

Q1

Interim Report July 2022 – September 2022

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

Opening remarks

The HAMLET family of drug candidates has remarkable effects and continues to show great promise for the prevention and treatment of cancer. Alpha1H kills tumor cell efficiently and attacks tumor tissue in patients with bladder cancer. A unique mechanism of action permits Alpha1H to target the tumor without damaging healthy bladder tissue. In bladder cancer patients, the tumor responds by releasing large numbers of tumor cells and tumor fragment into the urine, which is an efficient way of removing tumor tissue without causing a toxic effect. These positive findings suggest that Alpha1H can be used liberally to treat different types of cancer in the future.

During the first quarter of the new fiscal year, Hamlet Pharma has strengthened the clinical trial program for stand-alone use of Alpha1H in bladder cancer patients, continued the collaboration with Neurochase Ltd for the treatment of brain tumors with Alpha1H and, in collaboration with external partners, intensified the development of BAMLET as a drug candidate.

After a successful dose-finding study with positive clinical effects, the clinical program is aimed at defining the optimal treatment regimen. We are currently testing the effects of repeated treatment using a five times higher dose of Alpha1H compared to placebo. The patients will receive two rounds of treatment and the clinical outcome will be compared to the placebo group and to patients receiving one round of treatment. The dialogue with the US (FDA) and European (EMA) authorities has, with the help of experienced consultant organizations, been intensified during this first quarter.

The ongoing collaboration with Neurochase Ltd will explore Alpha1H for brain tumor therapy, where a novel drug delivery technology and methods to treat tumors in the central nervous system with Alpha1H will be developed. The work includes technology development and testing of the new device with Alpha1H in an animal study. The goal is to provide adequate materials and data to prepare for the first clinical study for this indication.

BAMLET, with strong tumoricidal effects, is the third member of the HAMLET family of compounds. In the first quarter, we have continued the development of BAMLET as a drug candidate, primarily in colon cancer. In an animal study in mice we have found that daily, long-term treatment with BAMLET in the drinking water inhibits tumor development and increases long-term survival, compared to mice not receiving BAMLET. The frequency of polyps and the polyp size was reduced already after eight weeks and with continued treatment. The mice remained symptom-free and survived significantly longer than control mice. Hamlet Pharma has also initiated discussions regarding the manufacturing of BAMLET for future clinical studies with external partners.

The stable financial position enables Hamlet Pharma to secure the development of the projects 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 Martin Erixon
Chairperson of the Board and CMO, and CEO,
respectively, of Hamlet Pharma AB

Significant events during the first quarter

Q1

On August 2, 2022, Hamlet Pharma published "Full speed ahead! – Hamlet Pharma adapts the clinical trial program for stand-alone use". Hamlet Pharma highlights the development of the clinical protocol in bladder cancer with Alpha 1H. The company has decided to interrupt the combination study where Alpha1H was used together with a chemotherapy drug. There was no evidence of a therapeutic advantage and the patients experienced side effects, which were not seen with Alpha1H alone. It was also announced that Hamlet Pharma is taking one more step towards the design of the Phase III clinical trial protocol by adding a second treatment round after the completion of the first round of treatment in the ongoing study. These decisions strengthen Hamlet Pharma's position as a company developing drug candidates with a more beneficial profile than traditional chemotherapeutic drugs.

On August 9, 2022, Hamlet Pharma published "Hamlet Pharma receives a new rapid approval in the Czech Republic". Hamlet Pharma announced the rapid approval of Hamlet Pharma's application to amend the clinical trial of Alpha1H in bladder cancer by the Czech regulatory authorities. This important new part of the ongoing study is now ready to start.

On September 29, 2022, Hamlet Pharma presented at the Nordic Life Science Days, a pharmaceutical and biotechnology conference held in Malmö. The title of the presentation was "High precision cancer treatment with low side effects".



Significant events after the first quarter

On October 2022, Catharina Svanborg attended the 17th Annual Peptide Therapeutics Symposium held at the Salk Institute in La Jolla, California and presented the Hamlet project to leaders in the field of peptide drug development. The title of the presentation was "A new approach to Cancer Therapy with Documented Clinical Effects".

On November 3, 2022, the annual report for the fiscal year 2021/2022 was published. It can be found on our updated homepage or on spotlight Stock Market's home page.

On November 9, 2022, Hamlet Pharma published "BAMLET in the drinking water; protection against intestinal cancer and potent beneficial health effects". We show that daily, long-term treatment with BAMLET in the drinking water inhibits intestinal tumor development in mice genetically susceptible to intestinal tumors, compared to mice not receiving BAMLET. The frequency of tumors and the tumor size was reduced already after short-term BAMLET treatment but with continued treatment, the mice remained symptom-free and survived significantly longer than control mice. BAMLET treatment also protected the mice from extra-intestinal manifestations of disease. These findings are conceptually important, as they suggest that local treatment of the intestine, by supplying BAMLET in the drinking water, can affect cancer development as well as disease states in other organs, suggesting a systemic as well as a local effect.

The findings highlight the beneficial properties of BAMLET and a broad range of effects affecting health and disease.

