

Q2

Interim report October – December 2020

Opening remarks

The second quarter of this fiscal year has been very productive for Hamlet Pharma. The clinical trials program has continued and in January, the first patient was included. The patients will receive increased doses of Alpha1H or combination therapy with Alpha1H and low doses of Epirubicin, an established bladder cancer drug. Information from this study program will be essential for the design of Phase III trials. Despite the COVID-19 pandemic, the team in Prague is very motivated and drives the clinical activities forward to develop Alpha1H towards a new drug for patients with bladder cancer.

News about the progress of the BAMLET (bovine α -lactalbumin made lethal to tumour cells) project was communicated during the second quarter, including new and promising data from animal studies. Hamlet Pharma owns the BAMLET patent rights and will take the drug candidate through the development process towards commercialization. The primary focus is on the use of BAMLET for the treatment and prevention of colon cancer. We believe in strong partnerships with market leaders in this segment, as the focus of Hamlet Pharma is to develop Alpha1H and BAMLET as therapeutics for various cancer diseases.

Reaching cancer patients in need of new treatments is our highest priority. Hamlet Pharma is an efficient organization built to ensure that our new drug candidates reach the clinic, hopefully improving the treatment of cancer patients. A combination of high competence and low cost has allowed the company to rapidly proceed towards these goals. The step-wise, fact-based approach of the company is also implemented to improve efficiency and reduce risk. We thank our shareholders for their understanding and support, our consultants for their competence and the committed team that handles the drug development challenges, with such efficiency.

We look forward to a very exciting spring with new clinical data and an expanding product profile including our drug candidates Alpha1H and the BAMLET pharmaceutical.

Catharina Svanborg and Mats Persson

Chairperson of the Board and CMO and CEO of Hamlet Pharma, respectively

Significant events during the second quarter

On October 6, 2020, potent therapeutic effects of BAMLET were announced, based on studies in animal models of colon cancer. Colon cancer development was markedly reduced in mice treated by oral administration of BAMLET, compared to mice receiving placebo. A significant reduction in tumor number and tumor size was observed after 2 weeks and the effect continued long-term. Treated mice survived for 27 weeks, which is much longer than untreated controls, where the disease developed faster. The results suggest that local administration of BAMLET may be effective in patients with colon cancer. Large scale production and clinical studies will be required to further define the potential of BAMLET in patients in need of a therapeutic and/or a prophylactic treatment approach.

On October 23, 2020, the formal kick-off of the H2020 EIC Accelerator Program for the European Union funded project was held by zoom. The goal of the EU project is to accelerate the development of Alpha1H as a novel treatment for patients suffering from bladder cancer. With the EIC Accelerator funding, Hamlet Pharma committed to finalize the Phase I/II clinical safety and efficacy study for publication and to advance the development of Alpha1H towards future Phase III trials.

On November 17, 2020, the Company announced discussions regarding BAMLET with major multinational companies. The discussions concern the future commercial use of BAMLET (bovine α -lactalbumin made lethal to tumor cells) in non-prescription and food products. The use of BAMLET as a non-prescription product is an interesting opportunity with a potential huge market. Hamlet Pharma is therefore progressing with this opportunity with support of experienced external partners.

On November 17, 2020, the Nutraceutical Patent for HAMLET and BAMLET was granted in Europe. Hamlet Pharma AB has secured patent protection in Europe for the manufacturing of BAMLET using a simplified process. The patent is based on results of an extensive academic research and discovery platform and is valid until August 8, 2033.

On November 25, 2020, Hamlet Pharma successfully secured patent protection in Europe for its lead clinical candidate, Alpha1H. The patent is valid until May 14, 2038. Alpha1H is currently used in clinical trials in patients with bladder cancer. Hamlet Pharma AB plans to seek equivalent protection in further key countries around the world.

On November 26, 2020, the film "This is Hamlet" was made public. The film was produced by the well-known TV journalists Calle Magnell and Fredrik Kron in collaboration with Jan-Olof Bengtsson. They tell the story about HAMLET and Alpha1H from discovery to clinical trials in cancer patients. In the film, members of the HAMLET team tell their stories about working with Alpha1H research and their thoughts about the process of translation from science to clinical use. The principal investigator Professor Babjuk at the University Hospital in Prague is also interviewed about the clinical studies in patients with bladder cancer carried out together with his team.

On November 26, 2020, the General Annual Meeting of Hamlet Pharma was held in Malmö. Due to the pandemic, shareholders were asked to send in their voting forms in advance. It was decided to appoint Catharina Svanborg, Bengt Westermark, Christer Köhler, Rolf Carlsson and Helena Lomberg as board members for the period until the end of the next Annual General Meeting.

