

# Q1

**Interim report July–September 2020**

# Opening remarks

The new fiscal year started well, with the actual transfer of funds from the European Union Horizon 2020 grant, allowing Hamlet Pharma to strengthen its organization by recruiting financial and business development expertise, as well as experts in specific technology areas. The research team of scientists from leading international universities further ensures that the Company will reach important strategic goals.

The clinical trials are being resumed, with permission from the Czech authorities. First, a dose-finding study will help to define the optimal dose for forthcoming phase III trials. Second, a combination study of Alpha1H and chemotherapy will be investigated, specifically with Epirubicin, which is commonly used and available in most European countries. Animal studies have clearly demonstrated increased therapeutic efficacy when combining Alpha1H with epirubicin compared to epirubicin alone. Higher doses of Alpha1H were also efficient as a stand alone treatment in this model.

The results of the Phase I/II study have been analyzed in great molecular detail and a publication detailing the data is being reviewed by a leading international journal. Furthermore, with new discoveries, Hamlet Pharma continues to develop its patent portfolio, in collaboration with the British firm of patent solicitors.

We would like to take the opportunity to thank everyone involved in the development of Alpha1H. Bladder cancer is defined by the FDA as a significant unmet medical need and we are committed to delivering new treatment options for patients suffering from this disease.

**Catharina Svanborg and Mats Persson**

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

# Significant events during the first quarter

## **EU GRANT AND STRENGTHENING OF THE ORGANISATION**

The first payment of 12.6 million SEK of a total of approximately 22.9 million SEK was received on July 1, 2020. The remainder of the grant will be paid incrementally during the project's 24 month duration, with the second payment of 8 million SEK expected in June 2021. Instructions accompanying the grant specify clinical development, scientific excellence, drug development and business development.

## **CLINICAL STUDIES ACCELERATED**

The company has announced that the clinical development of Alpha1H therapy in bladder cancer will be accelerated. Two studies will be conducted in parallel; a dose-escalation study, which will examine the efficacy of higher Alpha1H concentrations, and a combination study, combining Alpha1H with a currently used chemotherapeutic agent. Hamlet Pharma received the permission from the Czech authorities to resume its clinical trial activities, together with the team in Prague. There is a significant unmet medical need for new therapies in early stage bladder cancer. Over the last 30 years, only three drugs have been approved for this indication by the US Food and Drug Administration and there are issues with supply of these drugs, worldwide. Hamlet Pharma is committed to improve the treatment options for this large patient group, using Alpha1H alone or in combination with chemotherapeutic drugs.

## **SECURING ALPHA1H FOR FUTURE CLINICAL STUDIES**

The production of the peptide Alpha1H has been accelerated to ensure continued supply for future clinical trials. The company has invested heavily in peptide production, in collaboration with Polypeptide Laboratories. The formulation of Alpha1H according to patented procedures will be scaled up accordingly, for use in bladder cancer as well as in other indications.

## **PUBLICATION OF THE RESULTS FROM THE CLINICAL STUDY**

The positive results from our first double blind, placebo controlled study has been submitted after revision to a leading international journal. The results support a potential in the treatment of early stage bladder cancer and the patients did not develop drug-related side effects, confirming the safety of Alpha1H.

Combination therapy is widely used in cancer patients, to enhance treatment outcome and to reduce side effects. We have previously communicated that combining Alpha1H with low doses of chemotherapeutic agents, increases treatment efficacy in an animal model of bladder cancer. The promising results of combination therapy in the murine bladder cancer model are being finalized for publication, including gene expression data defining the death response of the cancer in more detail.

## **TERMINATION OF PATENT LICENSING AGREEMENT**

The board of Hamlet Pharma decided to accept a proposal from Linnane Pharma to terminate the patent license agreement of BAMLET from May 12, 2020. BAMLET is a complex formed by bovine alpha-lactalbumin and oleic acid. According to the agreement, Linnane Pharma would under Hamlet Pharma's patents develop the product BAMLET for non-pharmaceutical use. Since then, Linnane Pharma has worked intensively to drive the project forward. However, the board of Linnane Pharma has acknowledged synergies if Hamlet Pharma decides to develop BAMLET as a drug, not least in terms of manufacturing and formulation. The board of Linnane Pharma has therefore proposed that the licensing agreement from May 12 be terminated. The board of Hamlet Pharma has accepted the proposal from Linnane Pharma and thus all rights have been returned to Hamlet Pharma without any compensation to Linnane Pharma. Linnane Pharma is the parent company of Hamlet Pharma and owns 50.19 % of the shares of Hamlet Pharma.