The period in summary

FIRST QUARTER (JUL 1, 2022-SEP 30, 2022)

- Net sales for the quarter totaled KSEK 0 (0)
- Other operating income totaled KSEK 0 (3,927)
- Loss before tax amounted to KSEK -5,618 (-2,048)
- Loss after tax amounted to KSEK -5,618 (-2,048)
- Loss per share* was SEK -0.0508 (-0.0188), and SEK -0.0491 after dilution
- On September 30, 2022, the equity/assets ratio** was 94.0 (88.7) %

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

* Profit/loss after tax for the period divided by 110,529,666 (108,761,179) and 114,472,907, respectively, where 110,529,666 is the number of shares outstanding on September 30, 2022, and 114,472,907 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, 2021.

** 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 49.33% of the capital and 83.49% 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 induces cancer cell shedding after injection into the bladder of patients with bladder cancer. HAMLET has also shown therapeutic efficacy on skin papillomas in a placebo-controlled clinical trial.

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 tumor 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 clinical study program to include a dose-escalation arm and has extended the program further with a repeated dosing approach.

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 0 (3,927). 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 quarter was KSEK -5,618 (-2,048).

Financial position

The financial situation for Hamlet Pharma is very strong. During the previous financial year, the company carried out a successful rights issue, with a following redemption of subscription warrants. This process provided the Company with 52.4 MSEK after deductions for issue costs. Read more in the section "New share issue and subscription warrants" below.

At the end of the first quarter, the equity/assets ratio was 94.0 (88.7) %, and the Company's cash and cash equivalents were KSEK 32,900 (50,093).

Horizon 2020 EIC Accelerator Fund

In March 2020 Hamlet 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 have been paid incrementally during the project's duration. The first payment of 12.6 MSEK was received in July 2020, and the second payment of 6.7 MSEK in July 2021. A final payment of 1.2 MSEK will be made during this financial year. Grants received from Horizon 2020 have been reported as Other income.

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 staff corresponding to 5 (4) 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.

As of September 30, 2022, the number of shares registered at the Swedish Companies Registration Office (Bolagsverket) totaled 110,529,666. As of November 2, 2022, the registered current ratio of shares was 38,496,780 A-shares and 72,032,886 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. 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.

During period 17 - 31 May 2022 1,768,487 shares were subscribed for from the options in series TO3. The Company received MSEK 5.5, after issuance costs of KSEK 276.

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 13 per share for TO4. Upon full exercise of all warrants, the Company will receive an additional maximum of approximately SEK 51.3 million for TO4, before deduction of issue costs of approximately SEK 2.3 million. The warrants TO4 were admitted to trading on the Spotlight Stock Market as of September 10, 2021.

Transactions with related parties

During the quarter, KSEK 480 (480) was paid to Linnane Pharma AB, of which KSEK 105 (105) refers to consulting fees and KSEK 375 (375) refers to the technology platform. Furthermore, consulting fees of KSEK 0 (200) was paid to Fridsbo Pharma AB (Mats Persson).

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

Furthermore, salaries and allowances to board and management were paid during the period. Transactions with related parties is on market terms.

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 (2022-06-30).

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.

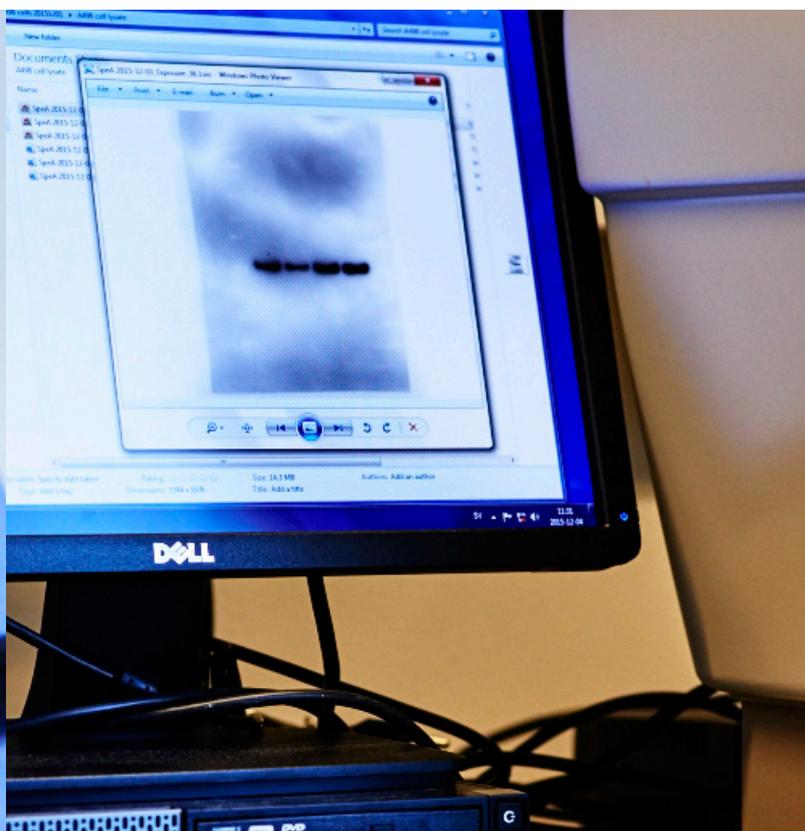
The company's accounting principles are unchanged compared with most recent financial year and are described in the most recent published annual report (2022-06-30).

