HAMLET PHARMA

Q1

Interim report July–September 2019

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

Opening remarks

The first quarter of the fiscal year 2019/2020 has been one of the most exiting in the history of Hamlet Pharma AB. As previously announced, the result from the first double blind, placebo controlled clinical study was announced at the end of July. It was with great pleasure and enthusiasm we concluded that Alpha1H treatment is effective in patients with bladder cancer without causing severe side effects. Alongside the clinical trial, the Company has laid the foundation for continued clinical development. In an animal model of bladder cancer, research has shown that a higher dose of Alpha1H increases the therapeutic effect. As previously announced, we have received regulatory approval for a dose-escalation study in patients with bladder cancer, with the aim of identifying an optimal dose for future studies. Moreover, we have gained support to continue the clinical trials in Prague with the excellent clinical team and external partners.

We are extremely grateful for the professionalism shown by our employees and external partners, which is a prerequisite for achieving the clinical and scientific goals set up by the company. We would like to take the opportunity to thank our investors and shareholders for their confidence in us, and we are looking forward to the next step in the development of Alpha1H towards an approved drug for the treatment of cancer.

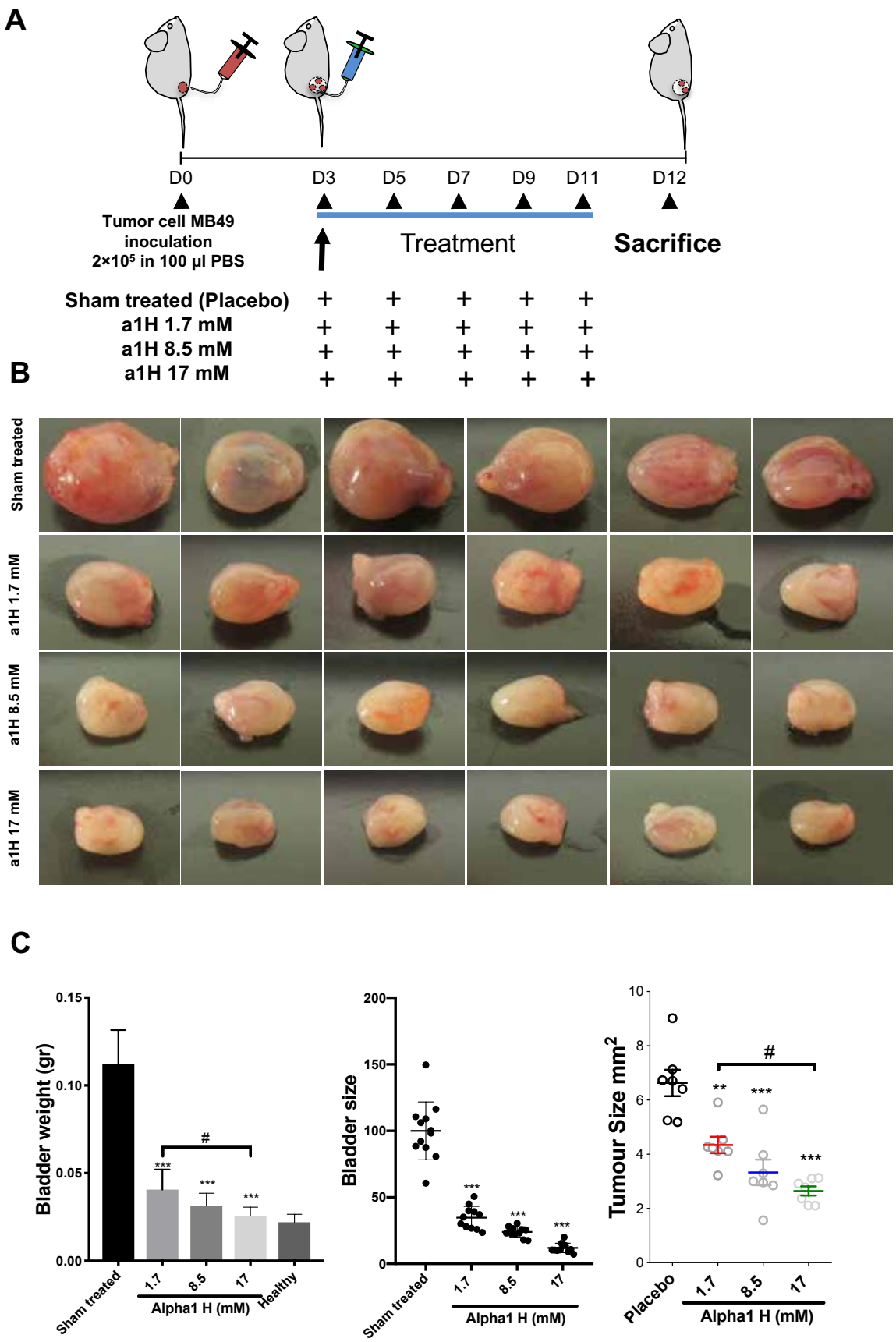
Catharina Svanborg
Chairperson of the Board & CMO

Mats Persson
CEO

Significant events during the first quarter

On July 18, 2019, the Company announced the positive outcome of the bladder cancer trial. The objective of the phase I/II trial was to investigate the safety and efficacy of Alpha1H treatment in patients with bladder cancer. Consistent with the results from animal toxicity studies, no side effects due to Alpha1H were registered, indicating that the treatment is safe and well tolerated. Alpha1H also demonstrated a very clear and significant effect compared to the placebo group. Furthermore, some patients treated with Alpha1H secreted whole tumour fragments, indicating efficacy of Alpha1H compared with placebo. Alpha1H also induced cell death in the tumour through apoptosis, which is a process by which tissues remove dead cells wihout damage to the tissue. These findings support the mechanisms of action for Alpha1H demonstrated in the laboratory experiments and in animal studies.

