



Interim report October – December 2021

The "Company" or "Hamlet Pharma" refers to Hamlet Pharma AB, corp. reg. no. 556568-8958

### Opening remarks

The second quarter of the fiscal year 2021/2022 has been very productive ending on a high with the completion of the clinical part of the dose-escalation study in December. The positive outcome was communicated in January 2022, showing stronger effects on the tumors with higher doses of Alpha1H. No drug related side effects were detected, further strengthening the profile of Alpha1H as a drug candidate with a high level of tumor specificity. These findings inspire us to proceed with the drug development towards Phase III trials. The dialogue with our US partners Target Health has been reactivated to proceed with the FDA process.

We have secured the production of larger quantities of Alpha1H, in preparation for the next steps in the clinical trials programme using a stable, large scale manufacturing process. Hamlet Pharma is collaborating with Rechon Life Science who offers complete pharmaceutical services, including formulation, packaging, and distribution of clinical trial supplies. The synthetic peptide Alpha1 is provided by PolyPeptide Laboratories, who have provided excellent material throughout our clinical trial programme.

To proceed with the development of BAMLET for clinical use, we have also entered into an agreement with Galenica AB, exploring potential formulations for different clinical indications. Experimental studies of BAMLET in different cancer models have shown positive results.

Forming strong partnerships with market leaders is a company priority to complete drug development and commercialization of Alpha1H and BAMLET. Hamlet Pharma is attracting interest from leaders in the field of drug development and business development. Our Think Tank has been established as a forum to engage these experts in strategic discussions and benefit from their experience and advice.

Hamlet Pharma has updated the website to become more informative and interactive. The focus on communication is strengthened by the recruitment of a new media strategist, who will increase our visibility and provide information about Hamlet Pharma to shareholders and other interested parties.

Hamlet Pharma offers a cost-efficient solution for the development of new cancer drugs, aided by continued access to new technology through Linnane Pharma. The support from our shareholders, our team members, the clinic in Prague and all our external partners is very important and a prerequisite to the success of developing new treatment options for patients.

#### Catharina Svanborg and Mats Persson

Chairman of the Board/CMO and CEO of Hamlet Pharma AB

## Significant events during the second quarter

**On October 28, 2021,** the shareholders of Hamlet Pharma were summoned to the Annual General Meeting on November 25, 2021.

On October 29, 2021, we announced that Hamlet Pharma has secured the production of larger quantities of Alpha1H, using a stable, large scale manufacturing process. Larger amounts of drug will be needed for the continued clinical trial program, which involves larger study populations. Hamlet Pharma is collaborating with Rechon Life Science for the production and formulation of the drug candidate Alpha1H. Rechon is a well-recognized contract manufacturing organization based in Malmö and offers a complete pharmaceutical service including preparation, packaging, and distribution of Clinical Trial Supplies for clinical studies phases I-IV. Production is carried out in accordance with GMP and Rechon is approved for pharmaceutical supply worldwide (including the US).

**On November 2, 2021,** Hamlet Pharma's Board of Directors proposed two new members for election to the company's Board of Directors. Ulla Trägårdh is a lawyer with broad experience in the area of business law. She has been involved in the development of both a major Swedish law firm, as well as a local niche law firm that she established 2003. Lars Hedbys has many years of experience from the pharmaceutical industry and has founded and listed several life science companies.

**On November 4, 2021,** the annual report for the fiscal year 2020/2021 was published. It can be found on our website or on Spotlight Stock Market's webpage.

**On November 11, 2021,** Q1 for the fiscal year 2021/2022 was published. It can be found on our website or on Spotlight Stock Market's webpage.

On November 25, 2021, the Annual General Meeting was held. Due to the corona virus pandemic, the meeting was conducted by advance voting with the support of temporary statutory rules. It was decided to appoint Catharina Svanborg, Bengt Westermark, Bill Hansson, Ulla Trägårdh, Lars Hedbys and Helena Lomberg as board members for the period until the end of the next Annual General Meeting. The AGM resolved to approve the income statement and balance sheet as included in the annual report. The AGM resolved to dispose the company's results in accordance with the Board's proposal in the annual report. Furthermore, it was decided that no dividend will be paid for the financial year 2020/2021. It was also resolved to grant the members of the Board of Directors and the CEO discharge from liability for the period covered by the annual report presented at the meeting. The relevant members of the Board of Directors or the CEO did not participate in this decision.

