



# Q2

**Interim report October 2022 – December 2022**

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

# Opening remarks

During the second quarter of the fiscal year, Hamlet Pharma has made significant progress in its clinical trial program for Alpha1H, a drug candidate in the HAMLET family, as a standalone treatment for bladder cancer patients. The company has also continued its collaboration with Neurochase for the treatment of brain tumors with Alpha1H and its collaboration with Linnane Pharma, to define the potential of BAMLET as a drug candidate.

## Bladder cancer

Alpha1H targets and effectively kills tumor cells in patients with bladder cancer. The placebo-controlled study has identified significant anti-tumor effects, which were increased further after treatment with a higher dose of Alpha1H, resulting in a further reduction in tumor number and tumor size. Other end points include increased shedding of tumor cells into the urine, increased uptake of Alpha1H by tumor tissue and increased cell death by an apoptosis-like mechanism. No evidence of toxicity for healthy tissue was observed, neither at the lower nor at the higher dose, confirming the safety of Alpha1H. The ongoing clinical trial program is currently focused on determining the optimal treatment regimen using five times higher dose of Alpha1H with two rounds of treatment. Hamlet Pharma is also working closely with regulatory authorities, to move drug development closer to market approval.

## Brain tumor

The ongoing collaboration with Neurochase Limited explores Alpha1H for brain tumor therapy. The intention is to develop novel drug delivery technology and methods to treat tumors in the central nervous system with Alpha1H. The work includes technology development and testing of the technology with Alpha1H in an animal study. The goal is to provide adequate background data for clinical trial applications.

## Colon cancer

BAMLET has shown strong tumoricidal effects in a colon cancer animal model. Daily, long-term treatment with BAMLET in the drinking water inhibited tumor development and increased survival in treated mice, compared to controls not receiving BAMLET. The frequency of polyps and the polyp size was reduced after eight weeks of treatment and with continued treatment, mice remained symptom-free and survived significantly longer than control mice. The results of the study also suggest that BAMLET may have a systemic effect on cancer development in other organs. Additionally, the treatment showed important functional physiological effects on lipid metabolism and glucose metabolism. These positive findings highlight the beneficial properties of BAMLET and its expected broad range of effects on health and disease in humans. BAMLET belongs to the family of molecules discovered by scientists at Lund University, which also includes HAMLET and Alpha1H. Hamlet Pharma owns certain patent rights to BAMLET but has not conducted its own research or development of the BAMLET drug product.

The developments during the second quarter further strengthened Hamlet Pharma's position as a company developing drug candidates with a more beneficial profile than traditional chemotherapeutic drugs. 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**

Chairman of the Board

**Martin Erixon**

CEO, of Hamlet Pharma AB

# Significant events during the second quarter

## Q2

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**On October 21 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 October 26, 2022**, the shareholders of Hamlet Pharma AB, were invited to the annual general meeting held on November 24, 2022 at 1700 at the High Court Malmö.

**On November 3, 2022**, the annual report for the fiscal year 2021/2022 was published. The Annual Report can be found at our website or at spotlight Stock Market's website.

**On November 9, 2022**, Hamlet Pharma released information describing major advances in BAMLET drug development entitled "BAMLET in the drinking water; protection against intestinal cancer and potent beneficial health effects".

Results in a mouse model relevant to human colon cancer, showed major protective effects compared to controls not receiving BAMLET. BAMLET treatment via the drinking water prevented intestinal cancer development, prolonged survival and reduced or delayed disease severity. Molecular analysis further shows that treated tissues became more similar to healthy tissues, unlike the controls where cancer development was pronounced. In addition, the results suggested that local treatment of the intestine, by supplying BAMLET in the drinking water, affected cancer development in other organs, suggesting both a systemic and a local effect.

It is important to note that BAMLET treatment did not cause side effects in healthy mice. Instead, BAMLET treatment had important functional physiological effects in healthy mice, such as positive effects on lipid metabolism, glucose metabolism and insulin resistance. The findings highlight the beneficial properties of BAMLET on health and disease.

**On November 11, 2022**, Hamlet Pharma published the Q1 Interim Report July 2022 – September 2022, which can be found on Hamlet Pharma's website and Spotlight Stock Market's website.

**On November 25, 2022**, Hamlet Pharma published a Communiqué from the Annual General Meeting of Hamlet Pharma AB held on November 24th in Malmö. The board was granted freedom from liability. Catharina Svanborg was elected chairman. It was decided that the board should consist of the chairman, Bill Hansson, Helena Lomberg and Ulla Trägårdh. All decisions were unanimous.

**On November 30, 2022**, Hamlet Pharma hosted a digital investors' meeting via video-link. The meeting was well attended and the discussion was lively. The presentation was recorded and the video is available on Hamlet Pharma's website (<https://hamletpharma.com/media-archive/>).

