

# Q1

**Interim report July–September 2021**

# Opening remarks

During the first quarter of the new fiscal year, Hamlet Pharma secured continued funding, by completing a round of financing with preferential rights for the company's shareholders. The rights issue was significantly oversubscribed, reflecting investor confidence and a commitment from the shareholders to help secure continued growth of the company.

Furthermore, the majority owner Linnane Pharma, demonstrated confidence in Hamlet Pharma by investing approximately 25.3 million SEK to match its share of the Rights Issue. The issue guarantees were therefore not used. Future warrants (TO3 and TO4) will give the company a possibility to raise an additional 90 million SEK. A TO3 warrant entitles the holder to subscribe for new B shares in May 2022, and a TO4 warrant for new B shares in May 2023.

Also in July, a successful evaluation, by the EU praising the company's achievements resulted in a decision to award the second payment from the EIC Accelerator Horizon 2020 fund of approximately 6.7 million SEK.

The clinical trials in patients with bladder cancer are proceeding according to plan, with the dose-escalation arm and the combination study arm running in parallel. Large-scale production of the drug candidate Alpha1H has been secured by technology transfer of a stable manufacturing process to Rechon Life Science; a multinational company with extensive experience in drug production and formulation. Developing the manufacturing of our drug candidate is essential for the extension of the clinical trial program in patients with bladder cancer.

Communicating with our shareholders and the general public is essential and we are exploring new ways to reach out to investors and increase media attention. Significant international interest in our Nature Communications publication is reflected by interviews for specialized science web-sites, several podcasts and a feature in South China Morning Post. The Prospect describing Hamlet Pharma was published in connection with the rights issue, and a series of successful virtual meetings were hosted during the summer to facilitate the dialogue with investors and the current status of the company and visions for the future.

The stable financial position, established clinical organization and drug production, now enables Hamlet Pharma to realize the potential of Alpha1H as a new cancer drug and to expand the development of other compounds in the Hamlet Pharma portfolio. Hamlet Pharma is committed to improving the treatment options for cancer patients, initially patients with bladder cancer, where there is a significant unmet medical need for new therapies

## **Catharina Svanborg and Mats Persson**

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

# Significant events during the first quarter

**On July 5, 2021**, the Prospect defining Hamlet Pharma's rights issue was published after approval and registration by the Swedish Financial Supervisory Authority (Finansinspektionen). Västra Hamnen Corporate Finance AB acted as financial advisor during the rights issue and the law firm Vinge as legal advisor.

**On July 6, 2021**, the successful outcome of the bladder cancer clinical trial was featured in South China Morning Post's Health & Wellness section. South China Morning Post is Hong Kong-based and has a circulation of 105,000 with 197 million page views per month.

**On July 9, 2021**, Hamlet Pharma invited investors to take part in on-line meetings to give participants the opportunity to ask questions and discuss the latest developments and future plans for the company.

**On July 9, 2021**, Hamlet Pharma's achievements were highlighted during an EU evaluation. Despite the COVID pandemic, the company has fully achieved its milestones. After this successful evaluation, Hamlet Pharma received the second payment from the EIC Accelerator Horizon 2020 fund of approximately 6.7 million SEK.

The EU evaluators state that: *"All required milestones and deliverables to date are without any significant deviations. This is particularly impressive considering the global Corona virus pandemic. To date, the beneficiary has succeeded in manufacturing the Investigational Medicinal Product (IMP) Alpha1H. The company has demonstrated non-clinical improvement of therapeutic efficacy of other cancer drugs like Mitomycin C and Epirubicin, when combined with Alpha1H and successfully continued with the Phase I/II study of Alpha1H in bladder cancer patients. There is evidence of good financial management in this project. The number of financial resources utilized to date is proportionate to the achievements of the project to date"*.

**On July 23, 2021**, it was announced that Hamlet Pharma's rights issue was significantly oversubscribed, B units by 260%. The issue guarantees were not used. The rights issue provides the company with approximately 50.4 million SEK, before deductions for issue costs of approximately SEK 4.1 million. Future warrants (TO3 and TO4) will potentially raise an additional SEK 90.7 million SEK before deduction of issue costs of approximately SEK 2.3 million SEK.

**On August 27 2021**, the Year-end Report for the fiscal year 2020 – 2021 was published. The focus during the past 12 months has been on i) finishing the evaluation and publication of the first part of the phase I/II trial ii) expanding the clinical trial program to include a dose-escalation part and combination therapy iii) securing the production of Alpha1H for future clinical trials, iv) developing business strategies and identifying partners for Alpha1H and BAMLET and v) securing continued funding of the company.

**On September 3, 2021**, it was announced that Hamlet Pharma's conversion of BTU B into shares and warrants of series TO3 B and TO4 B was on September 9, 2021. The first day for trading in warrants of series TO3 B and TO4 B will be September 10, 2021.

# Significant events after the fiscal year

**On October 28, 2021**, the shareholders of Hamlet Pharma were summoned to the Annual General Meeting on November 25, 2021. In light of the coronavirus, the meeting is conducted by advance voting with the support of temporary statutory rules. The notice is available on the company's website [www.hamletpharma.com](http://www.hamletpharma.com).