**On November 30, 2021,** the company invited investors to an on-line meeting to summarize the information normally presented at the Annual General Meeting and to provide a forum for a dialogue with the shareholders. About 80 participants took part and the discussions were lively and constructive.

**On November 30, 2021,** Hamlet Pharma signed a contract with Galenica AB. Hamlet Pharma is proceeding with the development of BAMLET for pharmaceutical use and a necessary first step is to establish technology for large-scale production of BAMLET. A new production method has been developed and patented and will be used as a basis for scaling up the production process together with Galenica AB. The parties have agreed on a development plan, including production technology transfer, testing of biological activity of the product and development of suitable formulations. Galenica AB is a contract research organisation (CRO) providing services in the field of pharmaceutical technology. The company has broad skills and experience in formulation, production and quality control of pharmaceuticals.

**On December 7, 2022,** Hamlet Pharma announced the new website and recruitment of a new media strategist. Hamlet Pharma increase focus on the company's digital channels to provide easier access for shareholders and the public. An updated website and digital meetings with shareholders are examples already implemented.

# Significant events after the end of the second quarter

On January 14, 2022, Strategic recruits to the Hamlet Pharma Think Tank were announced. The company has formed the Think Tank as a forum for strategic discussions important to the company's future. In addition to the competence that exists in the company, leading experts have been recruited in the areas of drug development, business development, finance and clinical strategy. The Think Tank will provide a forum for creative discussions and networking, a place where experience and expertise within the company's major strategic areas will be shared to reach innovative solutions.

**On January 17, 2022,** the successful completion of the dose-escalation extension of the Phase I/II study was announced. More potent effects of Alpha1H for key study parameters were seen for higher doses. The tumors were more strongly affected by Alpha1H at higher doses than in patients treated with the lower dose, as shown by more extensive shedding of tumor cells and tumor fragments into patient urine. As shown earlier, significant cell shedding or apoptosis did not occur in the placebo group, confirming the treatment effect. The results are very encouraging for our continued work towards Phase III trials.

**On January 31, 2022,** a newsletter was published to describe data from the dose-escalation study in greater detail. The correlation between dose and effect strongly indicate that Alpha1H shows characteristics indicative of its function as a drug against aggressive cancer, and that it may be possible in the future to administer Alpha 1H according to the special needs of the individual patient.



## **Important Milestones**

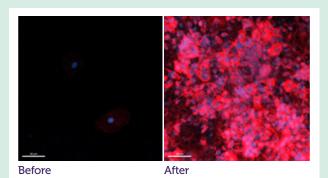
#### Successful hearing with the EU

After the successful round of financing, the financial situation of Hamlet Pharma is stable. The EU grant further supports the company growth. During a recent 18 month follow up hearing with the EU, the company presented results showing successful completion of most of the milestones and work packages.

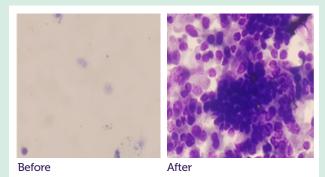
#### Clinical trial program

An extensive analysis of clinical and molecular data for the dose-escalation part of the clinical trial in bladder cancer is ongoing. The positive results from the first part were published in June 2021 in Nature Communications, a leading international journal. In January, we announced the positive data from the dose-escalation of Alpha1H. Patients were given Alpha1H or placebo directly into the bladder. By comparing urine samples from before and after the treatment, we detected a substantial increase in tumor cell shedding among the patients receiving active substance, along with an accumulation of cells containing Alpha1H. The purpose of a dose escalation study is to investigate if treatment with increased doses of Alpha1 results in increased effects in the patients with bladder cancer. The study showed that the tumors were more strongly affected with higher doses than in patients treated with the lower dose and those treated with placebo. The correlation between dose and efficacy strongly indicate that the substance elicits positive responses as can be expected from a functional drug showing dose response in terms of efficacy.

The patients were given Alpha1H or placebo directly into the bladder. By comparing urine samples from before and after the treatment, we detect a substantial increase in tumor cell shedding among the patients receiving active substance, along with an accumulation of cells containing Alpha1H.