Significant events after the end of the second quarter

On January 22, 2021, Hamlet Pharma proudly announced the inclusion of patients with bladder cancer in the next part of the clinical trials program. In the dose-escalation study, five times or ten times higher doses of Apha1H than those used in the previous part of the trial will be examined for safety and efficacy. The clinic in Prague has identified eligible patients and the clinical study team working with is experienced and highly motivated to continue the investigations to define its potential of Alpha1H in bladder cancer. The Food and Drug Administration in US has declared bladder cancer a great unmet medical need, and we are determined to fill this gap and improve treatment options. We feel confident that the recruitment of patients will proceed and we will work closely with the team in Prague to secure all necessary precautions during the study.

On January 29, 2021, the Board of Directors of Hamlet Pharma proposed to introduce A and B shares with different voting rights. The proposal is to hold a share split, dividing each existing share in Hamlet Pharma into 2 new A shares and 1 new B share, where each A share will have a voting value of 10 and each B share a voting value of 1. The shares will have the same right to future dividends. It is not the Board's ambition to have the A share listed and traded. Shareholders wishing to trade their Hamlet Pharma shares are therefore encouraged to convert a shares to B shares and the company will efficiently support this process. It is predicted that the B shares will take over the existing trading venue on the Spotlight Stock Market. An information leaflet will be sent to all shareholders to provide a background to this decision and fully explain practical aspects, to facilitate this process.

On January 29, 2021, shareholders were summoned to an Extraordinary General Meeting on Tuesday, March 2, 2021. The Board also proposes to the Extraordinary General Meeting a conversion procedure, in which shareholders can redeem their A shares against B shares free of charge. In light of the corona virus pandemic, the meeting is conducted by advance voting with the support of temporary statutory rules. Therefore, there will be no opportunity to attend in person or through a representative. More information can be found on our homepage.

Figures

SECOND QUARTER (OCT 1, 2020-DEC 31, 2020)

- Revenue for the second quarter totaled KSEK 0 (0)
- Loss before tax amounted to KSEK -2,828 (-7,986)
- Loss after tax amounted to KSEK -2,828 (-7,986)
- Loss per share* was SEK -0.0841 (-0.2448)

FIRST HALF (JUL 1, 2020-DEC 31, 2020)

- Revenue for the first half totaled KSEK 0 (0)
- Loss before tax amounted to KSEK -4,671 (-10,730)
- Loss after tax amounted to KSEK -4,671 (-10,730)
- Loss per share* was SEK -0.1389 (-0.3289)
- At December 31, 2020, the equity/assets ratio** was 39.4 (80.0)%

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 (32,624,899), respectively, where 33,624,899 is the number of shares outstanding at December 31, 2020. The comparative figure in parentheses was the number of shares at December 31, 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 tumor 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 α -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 second quarter, Hamlet Pharma's net sales amounted to KSEK 0 (0). Other operating income amounted to KSEK 1,640 (0). Read more in the section "Horizon 2020 EIC Accelerator Fund" below. Costs were related to the planning and regulatory approval of the continued clinical trials as well as R&D activities of the team at Lund University, which is coordinating the clinical trials of Alpha1H and plays a key role in the control and execution of laboratory testing of samples for the clinical trial. The team is further responsible for research and development, including drug-manufacturing methods, stability testing, chemical and functional characterization of existing and new drug substances, in cancer cells and animal models.

Loss before tax for the first half was KSEK -4,671 (-10,730). Loss before tax for the second quarter was KSEK -2,828 (-7,986).

Financial position

As stated last quarter, the first payment of 12,6 MSEK was received from the EU in July. 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. After the fiscal year and when starting the next phase of the clinical development of Alpha1H, the company will need additional funding. Therefore, during the next quarter and before the end of the fiscal year, the company will investigate various alternatives for future financing.

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 1st 2020. 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 1,613 KSEK was used from the fund, and 5,055 KSEK has been accumulated from the fund. The next payment of 8,000 KSEK is expected end of June 2021.

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 second quarter.

Depreciation

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

Employees

The company had the equivalent of 5 (2) full-time employees as of December 31, 2020.

The share

On December 31, 2020, the number of shares totaled 33,624,899. 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.

The Board of Directors of Hamlet Pharma has proposed the introduction of A and B shares with different voting rights. Provided that the Board's proposal is approved by the Extraordinary General Meeting on 2nd of March, shareholders will receive two (2) new A shares and one (1) new B share. The B share will take over the existing trading venue on the Spotlight Stock Market, while the A share will remain unlisted. All shareholders are given the opportunity to convert their A shares into B shares free of charge and thus continue to have their entire holding available for trading. Please note that the differentiation of voting rights will result in a discrepancy between shareholders' votes and capital.

Extraordinary General Meeting

The shareholders of Hamlet Pharma AB are called to an Extraordinary General Meeting on Tuesday, March 2, 2021. In light of the corona virus, the meeting is conducted by advance voting with the support of temporary statutory rules. No meeting with the opportunity to attend in person or by proxy will therefore take place. More information and voting forms are published on our home page.