**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. The new batches is essential for the extension of the clinical trial program in patients with bladder cancer. Hamlet Pharma is collaborating with Rechon Life Science for the production and formulation of the drug candidate Alpha1H. Rechon Life Science AB is a manufacturer approved for pharmaceutical supply worldwide, including the US. Production is carried out in accordance with Good Manufacturing Practice (GMP) and Alpha1H, packaged for clinical use, will be distributed to the clinical trial site.

**On November 2, 2021**, Hamlet Pharma's Board of Directors proposes two new members for election to the company's Board of Directors. Lars Hedbys who has many years of experience from the pharmaceutical industry and has founded and listed a number of life science companies and Ulla Trägårdh who is a lawyer with broad experience in business law.

**On November 4, 2021**, the annual report for the fiscal year 2020/2021 was published. It can be found on our updated homepage or on spotlight Stock Market's home page.

## IMPACT OF THE COVID-19 PANDEMIC

The COVID-19 pandemic has significantly affected drug development, not least the clinical trials. The European Medicines Agency (EMA) has acknowledged this and advised keeping activities on clinical trials to a level not impacting the priorities in the clinic. HAMLET Pharma has continued the clinical trials and the Czech authority has approved our applications. Moreover, the clinical team in Prague has done their utmost to recruit patients and support the study. Despite this, some delays are inevitable.

## The period in summary

### FIRST QUARTER (JUL 1, 2021-SEP 30, 2021)

- Net sales for the quarter totaled KSEK 0 (0)
- Other operating income totaled KSEK 3,927 (2,996)
- Loss before tax amounted to KSEK -2,048 (-1,843)
- Loss after tax amounted to KSEK -2,048 (-1,843)
- Loss per share\* was SEK -0.0188 (-0.0183), and SEK -0.0176 after dilution
- On September 30, 2021, the equity/assets ratio\*\* was 88.7 (41.2) %

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 September 30, 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 September 30, 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" below.

\*\* 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 50.19% of the capital and 79.8% 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 HAMLET 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 gastrointestinal tract.

## Revenue and earnings

During the first quarter, Hamlet Pharma's net sales amounted to KSEK 0 (0). Other operating income amounted to KSEK 3,927 (2,996). 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, and for securing future funding. 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 quarter was KSEK -2,048 (-1,843).

## 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 first quarter, the equity/assets ratio was 88,7 (41.2) %, and the Company's cash and cash equivalents were KSEK 50,093 (13,064).

## Horizon 2020 EIC Accelerator Fund

In March 2020 Hamlet Pharma (together with Linnane Pharma) was awarded a grant of 2.2 MEUR (approx. 22.4 MSEK) (of which 252 KEUR belongs to Linnane Pharma) from the EU's prestigious Horizon 2020 EIC Accelerator Fund. 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 first quarter KSEK 3,927 was used from the fund, and KSEK 13,685 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 (see Note 13). 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 first quarter.

## Depreciation

During the quarter, depreciation of equipment amounted to KSEK 9 (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 the secondary name of ATS Finans AB, a securities company under the Swedish Financial Supervisory Authority's supervision.

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 September 30, 2021, the number of shares registered at the Swedish Companies Registration Office (Bolagsverket) totaled 108,758,963 divided in 38,867,193 A-shares and 69, 891,800 B-shares.

As of October 31, 2021, the registered current ratio of shares was 38,815,438 A-shares and 69,945,741 B-shares.

## New share issue and subscription warrants

In July 2021 the Company carried out a rights issue ("Rights Issue"). This has provided the Company with 50.4 MSEK, before deductions for issue costs of 4.3 MSEK.

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.

As the issue guarantors are entitled to receive guarantee compensation in the form of newly issued units in the Company, the Board, with the support of authorization from the Extraordinary General Meeting held on 17 June 2021, decided on a set-off issue ("Offset Issue"), comprising a total of 72,746 B-units, consisting of 145,492 new B shares and 72,746 new warrants of series TO3 and 72,746 new warrants of series TO4 on the same terms as in the Rights Issue.

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 are admitted to trading on the Spotlight Stock Market as of September 10, 2021.

## Transactions with related parties

During the quarter, KSEK 480 (337) was paid to Linnane Pharma AB regarding consulting fees and technology platform, and KSEK 200 (120) 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 LinnanePharma 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 Linnane Pharma 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) published 4<sup>th</sup> November 2021.

