena Winstedt, born 1969

Head of clinical development since 2012. Doctorate in microbiology from Lund University and a Masters degree in molecular biology from Lund University and the University of Glasgow, Scotland.

**Experience:** Over ten years experience in clinical development of both protein pharmaceuticals and small molecules. She was most recently at BioInvent International AB, where she served as Clinical Project Manager focusing on phase I studies with antibody-based drug candidates in Europe and the United States. Prior to that, Winstedt worked as International Clinical Project Manager at the international biotech company Genmab A/S, and as a Clinical Research Associate at the pharmaceutical company H. Lundbeck AB.

**Number of shares:** 665 shares



### Emanuel Björne, born 1973

Corporate Development Director since 2014, previously CEO since 2007. Civil engineering degree in technical physics with a concentration in biophysical chemistry from Lund University and the University of California at Santa Barbara in the United States.

**Experience:** Björne assumed his position in connection with Hansa Medical's listing on Nasdaq First North and spinoff from Biolin Scientific, where he served as technical project manager focused on technology analysis and market analysis in the analytical instrument, pharmaceutical, and diagnostic business areas. Prior to that, he was an analytical development chemist at PolyPeptide Laboratories, focusing on the development of analytical methods based on mass spectrometry and chromatography for peptide pharmaceuticals in an early clinical phase.

**Number of shares:** 21,300 shares

# Internal control and risk management in respect of the financial reporting

## Introduction

The following description is based on guidelines issued in 2008 by the Confederation of Swedish Enterprise and FAR.

The company's internal control procedures in respect of the financial reporting have been formulated to ensure, with reasonable certainty, quality and accuracy in the reporting. The procedures are designed to ensure that the reporting is prepared in accordance with applicable laws and regulations as well as the requirements which are imposed on companies with shares admitted for trading on a regulated marketplace in Sweden. The important prerequisites for achieving this are: (i) the existence of a satisfactory control environment; (ii) the execution of reliable risk assessments; (iii) the existence of established control structures and control activities; and (iv) satisfactory information, communications and follow-up.

## Internal audit

The board has evaluated the need for an internal audit function and has concluded that it is not warranted for Hansa Medical due to the scope of the operations and because the board's follow-up of the internal control is deemed sufficient to ensure that the internal control is effective. The board will review the need in the event of changes which may give rise to re-evaluation and at least once annually.

## Control environment

Internal control is based on Hansa Medical's control environment, which comprises the values and ethics from which the board, the audit committee, the CEO, the management group, and other employees communicate and operate. The control environment also includes the Company's organizational structure, leadership, decisional structure, decision-making authority, responsibility, and employee proficiency.

## Risk assessment

Risk identification and evaluation must be carried out in the manner described above including regarding risks in respect of the financial reporting. As part of this procedure, items in the income statement and balance sheet entailing a great risk of significant error are identified. For Hansa Medical, accrued project costs in the Company's clinical projects have, at various times, involved significant amounts. The size of these is based, to great extent, on senior management's assessment of the degree of completion. For Hansa Medical, cash and equivalents, as well as current investments, comprise a significant percentage of the Company's total assets and are therefore deemed to give rise to a risk in the financial reporting. Moreover, the fact that Hansa Medical's administration is handled by a small number of individuals is listed as a risk since the dependency on a small number of key individuals becomes great and the possibility to allocate tasks and responsibility becomes limited. The Compa-

ny's financial handbook, which is to be prepared and adopted by the executive management, will include controls to prevent and detect shortcomings in these areas.

## Control structure and control activities

The board's rules of procedure and the instructions for the CEO and board committees ensure a clear allocation of roles and responsibility. The board has overall responsibility for internal control. The CEO is responsible for the development of the system of routines, procedures and controls for the day-to-day operations. This includes, among other things, guidelines and role descriptions for the various decision-makers as well as regular reporting to the board based on established routines. Routines and activities have been designed to manage and rectify significant risks which are related to the financial reporting and which are identified in the risk analysis. The most significant, overall, group-wide corporate governance documents are the work procedures for the Board of Directors, instructions for the CEO, financial policy, disclosure policy, insider instructions, and risk management policy.

The primary purpose of control activities is the prevention and early-stage detection of errors in the financial reporting so that they can be addressed and corrected. There are both manual and automated control activities on both the overall and more detailed levels. Access to IT systems is limited in accordance with powers and authorization. The CFO must compile monthly financial reports which, among other things, are to report earnings and cash flow for the preceding period and state budget deviations. These reports, and above all the budget deviations, must be analyzed and commented upon by the executive management. Follow-up takes place through regular meetings for review of these reports and analyses with the various managers and project managers. In this way, significant fluctuations and deviations are followed-up, minimizing the risk of errors in the financial reporting. The work involved with annual accounts and annual reports are processes which pose additional risks for errors in the financial reports. This work is of a less repetitive nature and contains more evaluative elements. Important control activities include, among other things, ensuring that there is a properly functioning reporting structure in which the various managers and project managers report pursuant to standardized reporting templates, and that important income statement and balance sheet items are specified and commented upon.