**On December 8, 2022**, an advertorial was published in The Guardian, highlighting the potential of the Alpha1H drug candidate for patients with bladder cancer. Hamlet Pharma was selected by the Guardian to participate in a major health supplement focusing on bladder cancer and colon cancer. Journalists from The Guardian wrote the piece, entitled "Successful new drug candidate for patients with bladder cancer – from discovery to the clinic"

# Significant events after the second quarter

**On January 31, 2023**, Hamlet Pharma filed a report summarizing the achievements made during the three years when the company received support through the Horizon 2020 grant (2.2 MEUR). The report of 76 pages highlighted the milestones reached by the company as outlined in the grant application.

## The period in summary

### SECOND QUARTER (OCT 1, 2022-DEC 31, 2022)

- Net sales totaled KSEK 0 (0)
- Other operating income totaled KSEK 0 (4,645)
- Loss before tax amounted to KSEK -6,213 (-2,950)
- Loss after tax amounted to KSEK -6,213 (-2,950)
- Loss per share\* was SEK -0.0562 (-0.0271), and SEK -0.0543 after dilution

### FIRST HALF (JUL 1, 2022-DEC 31, 2022)

- Net sales totaled KSEK 0 (0)
- Other operating income totaled KSEK 0 (8,572)
- Loss before tax amounted to KSEK -11,831 (-4,998)
- Loss after tax amounted to KSEK -11,831 (-4,998)
- Loss per share\* was SEK -0.1070 (-0.0460), and SEK -0.1034 after dilution
- On December 31, 2022, the equity/assets ratio\*\* was 88,0 (94,9) %

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 December 31, 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 December 31, 2021.

\*\* Equity divided by total capital.

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. The majority of Linnane Pharma is 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 develops drugs for use in the treatment and prevention of cancers; initially bladder cancer, a severe and costly form of cancer. 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 further expanded the study program to include a dose-escalation and a combination study arm. The dose escalation study has documented increased treatment effects of Alpha1H at higher doses.

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 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. That 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 second quarter, the equity/assets ratio was 88.0 (94.9) %, and the Company's cash and cash equivalents were KSEK 27,957 (45,872).

## Horizon 2020 EIC Accelerator Fund

In March 2020 Hamlet Pharma was awarded a grant of 2.2 MEUR 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 (0), and during the first half, depreciation of equipment amounted to KSEK 0 (9).

## Employees

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

## The share

The Company's shares have been traded on Spotlight Stock Market since October 23, 2015. The share is traded under the short name "HAMLET B" with ISIN code SE0015661152.

As of December 31, 2022, the number of shares registered at the Swedish Companies Registration Office (Bolagsverket) totaled 110,529,666. As of February 5, 2023, the registered current ratio of shares was 38,474,026 A-shares and 72,055,640 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 580 (480) was paid to Linnane Pharma AB, of which KSEK 105 (105) refers to consulting fees and KSEK 475 (375) refers to the technology platform. The fee to Linnane Pharma technology platform was increased from 125 KSEK to 175 KSEK per month in November 2022, due to the general increase in supplier costs, for maintaining technology and securing access to competence.

The consulting fees to Linnane Pharma, refers to compensation for central administrative services including HR and ongoing personnel administration.

Furthermore, salaries and allowances to board and management were paid during the period. Transactions with related parties are 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 recent annual report, published on November 3rd 2022.

### **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 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	2022-10-01 2022-12-31	2021-10-01 2021-12-31	2022-07-01 2022-12-31	2021-07-01 2021-12-31	2021-07-01 2022-06-30
Net sales	0	0	0	0	0
Other operating income	0	4 645 413	0	8 572 413	9 979 223
<b>Operating income</b>	<b>0</b>	<b>4 645 413</b>	<b>0</b>	<b>8 572 413</b>	<b>9 979 223</b>
Other external costs	-4 819 028	-6 388 933	-8 532 178	-11 296 982	-22 373 899
Employee benefit expenses	-1 485 609	-1 198 370	-3 380 676	-2 175 778	-4 685 474
Depreciation of tangible assets	0	0	0	-9 000	-9 000
Other operating expenses	-6 421	-7 807	-16 362	-13 027	-31 911
<b>Operating loss</b>	<b>-6 311 059</b>	<b>-2 949 697</b>	<b>-11 929 217</b>	<b>-4 922 374</b>	<b>-17 121 061</b>
Financial items	97 799	-265	97 799	-75 353	-75 682
<b>Loss before tax</b>	<b>-6 213 260</b>	<b>-2 949 962</b>	<b>-11 831 418</b>	<b>-4 997 726</b>	<b>-17 196 743</b>
Tax on loss for the period	0	0	0	0	0
<b>Loss after tax</b>	<b>-6 213 260</b>	<b>-2 949 962</b>	<b>-11 831 418</b>	<b>-4 997 726</b>	<b>-17 196 743</b>