# Significant events after the fiscal year

**On October 3, 2020**, new studies reveal potent therapeutic effects of BAMLET in an animal model of colon cancer. BAMLET administration in the drinking water markedly reduced colon cancer development in susceptible mice. The effect was quantified as a reduction in tumor number and tumor size after 2 weeks. Long-term effects were also found in mice that had been treated for 27 weeks, which survived longer than untreated controls, where the disease developed faster. BAMLET was taken up by tumour tissue and was shown to lower the cellular content of several cancer markers. Strikingly, cancer gene expression was inhibited in the treatment group, suggesting a pronounced effect and a return towards health. The results suggest that local BAMLET treatment may be effective against colon cancer also in man, with a therapeutic and prophylactic potential. Clinical studies will be required to define the clinical potential of BAMLET therapy in colon cancer.

**On October 23, 2020**, a kick-off meeting for the European Union funded project was held. This 2-year project falls under the H2020 EIC Accelerator Program to fund projects that have ground-breaking concepts that could shape new markets in Europe and worldwide. The goal of HAMLET-BC project is to accelerate development of Alpha1H as novel treatment for bladder cancer. Hamlet Pharma will advance Alpha1H along the clinical development pipeline as anti-cancer therapeutic for early stage bladder cancer. With the EIC Accelerator funding, Hamlet Pharma will finalise Phase I/II clinical safety and efficacy studies and advance development of Alpha1H towards a Phase III trial.

## IMPACT OF THE COVID 19 PANDEMIC

The COVID-19 pandemic has affected the infrastructure for clinical trials, world-wide. Despite this, HAMLET Pharma has continued the preparations for continued clinical trials and the Czech authority has approved the dose-escalation study and an extension of the ongoing study with combination therapy and the clinical study team is ready for such studies to start.

## Figures

### FIRST QUARTER (JUL 1, 2020-SEP 30, 2020)

- Net sales for the first quarter totaled KSEK 0 (0)
- Other operating income for the first quarter totaled KSEK 2,996 (0)
- Loss before tax amounted to KSEK -1,843 (-2,743)
- Loss after tax amounted to KSEK -1,843 (-2,743)
- Loss per share\* was SEK -0.0548 (-0.0868)
- At September 30, 2020, the equity/assets ratio\*\* was 41.2 (87.0)%

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

\* Profit/loss after tax for the period divided by 33,624,899 (31,624,899), respectively, where 33,624,899 is the number of shares outstanding at September 30, 2020. The comparative figure in parentheses was the number of shares at September 30, 2019.

\*\* Equity divided by total capital.

## Hamlet Pharma AB

Hamlet Pharma, whose shares are traded on Spotlight Stock Market, is part of a Group and is a subsidiary company of Linnane Pharma AB, which owns 50.19% of Hamlet Pharma AB. The Company is engaged in drug development based on a tumouricidal protein-lipid complex, HAMLET, formed by two generally regarded as safe (GRAS) molecules present in human milk. The novel therapeutic entity HAMLET is formed when alpha-lactalbumin (the primary protein component of human milk) undergoes a conformational change and binds to oleic acid. The aim is to develop drugs that can primarily be used for the treatment and prevention of cancers. HAMLET selects and removes tumour cells efficiently and has not shown toxicity in two proof-of-concept studies in humans. The agent has shown a therapeutic effect on skin papillomas in a placebo-controlled clinical trial and induces shedding of dead cancer cells after injection into the bladder of patients with bladder cancer.

Alpha1H is the synthetic variant of HAMLET, which has enabled development of the agent for clinical trials. Alpha1H kills different types of tumour cells and has demonstrated therapeutic effects on bladder cancer in animal models. Hamlet Pharma has one ongoing Phase I/II clinical trial with Alpha1H in patients with bladder cancer, a costly form of cancer that is difficult to treat and intends to expand its activities into other types of cancer. The first results from the ongoing clinical Phase I/II study shows no side effects of Alpha1H, indicating that the treatment is safe and well tolerated. Alpha1H also demonstrated clinical efficacy compared with patients who received placebo. In addition, Hamlet Pharma develops BAMLET, which is a molecular complex formed by bovine  $\alpha$ -lactalbumin and oleic acid. Research on mice suggest that local BAMLET treatment may be effective against colon cancer in man.