## Information and communication

The informational activities are governed by an information policy. There are guidelines for external communications which ensure that the Company meets high standards for providing correct information to the shareholders and the financial market. Hansa Medical's communications must be characterized by transparency and must be correct, relevant, reliable and clear; they may not be misleading. A uniform strategy for external communications reduces the risk of

erroneous information, rumours, and misunderstandings. All communications must take place in accordance with Nasdaq Stockholm's Issuer Rules, the Swedish Code of Corporate Governance, and the laws and requirements imposed on Swedish companies whose shares are admitted for trading on a regulated marketplace. The policy applies to all employees and directors of Hansa Medical and applies to both oral and written information.

The board adopts annual reports, financial statements and interim reports. All financial reports are published on the website [www.hansamedical.com](http://www.hansamedical.com) after having first been published pursuant to Nasdaq Stockholm's rules and regulations. The annual report is made available on the website and is provided as a hard copy to those shareholders who so wish.

### Follow-up

The board's follow-up of internal control in respect of the financial reporting takes place, among other things, through follow-up of the work and reports of the CFO and the external auditors. The work includes ensuring that measures are taken in respect of the shortcomings and proposed measures generated in conjunction with the external audit. The focus of the follow-up is Hansa Medical's compliance with its own rules and the existence of efficient and suitable processes for risk management, operational management, and internal control. Each year, the external auditor follows up on the selected elements of the internal control within the parameters of the statutory audit. The auditor reports the results of the examination to the board and the executive management. Significant observations are reported, where applicable, directly to the board.

The CEO is responsible for compiling all experience from the Company's risk management work and, following discussions with the executive management, proposing any changes which the CEO deems necessary or applicable. The board will decide on any changes.

## Auditors statement on the corporate governance report

To the Annual General Meeting of Hansa Medical AB, company reg. no. 556734-5359.

The Board of Directors is responsible for the corporate governance report for 2014 set forth on pages 68–79 and for ensuring that it is prepared in accordance with the Annual Accounts Act. We have read the corporate governance report and evaluated its statutorily-required content based on our knowledge of the company in order to form our opinion regarding whether the corporate governance report has been prepared and is consistent with the Annual Accounts Act and the consolidated accounts. We believe that a corporate governance report has been prepared and that its statutorily-required information is consistent with the Annual Accounts Act and the consolidated accounts.

Malmö, 29 April 2015

Dan Kjellqvist  
*Authorized public accountant*

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# Articles of Association

## Article 1

The company's name is Hansa Medical AB. The company is a public limited company (publ).

## Article 2

The registered office shall be in Lund.

## Article 3

The objects of the company shall be, directly or through subsidiaries, to conduct research, development, production, marketing and sales of medical, chemical and biotech products, and provide consulting activities within the above-stated areas and to conduct other activities compatible therewith.

## Article 4

The share capital shall be not less than SEK 20,000,000 and not more than SEK 80,000,000.

## Article 5

There shall be no fewer than 20,000,000 and no more than 80,000,000 shares.

## Article 6

The Board of Directors shall consist of three to ten members.

## Article 7

One to two auditors, with or without alternates, shall be appointed to audit the company's annual report and accounts and the management by the Board of Directors and CEO.

The auditors and alternate auditors shall be authorized public accountants or registered public accounting firms.

## Article 8

Notice of general meetings shall be given through an announcement in the Official Swedish Gazette (Post- och Inrikes Tidningar) and on the company's website. An announcement shall be published in Dagens Industri that notice has been given. Shareholders wishing to participate at general meetings must be entered in the printout of the entire share register evidencing the circumstances five days prior to the meeting and must notify the company not later than 12 PM on the date stated in the notice of the meeting, whereupon the number of assistants accompanying the shareholder to the meeting shall be stated. The latter-mentioned date may not be a Sunday, other public holiday, Saturday, Midsummer Eve, Christmas Eve or New Year's Eve and may not fall earlier than five weekdays prior to the meeting.

## Article 9

General meetings shall be held in Lund or Stockholm in the discretion of the Board of Directors.