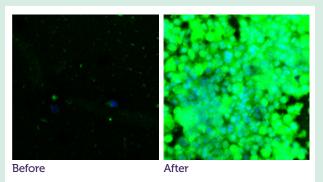


Uptake of Alpha1H (red) in urine samples taken after treatment with Alpha1H. Tumor cells are shown to contain large amounts of Alpha1H after but not before treatment.



Cancer cell shedding in urine samples taken after but not before the treatment with Alpha1H. Tumor cells and fragments are stained blue.

After just two hours, patients treated with the higher dose of Alpha1H started to shed large numbers of tumor cells into the urine and the shed cells contained large amounts of the Alpha1H drug candidate, suggesting that the tumor is fragmented and released into the urine. At the time of surgery, major changes were observed in the remaining tumor tissue, with a loss of viable tissue, areas of necrosis, evidence of tumor fragmentation and shedding of large fragments from the tumor surface.



Tumor cell death induced by Alpa1H. Large numbers of green, dying cells are seen in urine samples taken from the patients after treatment with Alpha1H.

The higher dose was also shown to trigger a strong apoptosis response and to shut down the transcriptional machinery of the tumor, which translates RNA into new proteins. This means that Alpha1H does not just target one part of the tumor cell machinery but has a general effect on essential tumor cell functions, limiting their growth and inducing cell death.

#### The period in summary

#### SECOND QUARTER (OCT 1, 2021-DEC 31, 2021)

- Net sales for the quarter totaled KSEK 0 (0)
- Other operating income totaled KSEK 4,645 (1,640)
- Loss before tax amounted to KSEK -2,950 (-2,828)
- Loss after tax amounted to KSEK -2,950 (-2,828)
- Loss per share\* was SEK -0.0271 (-0.0280), and SEK -0.0253 after dilution
- FIRST HALF (JUL 1, 2021-DEC 31, 2021)
- Net sales for the first half totaled KSEK 0 (0)
- Other operating income totaled KSEK 8,572 (4,637)
- Loss before tax amounted to KSEK -4,998 (-4,671)
- Loss after tax amounted to KSEK -4,998 (-4,671)
- Loss per share\* was SEK -0.0460 (-0.0463), and SEK -0.0428 after dilution
- On December 31, 2021, the equity/assets ratio\*\* was 94.9 (39.4) %

#### Amounts in parentheses above and below indicate the corresponding value in the preceding year.

- \* Profit/loss after tax for the period divided by 108.761.179 (3\*33,624,899=100,874,697) and 116 647 661, respectively, where 108.761.179 is the number of shares outstanding on December 31, 2021, and 116 647 661 will be the number of shares if the subscription warrants issued by the Company are exercised. The comparative figure in parentheses was the number of shares on December 31, 2020 considering the split that was registered at the Swedish Companies Registration Office (Bolagsverket) by April 14, 2021. The shares were splitted in the relation 3:1. Thus, the number of shares totals 100,874,697. Read more in the section "The share" on page 8.
- \*\* Equity divided by total capital.





#### **Hamlet Pharma AB**

Hamlet Pharma's shares are traded on Spotlight Stock Market. Hamlet Pharma is a subsidiary company of Linnane Pharma AB, which owns 50.13% of the capital and 83,38% of the votes of Hamlet Pharma AB and part of a group also comprising SelectImmune Pharma. Linnane Pharma is wholly owned by Catharina Svanborg, Chairman of Hamlet Pharma. Hamlet Pharma is engaged in the development of a new family of drugs, based on the tumoricidal protein-lipid complex, HAMLET, formed by two Generally Recognized As Safe (GRAS) molecules present in human milk. The therapeutic entity HAMLET is formed when alpha-lactalbumin (the primary protein component of human milk) undergoes a conformational change and binds to oleic acid. HAMLET selects and removes tumor cells efficiently and has shown therapeutic efficacy on skin papillomas in a placebo-controlled clinical trial and induction of cancer cells shedding after injection into the bladder of patients with bladder cancer.

The company goal is to develop drugs for use in the treatment and prevention of cancers; initially bladder cancer, a severe and costly disease. Drug development for bladder cancer has focused on Alpha1H, which is a synthetic variant of HAMLET, comprising the N-terminal peptide alpha1 bound to oleic acid. Alpha1H kills different types of tumour cells and has demonstrated therapeutic efficacy in bladder cancer models. Hamlet Pharma has completed the Phase I/II part of a clinical trial with Alpha1H, which showed no drug-related side effects, indicating that the treatment is safe and well tolerated. Alpha1H demonstrated significant clinical efficacy compared with patients who received placebo. The company has expanded the study program to include a dose-escalation and a combination study arm.