# Balance sheet

ASSETS, SEK	2022-12-31	2021-12-31	2022-06-30
<b>Fixed assets</b>			
Tangible assets	0	0	0
<b>Total fixed assets</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Current assets</b>			
Other receivables	500 720	728 545	847 046
Prepaid expenses	1 307 381	491 833	1 272 376
Cash and bank balances/financial investments	27 957 463	45 871 558	39 612 384
<b>Total current assets</b>	<b>29 765 564</b>	<b>47 091 936</b>	<b>41 731 807</b>
<b>TOTAL ASSETS</b>	<b>29 765 564</b>	<b>47 091 936</b>	<b>41 731 807</b>
EQUITY & LIABILITIES, SEK	2022-12-31	2021-12-31	2022-06-30
<b>Restricted equity</b>			
Share capital	1 105 297	1 087 612	1 105 297
Statutory reserve	20 000	20 000	20 000
<b>Total restricted equity</b>	<b>1 125 297</b>	<b>1 107 612</b>	<b>1 125 297</b>
<b>Non-restricted equity</b>			
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	-11 831 418	-4 997 726	-17 196 743
<b>Total non-restricted equity</b>	<b>25 057 217</b>	<b>43 581 149</b>	<b>36 888 635</b>
<b>Total equity</b>	<b>26 182 514</b>	<b>44 688 761</b>	<b>38 013 931</b>
<b>Current liabilities</b>			
Accounts payable	1 229 974	1 448 814	1 722 370
Tax liabilities	7 990	16 461	31 991
Other liabilities	319 592	143 527	138 581
Accrued expenses	2 025 494	794 374	1 824 933
<b>Total current liabilities</b>	<b>3 583 051</b>	<b>2 403 175</b>	<b>3 717 876</b>
<b>TOTAL EQUITY &amp; LIABILITIES</b>	<b>29 765 564</b>	<b>47 091 936</b>	<b>41 731 807</b>

# Cash flow statement

	2022-07-01 2022-12-31	2021-07-01 2021-12-31	2021-07-01 2022-06-30
<b>SEK</b>			
<b>Operating activities</b>			
Loss after financial items	-11 831 418	-4 997 726	-17 196 743
Adjusted for non-cash items, etc.	0	9 000	9 000
<b>Cash flow from operating activities before changes in working capital</b>	<b>-11 831 418</b>	<b>-4 988 726</b>	<b>-17 187 743</b>
<b>Cash flow from changes in working capital</b>			
Change in current receivables	311 321	4 042 402	3 143 358
Change in current liabilities	-134 825	-7 587 072	-6 272 371
<b>Cash flow from operating activities</b>	<b>-11 654 921</b>	<b>-8 533 396</b>	<b>-20 316 756</b>
<b>Investing activities</b>			
Acquisition of tangible assets	0	0	0
<b>Cash flow from investing activities</b>	<b>0</b>	<b>0</b>	<b>0</b>
<b>Financing activities</b>			
Rights Issue	0	50 316 435	56 117 072
Issuance costs	0	-3 384 518	-3 660 969
<b>Cash flow from financing activities</b>	<b>0</b>	<b>46 931 917</b>	<b>52 456 103</b>
<b>Cash flow for the period</b>	<b>-11 654 921</b>	<b>38 398 521</b>	<b>32 139 347</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>39 612 384</b>	<b>7 473 038</b>	<b>7 473 038</b>
<b>Cash and cash equivalents at the end of the period</b>	<b>27 957 463</b>	<b>45 871 558</b>	<b>39 612 384</b>

# Equity

Equity (SEK)	Share capital	Statutory reserve	Share premium reserve	Retained earnings	Loss for the period	Total
<b>Opening balance July 1, 2022</b>	<b>1 105 297</b>	<b>20 000</b>	<b>137 207 862</b>	<b>-83 122 485</b>	<b>-17 196 743</b>	<b>38 013 931</b>
Transfer of prior year's loss				-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
Loss for the period, Q2					-6 213 260	-6 213 260
<b>Equity December 31, 2022</b>	<b>1 105 297</b>	<b>20 000</b>	<b>137 207 862</b>	<b>-100 319 228</b>	<b>-11 831 418</b>	<b>26 182 514</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, February 23, 2023**

Catharina Svanborg  
**Chairman of the Board**

Ulla Trägårdh  
**Board member**

Helena Lomberg  
**Board member**

Bill Hansson  
**Board member**

Martin Erixon  
**CEO**



## For further information:

**Hamlet Pharma AB**

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