## Article 10

The annual general meeting shall be held each year within six months of the expiration of the financial year. The following business shall be addressed at the annual general meeting:

1. Election of a chairman of the meeting
2. Preparation and approval of the voting register
3. Approval of the agenda
4. Election of one or two persons to attest the minutes of the meeting
5. Determination of whether the meeting was duly convened
6. Presentation of the annual report and the auditor's report and, where applicable, the consolidated annual report and auditor's report for the group.
7. Resolutions
  - (a) regarding the adoption of the income statement and balance sheet and, where applicable, the consolidated income statement and balance sheet;
  - (b) regarding allocation of the company's profits or losses according to the adopted balance sheet;
  - (c) regarding a discharge from liability for the directors and CEO
8. Determination of the directors' fees and auditors' fees
9. Election of the directors, auditors and any alternates
10. Other business incumbent on the meeting pursuant to the Swedish Companies Act or the articles of association.

## Article 11

The company's financial year is the calendar year.

## Article 12

The company's shares shall be registered in a CSD (Central Securities Depository) register in accordance with the Financial Instruments Accounting Act (SFS 1998:1479).

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# Glossary

## Alpha-11

Alpha-11, or alpha-11/beta-1 which is the complete designation, is a surface protein on certain types of cells which is primarily found in inflamed synovial membrane, activated synovial fibroblasts.

## Antigen

A substance foreign to the body which activates the immune system. The activation of the immune system leads to immunity against the antigen.

## Antibody

A type of protein which is produced by the body's immune system with the intent to bind to foreign substances, bacteria, or viruses. Anti-bodies are also called immunoglobulins.

## Antibody mediated

An immunological reaction in which antibodies have crucial significance.

## Assay

A method for the detection or quantification of a specific protein, cell activity, enzyme activity, biomolecular interactions, etc.

## Autoantibodies

Antibodies which are manufactured in the body and react to the body's own substances or molecules.

## Autoimmune disease

Diseases which can arise when the body's immune system reacts to the body's own structures.

## Biological pharmaceutical

A pharmaceutical which is manufactured using biotechnical methods, for example recombinant proteins and antibodies.

## Biomarkers

A biomarker is often a protein which can be detected in blood and where there is a verified connection between the existence of the proteins in the blood and a particular illness.

## Biotechnology

The use of living cells or components from cells in order to produce or modify products used in healthcare, the handling of food, and agriculture.

## Clinical studies

The investigation of a new pharmaceutical or form of treatment with healthy test persons or with patients where the intention is to study the effects and safety of a form of treatment not yet approved.

## Clinical phase I

Phase I refers to the first time in which a pharmaceutical under development is administered to a human being. Phase I studies are often carried out with a small number of healthy volunteers in order to study the safety and dosages of a form of treatment not yet approved.

## Clinical phase II

Phase II refers the first time in which a pharmaceutical under development is administered to patients in order to study the safety, dosages and effects of a form of treatment not yet approved.

## Clinical phase III

Phase III trials include many patients and are often carried out for a longer period of time; they are intended to clarify the effects and side effects of the pharmaceutical during ordinary, but nonetheless carefully controlled, conditions.

## Diagnostics

A broad spectrum of various methods to identify diseases and medical conditions based on clinical symptoms and a series of different medical tests such as, for example, blood tests and radiology.

## Donor-specific antibodies

A repertoire of antibodies which can constitute an impediment to a patient undergoing a transplant with an organ from a specific donor. These antibodies are often HLA-type antibodies which were produced by the patient earlier in life, as a consequence of a blood transfusion, pregnancy or a transplant.

## EndoS

Endoglycosidase of *Streptococcus pyogenes*. Bacterial enzyme with the unique ability to modify a specific carbohydrate chain on IgG antibodies.

## Enzyme

A protein which speeds up, or initiates, a chemical reaction without itself being affected.

## GMP

Good Manufacturing Practice is an overall quality-assurance system applied in the production of pharmaceuticals.

## Guillain-Barrés syndrome

A rare and acute autoimmune disease of the nervous system in which antibodies are formed which are primarily targeted against the isolated myelin sheath of nerves and nerve roots.

## HBP

HBP, Heparin Binding Protein, is a protein occurring naturally in the body which is used by certain immune cells, neutrophil granulocytes, for, among other things, transportation from the circulatory system into other tissues.

## HLA

HLA, Human Leukocyte Antigen, is a protein complex which is found on the surface of all human cells. The immune system uses HLA to distinguish between the body's own substances and foreign substances.

## Humoral immune system

that part of the immune system which uses antibodies in order to stop and eliminate infections.

### **IdeS**

IdeS, Immunoglobulin G-degrading enzyme of *Streptococcus pyogenes* is a bacterial enzyme with strict specificity for IgG antibodies. The enzyme has the unique ability to cleave and thus inactivate human IgG antibodies.

