



Interim report January – March 2021

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

Opening remarks

The third quarter has been an intense and exciting period for Hamlet Pharma.

In January, the first patients were included in the dose-escalation part of the Phase I/II trial. On may 10, the company announced the successful outcome of this study, where an initial data analysis had revealed a dramatic increase in the tumor response to increasing amounts of Alpha1H. The effect was measured both as shedding of cells and of tumor fragments into the urine as well as of pronounced changes in tumor tissue, with large areas of cells undergoing apoptosis or necrosis. DNA fragmentation indicative of apoptosis was visible in cells and tumor tissue, as well as a marked uptake of the Alpha1H compound. The evaluation of the study data continues and further results will be communicated and published in scientific journals.

In parallel, a study of Alpha1H in combination with epirubicin has been started. As previously announced, animal studies have clearly demonstrated a further increase in therapeutic efficacy of Alpha1H when combined with chemo-therapeutic drugs such as epirubicin.

The report of the initial Phase I/II study has been accepted for publication in Nature Communications. The paper analyses the tumor killing effects of Alpha1H, the structural basis of its effect and the successful clinical trial of Alpha1H in patients with bladder cancer. Publishing in leading international journals is a major achievement.

During the third quarter the Board of Directors of Hamlet Pharma proposed to introduce A and B shares with different voting rights. An Extra General Meeting decided to issue shares in two series, series A and series B. The split means that strategic and long-term owners can focus on retaining their strong A-shares. The split will help secure the long term strategic vision of the company with strong science- and knowledge-driven focus on research and development. This strategy has since inception of the company been an important success factor, and will in the future be even more important in building long-term value for our shareholders .

We look forward to a very exciting next quarter with our drug candidate Alpha1H and BAMLET Pharmaceutical. The support from our shareholders, our team members, the clinic in Prague and all our external partners is invaluable and a prerequisite to the success of new treatment options for cancer patients.

Catharina Svanborg and Mats Persson

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

Significant events during the third quarter

On January 22, 2021, the first patient was included in the dose-escalation study. The clinic in Prague has identified eligible patients and the local clinical study team is experienced and highly motivated to continue the investigations to define the potential of Alpha1H in bladder cancer treatment. We also communicated that we expect to recruit patients within the next months and that we will work closely with the team in Prague to secure all necessary precautions due to COVID-19 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. Each existing share in Hamlet Pharma is split 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. Shareholders wishing to trade their Hamlet Pharma shares are therefore encouraged to convert all 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.

On March 2, 2021, an Extraordinary General Meeting was held. Due to the corona virus pandemic, the meeting was conducted by advance voting with the support of temporary statutory rules. It was decided, in accordance with the Board's proposal, to amend the Articles of Association, whereby the possibility of issuing shares in two series, series A and series B, was introduced. Following the completion of the division, the total number of shares in the company will increase from 33,624,899 to 100,874,697 shares, of which 67,249,798 shares will be series A shares and 33,624,899 shares will be Series B shares.

It was also decided to elect Professor Bill Hansson to the board of Hamlet Pharma. Bill Hansson is an internationally recognized scientist in the field of biology and his extensive academic leadership includes his directorship at the Max Planck Institute for Chemical Ecology in Jena. Bill Hansson was recently awarded the Federal Cross of Merit 1st Class by the President of Germany.

On March 9, 2021, the Board of Directors decided that the recording date for the division of shares shall be Tuesday, March 16, 2021. The first day for trading of the divided shares was set to Monday, March 15, 2021. In connection with the share split, the B share took over the existing trading venue on Spotlight Stock Market. The A share will remain unlisted. Further information on the introduction of A and B shares and the procedure for conversion from A shares to B shares can be found in the information brochure sent out to all shareholders and published on our homepage.

On March 10, an information leaflet was sent to all shareholders with the background information to the decision as well as instructions on the practical aspects, to facilitate this conversion process.

On March 18, 2021, the company announced new treatment advances in an experimental animal model of bladder cancer. Repeated Alpha1H treatment prevented tumor growth and upon visual/microscopic inspection the bladders remained similar to the control group without tumors in mice. In contrast, mice treated with placebo showed rapid tumor progression and severe disease after 12 days. The first round of Alpha1H treatment prevented tumor development for 4 weeks and long-term protection was achieved when treatment was repeated at 4-week intervals, as evidenced by marked differences in tumor size, pathology score, biomarkers, and gene expression.