An extensive patent portfolio protects Alpha1H with granted patents in both Europe, Asia and the US. The company's drug development program is based on access to R&D expertise regulated by a collaboration agreement with Lund University. To extend the access to necessary competence, IP rights, know-how and technology, Hamlet Pharma has entered into an agreement with Linnane Pharma and the technology platform developed by the scientists.

The scientists have also identified and patented the active HAM-LET analogue BAMLET, which is a molecular complex formed by bovine alpha-lactalbumin and oleic acid. Patent rights reside with HAMLET Pharma and steps are now taken to develop BAMLET as a prophylactic or therapeutic agent, primarily against cancers in the gastro-intestinal tract.

#### Revenue and earnings

Hamlet Pharma's net sales amounted to KSEK 0 (0) during the first half, and to KSEK 0 (0) during the second quarter. Other operating income amounted to KSEK 8,572 (4,637) during the first half, and to KSEK 4,645 (1,640) during the second quarter. Read more in the section "Horizon 2020 EIC Accelerator Fund" below. Costs were related to the continued R&D activities of the research team at Lund University. The team at Lund University is also responsible for the development of manufacturing methods, stability testing and chemical and functional characterization of existing and new drug substances and plays a key role in the coordination of laboratory testing in the

clinical trial. Costs were also related to manufacturing of the Alpha1H drug candidate, for use in ongoing and forthcoming clinical trials.

Loss before tax for the first half was KSEK -4,998 (-4,671). Loss before tax for the second quarter was KSEK -2,950 (-2,828).

#### Financial position

The financial situation for Hamlet Pharma is very strong. During July 2021, the company carried out a rights issue. The issue provided the Company with 46.9 MSEK, after deductions for issue costs of 4.3 MSEK. Read more in the section "New share issue and subscription warrants" below. Furthermore, a second payment of 6.7 MSEK was received from the EU in July 2021. Read more in the section "Horizon 2020 EIC Accelerator Fund" below.

At the end of the second quarter, the equity/assets ratio was 94.9 (39.4) %, and the Company's cash and cash equivalents were KSEK 45,872 (9,726).

#### Horizon 2020 EIC Accelerator Fund

In March 2020 Hamlet Pharma (together with Linnane Pharma) was awarded a grant of 2.2 MEUR from the prestigious Horizon 2020 EIC Accelerator Fund (approx. 22.4 MSEK of which 252 KEUR belongs to Linnane Pharma). The funds will be paid incrementally during the project's 24-month duration. The first payment of 12.6 MSEK was done in July 2020, and the second payment of 6.7 MSEK was done in July 2021. Grants received from Horizon 2020 will be reported as other income as performance within the framework of the agreement is performed. During the second quarter KSEK 4,645 was used from the fund, and KSEK 18,330 has been used accumulated from the fund.

#### **Access to Technology Platform**

In addition to the collaboration with Lund University, Hamlet Pharma has access to current and innovative cutting-edge expertise via Linnane Pharma. Linnane Pharma offers a technology platform that provides access to a unique combination of cutting-edge expertise, large-scale analysis methods such as proteomics, RNA and DNA sequencing, methods for analysis of clinical materials and animal models for design of clinical studies for drug development, etc. The agreement is valid for two years and the technology platform is available on a subscription basis. This is an effective way to gain access to cutting-edge expertise and new technology at low cost. The agreement does not contain any further financial commitments to Linnane Pharma. We see this as an efficient and financially attractive model that many biotech companies could benefit from.

#### **Investments**

No intangible assets were capitalized during the period, since the Company is in an R&D stage. R&D costs are therefore recognized as operating expenses in the income statement. No new investments in tangible assets were capitalized during the quarter.

#### Depreciation

During the quarter, depreciation of equipment amounted to KSEK 0 (9).

#### **Employees**

The company had the corresponding 4 (5) full-time employees during the quarter.

#### The share

The Company's shares have been traded on Spotlight Stock Market since October 23, 2015. Spotlight Stock Market is a line of business within, and constitutes a special company name for, Spotlight Group AB.