Transactions with related parties

During the quarter, KSEK 337 (105) was paid to Linnane Pharma AB regarding consulting fees and re-invoicing of materials, and KSEK 120 (294) 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

Interim report for Q3, 2020/2021

Year-end report (Q4), 2020/2021

Annual Report for 2020/2021

Interim report for Q1, 2021/2022

Annual General Meeting for 2020/2021

May 21, 2021

August 27, 2021

November 4, 2021

November 11, 2021

November 25, 2021



Income statement

SEK	2020-10-01 2020-12-31	2019-10-01 2019-12-31	2020-07-01 2020-12-31	2019-07-01 2019-12-31	2019-07-01 2020-06-30
Net sales	0	0	0	0	0
Other operating income	1,640,373	0	4,636,583	0	447,676
Operating income	1,640,373	0	4,636,583	0	447,676
Other external costs	-3,399,108	-7,571,042	-7,383,495	-9,855,356	-21,568,420
Employee benefit expenses	-1,067,817	-454,448	-1,883,213	-881,955	-2,265,116
Depreciation of tangible assets	-9,000	-9,000	-18,000	-18,000	-36,000
Other operating expenses	8,041	48,807	-28,537	26,130	0
Operating Profit/Loss	-2,827,511	-7,985,683	-4,676,662	-10,729,181	-23,421,860
Financial items	-50	-366	5,858	-366	-10,361
Profit/Loss before tax	-2,827,561	-7,986,049	-4,670,804	-10,729,547	-23,432,221
Tax on loss for the period	0	0	0	0	0
Loss after tax	-2,827,561	-7,986,049	-4,670,804	-10,729,547	-23,432,221

Balance sheet

ASSETS, SEK	2020-12-31	2019-12-31	2020-06-30
Fixed assets			
Tangible assets	27,000	63,000	45,000
Total fixed assets	27,000	63,000	45,000
Current assets			
Other receivables	375,630	743,793	754,306
Prepaid expenses	4,607,596	377,945	514,129
Cash and bank balances/financial investments	9,726,439	11,622,223	13,240,400
Total current assets	14,709,665	12,743,960	14,508,835
TOTAL ASSETS	14,736,665	12,806,960	14,553,835
EQUITY & LIABILITIES, SEK	2020-12-31	2019-12-31	2020-06-30
Restricted equity			
Share capital	1,008,747	978,747	1,008,747
Statutory reserve	20,000	20,000	20,000
Total restricted equity	1,028,747	998,747	1,028,747
Non-restricted equity			
Share premium reserve	84,848,309	71,941,109	84,848,309
Retained earnings	-75,400,981	-51,968,760	-51,968,760
Loss for the period	-4,670,804	-10,729,547	-23,432,221
Total non-restricted equity	4,776,524	9,242,801	9,447,328
Total equity	5,805,271	10,241,548	10,476,075
Current liabilities			
Accounts payable	653,175	1,980,607	2,850,244
Tax liabilities	1,525	0	1,525
Other liabilities	165,265	81,370	320,522
Accrued expenses	8,111,430	503,436	905,469
Total current liabilities	8,931,394	2,565,412	4,077,760
TOTAL EQUITY & LIABILITIES	14,736,665	12,806,960	14,553,835

Cash flow statement

SEK	2020-07-01 2020-12-31	2019-07-01 2019-12-31	2019-07-01 2020-06-30
Operating activities			
Loss after financial items	-4,670,804	-10,729,547	-23,432,221
Adjusted for non-cash items, etc.	18,000	18,000	36,000
	-4,652,804	-10,711,547	-23,396,221
Paid income tax	0	0	1,525
Cash flow from operating activities before changes in working capital	-4,652,804	-10,711,547	-23,394,696
Cash flow from changes in working capital			
Change in current receivables	-3,714,791	-535,070	-681,767
Change in current liabilities	4,853,634	-685,930	824,893
Cash flow from operating activities	-3,513,960	-11,932,548	-23,251,570
Financing activities			
New share and subscription warrant issues	0	12,950,000	25,900,000
Issuance costs	0	-12,800	-25,600
Cash flow from financing activities	0	12,937,200	25,874,400
Cash flow for the period	-3,513,960	1,004,652	2,622,830
Cash and cash equivalents at the beginning of the period	13,240,400	10,617,570	10,617,570
Cash and cash equivalents at the end of the period	9,726,439	11,622,222	13,240,400

Equity

Equity (SEK)	Share capital	Statutory reserve	Share premium reserve	Retained earnings	Loss for the period	Total
Opening balance July 1, 2020	1,008,747	20,000	84,848,309	-51,968,760	-23,432,221	10,476,075
Transfer of prior year's loss				-23,432,221	23,432,221	0
Loss for the period, Q1					-1,843,243	-1,843,243
Loss for the period, Q2					-2,827,561	-2,827,561
Equity December 31, 2020	1,008,747	20,000	84,848,309	-75,400,981	-4,670,804	5,805,271

Malmö, February 26, 2021

Catharina Svanborg
Chairperson of the Board

Bengt Westermark
Board member

Christer Köhler
Board member

Helena Lomberg
Board member

Rolf Carlsson
Board member

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