Significant events after the end of the third quarter

On April 7, 2021, Hamlet Pharma signed a contract with Rechon Life Science AB for the manufacture of clinical batches of Alpha1H. The batches will be used for continued phase II and future phase III clinical trials in patients with bladder cancer. Larger amounts of drug will be needed for the continued clinical trial program, which involves larger study populations. Rechon is a well-recognized contract manufacturing organization based in Malmö and offers a complete pharmaceutical service including preparation, packaging, and distribution of Clinical Trial Supplies for clinical studies phases I-IV. Production is carried out in accordance with GMP and Rechon is approved for pharmaceutical supply worldwide (including the US). The production will be preceded by technology transfer from our laboratory as well as from previous suppliers.

On April 21, 2021, the report of the phase I/II bladder cancer trial was accepted for publication in Nature Communications: a leading international journal. The paper is entitled "Bladder cancer therapy using a conformationally fluid tumoricidal peptide complex". The Nature journals are very competitive and only accept innovative science of highest quality and with significant interest for a discerning audience. The paper analyses the structure of the Alpha1H complex, characterizes its tumor killing effects and describes the successful clinical trial of Alpha1H in patients with bladder cancer. A detailed analysis of primary and secondary end points is provided and differences between the Alpha1H treated patients and the placebo group are described for several crucial efficacy variables.

On May 10, 2021, the company announced the successful outcome of the extended Phase I/II trial, aiming to investigate effects of higher amounts of Alpha1H in patients with bladder cancer. The first data analysis revealed a potent, dose-dependent increase in several effect variables and without any evidence of serious adverse events.

Figures

THIRD QUARTER (JAN 1, 2021-MAR 31, 2021)

- Net sales for the third quarter totaled KSEK 0 (0)
- Other operating income totaled KSEK 1,393 (0)
- Loss before tax amounted to KSEK -2,346 (-6,231)
- Loss after tax amounted to KSEK -2,346 (-6,231)
- Loss per share* was SEK -0.0698 (-0.1853)
- Loss per share with split** was SEK -0.0233 (-0.0618)

NINE MONTHS (JUL 1, 2020-MAR 31, 2021)

- Net sales for the first nine months totaled KSEK 0 (0)
- Other operating income totaled KSEK 6,029 (25)
- Loss before tax amounted to KSEK -7,017 (-16,961)
- Loss after tax amounted to KSEK -7,017 (-16,961)
- Loss per share* was SEK -0.2087 (-0.5044)
- Loss per share with split** was SEK -0.0696 (-0.1681)
- At March 31, 2021, the equity/assets ratio*** was 30,2 (75.9)%

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 (33,624,899), respectively, where 33,624,899 is the number of shares outstanding on March 31, 2021. The comparative figure in parentheses was the number of shares on March 31, 2020.
- ** Profit/loss after tax for the period taking into account the split decided at the extraordinary general meeting on March 2, 2021, that was registered 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, 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 the two completed proof-of-concept studies in humans. The agent has shown a therapeutic effect on skin papillomas in a placebocontrolled 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 third quarter, Hamlet Pharma's net sales amounted to KSEK 0 (0). Other operating income amounted to KSEK 1,393 (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 clinical study and production and formulation of our drug candidate Alpha1H for use in ongoing and forthcoming clinical trials. 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.

Loss before tax for the first nine months was KSEK -7,017 (-16,961). Loss before tax for the third quarter was KSEK -2,346 (-6,231).

Financial position

A first payment of 12,6 MSEK was received from the EU in July 2020. The next payment of 8,0 MSEK is expected end of June 2021. Read more in the section "Horizon 2020 EIC Accelerator Fund" below. 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, 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 third quarter 1,393 KSEK was used from the fund, and 6,447 KSEK has been used 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 third 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 March 31, 2021.

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 will undergo a split with relation 3:1 and 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. The last day of trading before the split and reclassification was March 12, 2021. The first day of trading in the B-share after the split was March 15, 2021. 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.

On March 31, 2021, the number of shares registered at the Swedish Companies Registration Office (Bolagsverket) totaled 33,624,899. However, by April 14, 2021, the split was registered at the Swedish Companies Registration Office (Bolagsverket) and the number of shares totaled 100,874,697. On May 11, 2021, the registered number of shares was 39,066,228 A-shares and 61,808,469 B-shares.