## 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 Q2 (half-year), 2021/2022	February 25, 2022
Interim report for Q3, 2021/2022	May 20, 2022
Year-end report for 2021/2022	August 26, 2022
Annual Report for 2021/2022	November 3, 2022
Interim report for Q1, 2022/2023	November 11, 2022
Annual General Meeting for 2021/2022	November 24, 2022

# Income statement

SEK	2021-07-01 2021-09-30	2020-07-01 2020-09-30	2020-07-01 2021-06-30
Net sales	0	0	0
Other operating income	3 927 000	2 996 210	9 339 727
<b>Operating income</b>	<b>3 927 000</b>	<b>2 996 210</b>	<b>9 339 727</b>
Other external costs	-4 908 049	-3 984 387	-12 657 319
Employee benefit expenses	-977 408	-815 396	-4 084 146
Depreciation of tangible assets	-9 000	-9 000	-36 000
Other operating expenses	-5 219	-36 578	-64 624
<b>Operating loss</b>	<b>-1 972 676</b>	<b>-1 849 151</b>	<b>-7 502 362</b>
Financial items	-75 088	5 908	-219 142
<b>Loss before tax</b>	<b>-2 047 764</b>	<b>-1 843 243</b>	<b>-7 721 504</b>
Tax on loss for the period	0	0	0
<b>Loss after tax</b>	<b>-2 047 764</b>	<b>-1 843 243</b>	<b>-7 721 504</b>

# Balance sheet

<b>ASSETS, SEK</b>	2021-09-30	2020-09-30	2021-06-30
<b>Fixed assets</b>			
Tangible assets	0	36 000	9 000
<b>Total fixed assets</b>	<b>0</b>	<b>36 000</b>	<b>9 000</b>
<b>Current assets</b>			
Other receivables	1 185 926	2 507 862	495 523
Prepaid expenses	2 444 649	5 323 715	4 767 257
Cash and bank balances/financial investments	50 093 103	13 064 373	7 473 038
<b>Total current assets</b>	<b>53 723 678</b>	<b>20 895 950</b>	<b>12 735 818</b>
<b>TOTAL ASSETS</b>	<b>53 723 678</b>	<b>20 931 950</b>	<b>12 744 818</b>
<b>EQUITY &amp; LIABILITIES, SEK</b>	2021-09-30	2020-09-30	2021-06-30
<b>Restricted equity</b>			
Share capital	1 087 612	1 008 747	1 008 747
Statutory reserve	20 000	20 000	20 000
<b>Total restricted equity</b>	<b>1 107 612</b>	<b>1 028 747</b>	<b>1 028 747</b>
<b>Non-restricted equity</b>			
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	-2 047 764	-1 843 243	-7 721 504
<b>Total non-restricted equity</b>	<b>46 531 111</b>	<b>7 604 085</b>	<b>1 725 824</b>
<b>Total equity</b>	<b>47 638 723</b>	<b>8 632 832</b>	<b>2 754 571</b>
<b>Current liabilities</b>			
Accounts payable	854 249	2 514 462	1 181 577
Tax liabilities	16 461	1 525	17 986
Other liabilities	137 496	176 872	6 131 606
Accrued expenses	5 076 748	9 606 259	2 659 078
<b>Total current liabilities</b>	<b>6 084 955</b>	<b>12 299 118</b>	<b>9 990 247</b>
<b>TOTAL EQUITY &amp; LIABILITIES</b>	<b>53 723 678</b>	<b>20 931 950</b>	<b>12 744 818</b>



# Cash flow statement

SEK	2021-07-01 2021-09-30	2020-07-01 2020-09-30	2020-07-01 2021-06-30
<b>Operating activities</b>			
Loss after financial items	-2 047 764	-1 843 243	-7 721 504
Adjusted for non-cash items, etc.	9 000	9 000	261 000
<b>Cash flow from operating activities before changes in working capital</b>	<b>-2 038 764</b>	<b>-1 834 243</b>	<b>-7 460 504</b>
<b>Cash flow from changes in working capital</b>			
Change in current receivables	1 632 205	-6 563 143	-3 994 345
Change in current liabilities	-3 905 292	8 221 358	5 687 487
<b>Cash flow from operating activities</b>	<b>-4 311 852</b>	<b>-176 027</b>	<b>-5 767 362</b>
<b>Financing activities</b>			
Rights Issue	50 316 435	0	0
Issuance costs	-3 384 518	0	0
<b>Cash flow from financing activities</b>	<b>46 931 917</b>	<b>0</b>	<b>0</b>
<b>Cash flow for the period</b>	<b>42 620 065</b>	<b>-176 027</b>	<b>-5 767 362</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>7 473 038</b>	<b>13 240 400</b>	<b>13 240 400</b>
<b>Cash and cash equivalents at the end of the period</b>	<b>50 093 103</b>	<b>13 064 373</b>	<b>7 473 038</b>

# Equity

Equity (SEK)	Share capital	Statutory reserve	Share premium reserve	Retained earnings	Loss for the period	Total
<b>Opening balance July 1, 2021</b>	<b>1 008 747</b>	<b>20 000</b>	<b>84 848 309</b>	<b>-75 400 981</b>	<b>-7 721 504</b>	<b>2 754 571</b>
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
<b>Equity September 30, 2021</b>	<b>1 087 612</b>	<b>20 000</b>	<b>131 701 361</b>	<b>-83 122 485</b>	<b>-2 047 764</b>	<b>47 638 723</b>

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, November 10, 2021**

Catharina Svanborg  
**Chairperson of the Board**

Bengt Westermark  
**Board member**

Christer Köhler  
**Board member**

Helena Lomberg  
**Board member**

Bill Hansson  
**Board member**

Mats Persson  
**CEO**



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