The company's operations are based on R&D. The Company has therefore concluded an agreement with Lund University to ensure that Hamlet Pharma gains access to the research findings underlying the continued development of its research portfolio. The protein-lipid complex HAMLET is formed when alpha-lactalbumin (a human milk protein) binds to oleic acid (a fatty acid), which is also present in milk. The Company has also identified the active components of the HAMLET molecule that are responsible for the tumoricidal activity and developed large-scale production of these components. The peptide complex that we have named Alpha1H has demonstrated efficacy on bladder cancer. Alpha1H has been granted patents in both Europe and the US.

## Revenue and earnings

During the first quarter, Hamlet Pharma's net sales amounted to KSEK 0 (0). Other operating income amounted to KSEK 2,996 (0). 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. During the first quarter, significant costs were also related to production of the Alpha1H drug candidate, for use in ongoing and forthcoming clinical trials. Loss before tax for the first quarter was KSEK -1,843 (-2,743).

## Financial position

In July, the first payment of 12,6 MSEK was received from the EU. Read more in the section "Horizon 2020 EIC Accelerator Fund" below. The financial position is therefore strong and the cash and cash equivalents are deemed sufficient for operations during the entire fiscal year.

## Horizon 2020 EIC Accelerator Fund

In March 2020 Hamlet Pharma was awarded a grant of 2.2 MEUR (approx. 22.9 MSEK) 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 12,580 KSEK was done on July 1<sup>st</sup> 2020. 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 2,996 KSEK was used from the fund, and 3,441 KSEK has been used accumulated from the fund.

## Cash flow and 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 5 (2) full-time employees as of September 30, 2020.

## The share

At September 30, 2020, the number of shares totaled 33,624,899. The Company's shares have been traded on Spotlight Stock Market (formerly AktieTorget) 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.

## Transactions with related parties

During the quarter, KSEK 336 (0) was paid to Linnane Pharma AB regarding consulting fees and re-invoicing of materials, and KSEK 120 (0) 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.

## 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 (2020-06-30).

## 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 (2020-06-30).

## Review

This interim report has not been audited.

## Financial calendar

Annual General Meeting for 2019/2020	November 26, 2020
Interim report for Q2 (half-year)2020/2021	February 26, 2021
Interim report for Q3 2020/2021	May 21, 2021
Year-end report for 2020/2021	August 27, 2021
Annual Report for 2020/2021	November 4, 2021
Interim report for Q1 2021/2022	November 11, 2021
Annual General Meeting for 2020/2021	November 25, 2021

# Income statement

SEK	2020-07-01 2020-09-30	2019-07-01 2019-09-30	2019-07-01 2020-06-30
Net sales	0	0	0
Other operating income	2,996,210	0	447,676
<b>Operating income</b>	<b>2,996,210</b>	<b>0</b>	<b>447,676</b>
Other external costs	-3,984,387	-2,284,314	-21,568,419
Employee benefit expenses	-815,396	-427,507	-2,265,116
Depreciation of tangible assets	-9,000	-9,000	-36,000
Other operating expenses	-36,578	-22,677	0
<b>Operating loss</b>	<b>-1,849,151</b>	<b>-2,743,498</b>	<b>-23,421,859</b>
Financial items	5,908	0	-10,361
<b>Loss before tax</b>	<b>-1,843,243</b>	<b>-2,743,498</b>	<b>-23,432,221</b>
Tax on loss for the period	0	0	0
<b>Loss after tax</b>	<b>-1,843,243</b>	<b>-2,743,498</b>	<b>-23,432,221</b>