Transactions with related parties

During the quarter, KSEK 146 (131) was paid to Linnane Pharma AB regarding consulting fees, 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

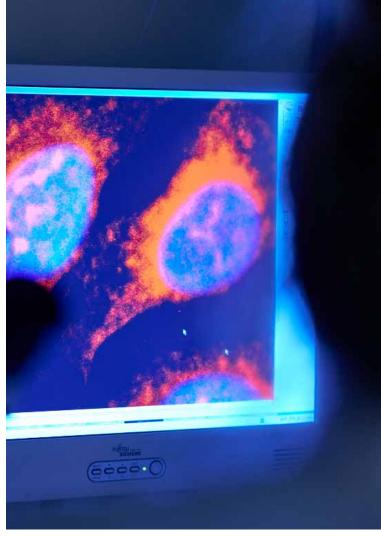
Year-end report (Q4), 2020/2021 August 27, 2021

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

CEIV	2021-01-01	2020-01-01	2020-07-01	2019-07-01	2019-07-01
SEK	2021-03-31	2020-03-31	2021-03-31	2020-03-31	2020-06-30
Net sales	0	0	0	0	0
Other operating income	1,392,800	0	6,029,383	24,714	447,676
Operating income	1,392,800	0	6,029,383	24,714	447,676
Other external costs	-2,669,076	-5,744,276	-10,052,571	-15,599,632	-21,568,419
Employee benefit expenses	-1,040,016	-466,653	-2,923,229	-1,348,608	-2,265,116
Depreciation of tangible assets	-9,000	-9,000	-27,000	-27,000	-36,000
Other operating expenses	-20,883	-1,415	-49,420	0	0
Operating loss	-2,346,174	-6,221,344	-7,022,836	-16,950,526	-23,421,859
Financial items	0	-9,995	5,858	-10,361	-10,361
Loss before tax	-2,346,174	-6,231,339	-7,016,978	-16,960,886	-23,432,221
Tax on loss for the period	0	0	0	0	0
Loss after tax	-2,346,174	-6,231,339	-7,016,978	-16,960,886	-23,432,221

Balance sheet

ASSETS, SEK	2021-03-31	2020-03-31	2020-06-30
Fixed assets			
Tangible assets	18,000	54,000	45,000
Total fixed assets	18,000	54,000	45,000
Current assets			
Other receivables	522,555	1,027,316	754,306
Prepaid expenses	4,586,622	223,459	514,129
Cash and bank balances/financial investments	6,328,127	21,028,266	13,240,400
Total current assets	11,437,303	22,279,041	14,508,835
TOTAL ASSETS	11,455,303	22,333,041	14,553,835
EQUITY & LIABILITIES, SEK	2021-03-31	2020-03-31	2020-06-30
Restricted equity			
Share capital	1,008,747	1,008,747	1,008,747
Statutory reserve	20,000	20,000	20,000
Total restricted equity	1,028,747	1,028,747	1,028,747
Non-restricted equity			
Share premium reserve	84,848,309	84,848,309	84,848,309
Retained earnings	-75,400,981	-51,968,760	-51,968,760
Loss for the period	-7,016,978	-16,960,886	-23,432,221
Total non-restricted equity	2,430,349	15,918,662	9,447,328
Total equity	3,459,096	16,947,409	10,476,075
Current liabilities			
Accounts payable	952,252	4,099,080	2,850,244
Tax liabilities	1,525	4,093,000	1,525
Other liabilities	148,411	91,113	320,522
Accrued expenses	6,894,019	1,195,439	905,469
Total current liabilities	7,996,207	5,385,632	4,077,760
TOTAL FOLLITY & LIABILITIES	11 455 202	22 222 041	14 552 025
TOTAL EQUITY & LIABILITIES	11,455,303	22,333,041	14,553,835

Cash flow statement

	2020-07-01	2019-07-01	2019-07-01
SEK	2021-03-31	2020-03-31	2020-06-30
Operating activities			
Loss after financial items	-7,016,978	-16,960,886	-23,432,221
Adjusted for non-cash items, etc.	27,000	27,000	36,000
Cash flow from operating activities before changes in working capital	-6,989,978	-16,933,886	-23,396,221
Cash flow from changes in working capital			
Change in current receivables	-3,840,742	-664,107	-681,767
Change in current liabilities	3,918,447	2,134,289	826,417
Cash flow from operating activities	-6,912,273	-15,463,704	-23,251,571
Financing activities			
New share and subscription warrant issues	0	25,900,000	25,900,000
Issuance costs	0	-25,600	-25,600
Cash flow from financing activities	0	25,874,400	25,874,400
Cash flow for the period	-6,912,273	10,410,696	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	6,328,127	21,028,266	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	10,476,074
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
Loss for the period, Q3					-2,346,174	-2,346,174
Equity March 31, 2021	1,008,747	20,000	84,848,309	-75,400,981	-7,016,978	3,459,096

Malmö, May 21, 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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