At the extraordinary general meeting in Hamlet Pharma AB on March 2, 2021, it was decided that the company's common shares would undergo a split with relation 3:1 and would be reclassified as A- and B-shares. The B-shares will be traded on Spotlight Stock Market. The A-shares will not be listed. Each A-share entitles to ten votes and B-shares entitles to one vote. Furthermore, it is possible for shareholders to convert A-shares to B-shares, which can be traded on Spotlight Stock Market. This conversion program is ongoing with no current deadline. This means that the ratio between A- and B-shares will change over time. The split was registered at the Swedish Companies Registration Office (Bolagsverket) by April 14, 2021.

As of December 31, 2021, the number of shares registered at the Swedish Companies Registration Office (Bolagsverket) totaled 108,761,179. As of January 14, 2022, the registered current ratio of shares was 38,737,666 A-shares and 70,023,513 B-shares.

#### New share issue and subscription warrants

In July 2021 a total of 3,870,495 units were issued. A unit consists of two shares (A or B shares depending on previous ownership), a warrant in series TO3 and a warrant in series TO4. The warrants were issued free of charge. A warrant of series TO3 entitles the holder to subscribe for a new B share in the Company during the period 17 - 31 May 2022, and a warrant of series TO 4 entitles the holder to subscribe for a new B share in the Company during the period 17 - 31 May 2023. The subscription prices amount to 75% of the volume-weighted average prices for the Company's share in the ten trading days immediately preceding the start of the respective exercise period. However, a maximum of SEK 10 per share for TO3 and a maximum of SEK 13 per share for TO4.

Upon full exercise of all warrants, the Company will receive an additional maximum of SEK 39.4 million for TO3 and a maximum of approximately SEK 51.3 million for TO4, before deduction of issue costs of approximately SEK 2.3 million.

The share capital after the Rights Issue and the Offsetting Issue amounts to SEK 1,087,611.79, divided into a total of 108,761,179 shares. The warrants TO3 and TO4 were admitted to trading on the Spotlight Stock Market as of September 10, 2021.

#### Transactions with related parties

During the quarter, KSEK 480 (187) was paid to Linnane Pharma AB regarding consulting fees and technology platform, and KSEK 160 (80) to Fridsbo Pharma AB. Furthermore, salaries and allowances to board and management were paid during the period. Transactions with related parties is on market terms.

The consulting fee to Fridsbo Pharma refers to work with the clinical trial program. For the consulting fee to Linnane Pharma, KSEK 105 (105) refers to compensation for central administrative services including HR and ongoing personnel administration. The remainder refers to costs for project administration.

An agreement for support based on a technology and science platform has been written between Hamlet Pharma AB and Linnane Pharma AB, to ensure access to advanced science and technology. The agreement runs for two years. This technology platform is available for Hamlet Pharma, on a subscription basis. This is an effective way to get access at a low fixed cost to cutting-edge expertise and new technology. During the quarter KSEK 375 (0) was paid to LinnanePharma AB regarding technology platform.

#### Significant risks and uncertainties

The Board's assessment of significant risks and uncertainties is unchanged compared with the most recent financial year and is described in the most recently published annual report (2021-06-30).

#### Basis of preparation for the interim report

The Company prepares its accounts in accordance with the Swedish Annual Accounts Act and the K3 framework (BFNAR 2012:1) of the Swedish Accounting Standards Board.

The company's accounting principles are unchanged compared with most recent financial year and are described in the most recent published annual report (2021-06-30).

#### **Review**

This interim report has not been audited.

#### Financial calendar

Interim report for Q3, 2021/2022 Year-end report for 2021/2022 Annual Report for 2021/2022 Interim report for Q1, 2022/2023 Annual General Meeting for 2021/2022 May 20, 2022 August 26, 2022 November 3, 2022 November 11, 2022 November 24, 2022

## **Income statement**

	2021-10-01	2020-10-01	2021-07-01	2020-07-01	2020-07-01
SEK	2021-12-31	2020-12-31	2021-12-31	2020-12-31	2021-06-30
Net sales	0	0	0	0	0
Other operating income	4 645 413	1 640 373	8 572 413	4 636 583	9 339 727
Operating income	4 645 413	1 640 373	8 572 413	4 636 583	9 339 727
Other external costs	-6 388 933	-3 399 108	-11 296 982	-7 383 495	-12 657 319
Employee benefit expenses	-1 198 370	-1 067 817	-2 175 778	-1 883 213	-4 084 146
Depreciation of tangible assets	0	-9 000	-9 000	-18 000	-36 000
Other operating expenses	-7 807	8 041	-13 027	-28 537	-64 624
Operating loss	-2 949 697	-2 827 511	-4 922 374	-4 676 662	-7 502 362
Financial items	-265	-50	-75 353	5 858	-219 142
Loss before tax	-2 949 962	-2 827 561	-4 997 726	-4 670 804	-7 721 504
Tax on loss for the period	0	0	0	0	0
Loss after tax	-2 949 962	-2 827 561	-4 997 726	-4 670 804	-7 721 504