# Balance sheet

<b>ASSETS, SEK</b>	2020-09-30	2019-09-30	2020-06-30
<b>Fixed assets</b>			
Tangible assets	36,000	72,000	45,000
<b>Total fixed assets</b>	<b>36,000</b>	<b>72,000</b>	<b>45,000</b>
<b>Current assets</b>			
Other receivables	2,507,862	452,876	754,306
Prepaid expenses	5,323,715	514,420	514,129
Cash and bank balances/financial investments	13,064,373	5,040,696	13,240,400
<b>Total current assets</b>	<b>20,895,950</b>	<b>6,007,991</b>	<b>14,508,835</b>
<b>TOTAL ASSETS</b>	<b>20,931,950</b>	<b>6,079,991</b>	<b>14,553,835</b>
<b>EQUITY &amp; LIABILITIES, SEK</b>	2020-09-30	2019-09-30	2020-06-30
<b>Restricted equity</b>			
Share capital	1,008,747	948,747	1,008,747
Statutory reserve	20,000	20,000	20,000
<b>Total restricted equity</b>	<b>1,028,747</b>	<b>968,747</b>	<b>1,028,747</b>
<b>Non-restricted equity</b>			
Share premium reserve	84,848,309	59,033,909	84,848,309
Retained earnings	-75,400,981	-51,968,760	-51,968,760
Loss for the period	-1,843,243	-2,743,498	-23,432,221
<b>Total non-restricted equity</b>	<b>7,604,085</b>	<b>4,321,650</b>	<b>9,447,328</b>
<b>Total equity</b>	<b>8,632,832</b>	<b>5,290,397</b>	<b>10,476,075</b>
<b>Current liabilities</b>			
Accounts payable	2,514,462	396,735	2,850,244
Tax liabilities	1,525	0	1,525
Other liabilities	176,872	81,370	320,522
Accrued expenses	9,606,259	311,489	905,469
<b>Total current liabilities</b>	<b>12,299,118</b>	<b>789,594</b>	<b>4,077,760</b>
<b>TOTAL EQUITY &amp; LIABILITIES</b>	<b>20,931,950</b>	<b>6,079,991</b>	<b>14,553,835</b>

# Cash flow statement

SEK	2020-07-01 2020-09-30	2019-07-01 2019-09-30	2019-07-01 2020-06-30
<b>Operating activities</b>			
Loss after financial items	-1,843,243	-2,743,498	-23,432,221
Adjusted for non-cash items, etc.	9,000	9,000	36,000
	-1,834,243	-2,734,498	-23,396,221
Paid income tax	0	0	1,525
<b>Cash flow from operating activities before changes in working capital</b>	<b>-1,834,243</b>	<b>-2,734,498</b>	<b>-23,394,696</b>
<b>Cash flow from changes in working capital</b>			
Change in current receivables	-6,563,143	-380,628	-681,767
Change in current liabilities	8,221,358	-2,461,749	824,892
<b>Cash flow from operating activities</b>	<b>-176,027</b>	<b>-5,576,874</b>	<b>-23,251,570</b>
<b>Financing activities</b>			
New share and subscription warrant issues	0	0	25,900,000
Issuance costs	0	0	-25,600
<b>Cash flow from financing activities</b>	<b>0</b>	<b>0</b>	<b>25,874,400</b>
<b>Cash flow for the period</b>	<b>-176,027</b>	<b>-5,576,874</b>	<b>2,622,830</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>13,240,400</b>	<b>10,617,570</b>	<b>10,617,570</b>
<b>Cash and cash equivalents at the end of the period</b>	<b>13,064,373</b>	<b>5,040,696</b>	<b>13,240,400</b>



# Equity

Equity (SEK)	Share capital	Statutory reserve	Share premium reserve	Retained earnings	Loss for the period	Total
<b>Opening balance July 1, 2020</b>	<b>1,008,747</b>	<b>20,000</b>	<b>84,848,309</b>	<b>-51,968,760</b>	<b>-23,432,221</b>	<b>10,476,075</b>
Transfer of prior year's loss - Preliminary				-23,432,221	23,432,221	0
Loss for the period, Q1					-1,843,243	-1,843,243
<b>Equity September 30, 2020</b>	<b>1,008,747</b>	<b>20,000</b>	<b>84,848,309</b>	<b>-75,400,981</b>	<b>-1,843,243</b>	<b>8,632,832</b>

**Malmö, November 12, 2020**

Catharina Svanborg  
**Chairperson of the Board**

Bengt Westermark  
**Board member**

Christer Köhler  
**Board member**

Helena Lomberg  
**Board member**

Rolf Carlsson  
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**CEO**



## For further information:

### Hamlet Pharma AB

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