### **IgG**

IgG, Immunoglobulin class G, is the dominant type of antibody in serum.

### **Immunoabsorption**

A type of dialysis in which IgG antibodies are gradually removed from the blood circulation with the aid of a pump connected to a column which specifically captures IgG antibodies.

### **Immunology**

The study of the structure and function of the immune system in illness and health.

### **Immunomodulating**

That which has an effect on the immune system.

### **In vitro**

The term is used in biomedical science to indicate that an experiment or observation has been made in a test tube, for example, i.e. in an artificial environment and not in a living organism.

### **In vivo**

A term used in biomedical science to indicate that an experiment or observation has been made on or in living organisms.

### **Milestone compensation**

Compensation which a company receives pursuant to a cooperation agreement when the cooperation reaches a predetermined goal, for example proof-of-concept.

### **Pathogen**

Something which causes disease, for example contagious substances and autoimmunity.

### **Pharmaceutical candidate**

A substance with the potential of being developed into a pharmaceutical.

### **Plasmapheresis**

Plasmapheresis is a medical-technical method in which proteins dissolved in the blood are removed from the blood outside of the body.

### **Preclinical development**

Testing and documentation of the qualities of a pharmaceutical candidate in modeling systems.

### **Recombinant DNA**

DNA molecules which are produced artificially from DNA from various sources.

### **Rheumatoid arthritis**

also referred to as chronic rheumatoid arthritis, is an autoimmune disease in which the body attacks the joints giving rise to damage to cartilage, bones and surrounding soft tissue with significant pain and reduced functioning as a consequence.

### **Sensitized**

Carries significant levels of HLA antibodies. These antibodies constitute an obstacle to transplant as a consequence of an increased risk of rejection of the implanted organ.

### **Sepsis**

Diagnosed or suspected infection in combination with the patient having Systemic Inflammatory Response Syndrome (SIRS). Clinical symptoms of systematic inflammation may include a combination of fever, increased heart rate, and increased respiratory rate.

### **Severe sepsis**

Sepsis becomes severe sepsis when the patient also suffers from circulatory effects and diminished functions in vital organs such as the brain, heart, lungs, kidney or liver.

### **Streptococcus pyogenes**

A gram-positive bacteria which is primarily found in the upper respiratory tracts of human beings. Certain strains can cause throat infections and infected sores.

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## Definitions

### **Earnings per share prior to dilution**

Profit/loss for the period divided by the weighted average number of shares during the period prior to dilution.

### **Earnings per share after dilution**

Profit/loss divided by the weighted average number of shares during the period after dilution.

### **Equity ratio**

Shareholders' equity in relation to total balance sheet assets at the end of the period.

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## Addresses

### **Hansa Medical AB**

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### **Auditor**

Dan Kjellqvist  
KPMG AB  
Box 227  
SE-201 22 Malmö, Sweden

### **Certified adviser**

Remium Nordic AB  
Kungsgatan 12-14  
SE-111 35 Stockholm, Sweden

“This is really elegant research at its best!  
We now have the chance to help people in  
need by giving them a new life”

Bo Håkansson

1946 – 2014



Bo once asked me: “*What makes you tick?*” With his extroverted personality, he wanted to understand how I could stand working with the same basic scientific issues year in and year out. When I explained that the driving force and reward were intellectually beautiful and liberating experiments which, ultimately, could help people suffering with severe illness, he replied: “*If you take care of those beautiful experiments, I’ll take care of everything else*”.

Bo and I were, in certain respects, very different from each other, but we understood and respected each other. For 30 years, we had a close, stimulating and friction-free cooperation based on the insight and obligation that each of us would contribute with what we were good at. We allowed each other to be interested in what the other was doing but not to interfere. Bo has left us, but his commitment to people and excellence continues to thrive at Hansa.

**Lars Björck**

Professor of Infectious Medicines at Lund University

Bo was extremely well read when he founded Hansa Medical, based on decades of insight into the research of Professor Lars Björck. At Hansa Medical, Bo combined his impatient thirst for knowledge regarding medical research and science with his experience of building long-lasting companies and his curiosity for committed people.

Bo’s vision for Hansa Medical was unyielding. He was certain of IdeS’ place in the care of acutely ill patients. Or, as he could describe it to his colleagues or very patient shareholders: “*I’m hanging onto Hansa, even if I have to sell my garden furniture*”. This is exactly how we at Hansa remember Bo: a well-read, inquiring and visionary entrepreneur, always ready for a good laugh and with a great sense of humor – a spirit who most definitely lives on at Hansa Medical, carrying us to a very exciting future.

**Emanuel Björne**

Commercial Development Director, Hansa Medical AB