## **Balance sheet**

ASSETS, SEK	2021-12-31	2020-12-31	2021-06-30
Fixed assets			
Tangible assets	0	27 000	9 000
Total fixed assets	0	27 000	9 000
Current assets			
Other receivables	728 545	375 630	495 523
Prepaid expenses	491 833	4 607 596	4 767 257
Cash and bank balances/financial investments	45 871 558	9 726 439	7 473 038
Total current assets	47 091 936	14 709 665	12 735 818
TOTAL ASSETS	47 091 936	14 736 665	12 744 818
EQUITY & LIABILITIES, SEK	2021-12-31	2020-12-31	2021-06-30
Restricted equity			
Share capital	1 087 612	1 008 747	1 008 747
Statutory reserve	20 000	20 000	20 000
Total restricted equity	1 107 612	1 028 747	1 028 747
Non-restricted equity			
Share premium reserve	131 701 361	84 848 309	84 848 309
Retained earnings	-83 122 485	-75 400 981	-75 400 981
Loss for the period	-4 997 726	-4 670 804	-7 721 504
Total non-restricted equity	43 581 149	4 776 524	1 725 824
Total equity	44 688 761	5 805 271	2 754 571
Current liabilities			
Accounts payable	1 448 814	653 175	1 181 577
Tax liabilities	16 461	1 525	17 986
Other liabilities	143 527	165 265	6 131 606
Accrued expenses	794 374	8 111 430	2 659 078
Total current liabilities	2 403 175	8 931 394	9 990 247
TOTAL EQUITY & LIABILITIES	47 091 936	14 736 665	12 744 818

## **Cash flow statement**

	2021-07-01	2020-07-01	2020-07-01
SEK	2021-12-31	2020-12-31	2021-06-30
Operating activities			
Loss after financial items	-4 997 726	-4 670 804	-7 721 504
Adjusted for non-cash items, etc.	9 000	18 000	261 000
Cash flow from operating activities before changes in working capital	-4 988 726	-4 652 804	-7 460 504
Cash flow from changes in working capital			
Change in current receivables	4 042 402	-3 714 791	-3 994 345
Change in current liabilities	-7 587 072	4 853 634	5 687 487
Cash flow from operating activities	-8 533 396	-3 513 960	-5 767 362
Financing activities			
Rights Issue	50 316 435	0	0
Issuance costs	-3 384 518	0	0
Cash flow from financing activities	46 931 917	0	0
Cash flow for the period	38 398 521	-3 513 960	-5 767 362
Cash and cash equivalents at the beginning of the period	7 473 038	13 240 400	13 240 400
Cash and cash equivalents at the end of the period	45 871 558	9 726 439	7 473 038

## **Equity**

Equity (SEK)	Share capital	Statutory reserve	Share premium reserve	Retained earnings	Loss for the period	Total
Opening balance July 1, 2021	1 008 747	20 000	84 848 309	-75 400 981	-7 721 504	2 754 571
Transfer of prior year's loss - Preliminary				-7 721 504	7 721 504	0
Rights Issue	77 410		45 908 807			45 986 217
Offset Issue	1 455		944 245			945 700
Loss for the period, Q1					-2 047 764	-2 047 764
Loss for the period, Q2					-2 949 962	-2 949 962
Equity December 31, 2021	1 087 612	20 000	131 701 361	-83 122 485	-4 997 726	44 688 761

The Board of Directors and the Chief Executive Officer assure that the interim report provides a true and fair view of the Company's operations, position and results.

#### Malmö, February 25, 2022

Catharina Svanborg  Chairperson of the Board	Bengt Westermark <b>Board member</b>
Lars Hedbys  Board member	Helena Lomberg  Board member
Ulla Trägårdh Board member	Bill Hansson Board member
Mats Persson CEO	





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