Review

This interim report has not been audited.

Financial calendar

Interim report for Q2 (half-year), 2022/2023	February 23, 2023
Interim report for Q3, 2022/2023	May 26, 2023
Year-end report for 2022/2023	August 28, 2023
Annual Report for 2022/2023	November 02, 2023
Interim report for Q1, 2023/2024	November 17, 2023
Annual General Meeting for 2022/2023	November 23, 2023



Income statement

SEK	2022-07-01 2022-09-30	2021-07-01 2021-09-30	2021-07-01 2022-06-30
Net sales	0	0	0
Other operating income	0	3 927 000	9 979 223
Operating income	0	3 927 000	9 979 223
Other external costs	-3 713 150	-4 908 049	-22 373 899
Employee benefit expenses	-1 895 067	-977 408	-4 685 474
Depreciation of tangible assets	0	-9 000	-9 000
Other operating expenses	-9 941	-5 219	-31 911
Operating loss	-5 618 158	-1 972 676	-17 121 061
Financial items	0	-75 088	-75 682
Loss before tax	-5 618 158	-2 047 764	-17 196 743
Tax on loss for the period	0	0	0
Loss after tax	-5 618 158	-2 047 764	-17 196 743

Balance sheet

ASSETS, SEK	2022-09-30	2021-09-30	2022-06-30
Fixed assets			
Tangible assets	0	0	0
Total fixed assets	0	0	0
Current assets			
Other receivables	257 999	1 185 926	847 046
Prepaid expenses	1 292 612	2 444 649	1 272 376
Cash and bank balances/financial investments	32 899 618	50 093 103	39 612 384
Total current assets	34 450 230	53 723 678	41 731 807
TOTAL ASSETS	34 450 230	53 723 678	41 731 807
EQUITY & LIABILITIES, SEK	2022-09-30	2021-09-30	2022-06-30
Restricted equity			
Share capital	1 105 297	1 087 612	1 105 297
Statutory reserve	20 000	20 000	20 000
Total restricted equity	1 125 297	1 107 612	1 125 297
Non-restricted equity			
Share premium reserve	137 207 862	131 701 361	137 207 862
Retained earnings	-100 319 228	-83 122 485	-83 122 485
Loss for the period	-5 618 158	-2 047 764	-17 196 743
Total non-restricted equity	31 270 477	46 531 111	36 888 635
Total equity	32 395 773	47 638 723	38 013 931
Current liabilities			
Accounts payable	607 742	854 249	1 722 370
Tax liabilities	12 514	16 461	31 991
Other liabilities	290 263	137 496	138 581
Accrued expenses	1 143 938	5 076 748	1 824 933
Total current liabilities	2 054 456	6 084 955	3 717 876
TOTAL EQUITY & LIABILITIES	34 450 229	53 723 678	41 731 807

Cash flow statement

SEK	2022-07-01 2022-09-30	2021-07-01 2021-09-30	2021-07-01 2022-06-30
Operating activities			
Loss after financial items	-5 618 158	-2 047 764	-17 196 743
Adjusted for non-cash items, etc.	0	9 000	9 000
Cash flow from operating activities before changes in working capital	-5 618 158	-2 038 764	-17 187 743
Cash flow from changes in working capital			
Change in current receivables	568 811	1 632 205	3 143 358
Change in current liabilities	-1 663 419	-3 905 292	-6 272 371
Cash flow from operating activities	-6 712 766	-4 311 851	-20 316 756
Financing activities			
Rights Issue	0	50 316 435	56 117 072
Issuance costs	0	-3 384 518	-3 660 969
Cash flow from financing activities	0	46 931 917	52 456 103
Cash flow for the period	-6 712 766	42 620 065	32 139 346
Cash and cash equivalents at the beginning of the period	39 612 384	7 473 038	7 473 038
Cash and cash equivalents at the end of the period	32 899 618	50 093 103	39 612 384

Equity

Equity (SEK)	Share capital	Statutory reserve	Share premium reserve	Retained earnings	Loss for the period	Total
Opening balance July 1, 2022	1 105 297	20 000	137 207 862	-83 122 485	-17 196 743	38 013 931
Transfer of prior year's loss - Preliminary				-17 196 743	17 196 743	0
Rights Issue	0		0			0
Offset Issue	0		0			0
Loss for the period, Q1	0	0	0	0	-5 618 158	-5 618 158
Equity September 30, 2022	1 105 297	20 000	137 207 862	-100 319 228	-5 618 158	32 395 773

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 11, 2022

Catharina Svanborg
Chairperson of the Board

Bengt Westermark
Board member

Lars Hedbys
Board member

Helena Lomberg
Board member

Ulla Trägårdh
Board member

Bill Hansson
Board member

Martin Erixon
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