DOSE-ESCALATION STUDIES IN AN ANIMAL MODEL OF BLADDER CANCER
To counteract the aggressive behavior of cancer cells, therapies are often highly toxic and almost invariably accompanied by severe side effects. This study in an animal model addressed if a better balance between efficacy and toxicity can be attained, using the tumoricidal peptide-oleic acid complex Alpha1H. Results in an animal model show that a dose-dependent increase in therapeutic efficacy can be achieved, without a parallel increase in side effects. Intravesical instillation of Alpha1H resulted in a dose-dependent reduction in tumor size, bladder size, bladder weight and the tumor markers Ki-67, Cyclin D1 and VEGF. In parallel, the expression of cancer-related genes was inhibited. Remarkably, toxicity for healthy tissue was not detected in treated tumor-bearing mice even at the highest concentration of Alpha1H as organ weights, clinical chemistry and hematology parameters remained unaffected. The results define a dose-dependent therapeutic effect of Alpha1H in a murine bladder cancer model, without local or systemic side effects.



Dose-dependent therapeutic effect of alpha1-oleate in a murine bladder tumor model.

A Schematic treatment model. Bladder cancer was induced in C57BL/6J female mice by intravesical instillation of MB49 cells (2×105 in 100 µl PBS). Mice were treated by intravesical instillation of alpha1-oleate (1.7 mM, 8.5 mM or 17 mM) on days 3, 5, 7, 9 and 11 and sacrificed on day 12. Sham treated mice received PBS.

B Dose dependent effect of alpha1-oleate, deduced from macroscopic inspection of gross bladder pathology.

C Comparison of bladder weight, bladder size and tumor area. Data is presented as means ± SEMs of two experiments (n = 6 + 5 mice, * P < 0.05, ** P < 0.01 and *** P < 0.001 compared to sham treated mice).

Significant events after the first quarter

On October 7, 2019, the Company received KSEK 12,950 by redemption of the first serie of subscription warrants. No issue costs were paid. For more information, please see below under the heading 'Issue of new shares and subscription warrants'.

On October 11, 2019, the Company released further data from the clinical study. Detailed data analyses and statistical tests were performed.

SAFETY ANALYSES
The objectives of the ongoing clinical trial are to assess the safety and efficacy of Alpha1H treatment in patients with bladder cancer. There were no side effects related to the Alpha1H treatment showing that instillations of 1.7 mM of Alpha1H into the bladder can be regarded as safe.

EFFICACY ANALYSES
Several efficacy end points were met.

I. Alpha1H triggered massive shedding of tumor cells into patient urine
A rapid increase in cell shedding was detected in patients, who received Alpha1H compared to placebo ($P<0.0001$). Cell shedding occurred each time the patients received Alpha1H (Visit 1-6). A similar increase was observed for tumor fragments, which were released into the urine of patients receiving Alpha1H ($P<0.0001$).

II. Alpha1H triggers cell death in the tumor (apoptosis)
To examine how the tumor responds to Alpha1H treatment, biopsies were obtained from the tumor at the time of surgery. Cell death was defined by TUNEL staining, which detects apoptosis; a beneficial, non-toxic form of cell death. A highly significant increase was observed, compared to the placebo group. The results suggest that Alpha1H accelerates cell death in the tumor.

III. Alpha1H is taken up by tumor cells
By fluorescence microscopy, we showed that Alpha1H was taken up by tumor cells, providing evidence that the drug candidate alpha1H interacts with the tumor.

FOLLOW UP STUDIES
The ongoing clinical study includes an extended follow-up period of 24 months for each participating patient.

The dose escalation study amendment was recently approved by the Czech authorities,. Two dose levels of Alpha1H, 8 mM and 17 mM, will be tested. Up to 12 additional subjects may be included depending on the safety outcome. A Maximum Tolerated Dose (MTD) will be defined.

Figures

FIRST QUARTER (JUL 1, 2019-SEP 30, 2019)

– Revenue for the first quarter totaled KSEK 0 (0)
– Profit/Loss before tax amounted to KSEK -2,743 (-2,980)
– Profit/Loss after tax amounted to KSEK -2,743 (-2,980)
– Profit/Loss per share* was SEK -0.0868 (-0.0973), and SEK -0.0816 after dilution
– At September 30, 2019, the equity/assets ratio** was 87.0% (87.7%)

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

* Profit/loss after tax for the period divided by 31,624,899 (30,624,899) and 33,624,899 shares, respectively, where 31,624,899 is the number of shares outstanding at September 30, 2019, and 33,624,899 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 at September 30, 2018.
** 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 about 53% 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 Phasel/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.

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 in relevant animal models and is currently being tested in a clinical trial. Alpha1H has been granted patents in both Europe and the US.

Revenue and earnings

During the first quarter, Hamlet Pharma's sales amounted to KSEK 0 (0). Costs were related to the continued R&D activities of the research team at Lund University as well as costs for the ongoing clinical trial in bladder cancer patients. The team at Lund University is 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 production of the Alpha1H peptide and preparation of the clinical trial materials for use in ongoing and forthcoming clinical trials. Loss before tax for the first quarter was KSEK -2,743 (-2,980).

Financial position

No financial activities have affected the Company during the first quarter. However, the Company have issued subscription warrants after the end of the quarter.

At the end of the first quarter, the equity/assets ratio was 87.0% (87,7%), and the Company's cash and cash equivalents were KSEK 5,041 (12,366). The Company expects that the issuances in October 2019 and January/ February 2020 will generate approximately MSEK 26, which will secure continuing operations during the fiscal year.

Read more under New share issue and subscription warrants.

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.

The share

At September 30, 2019, the number of shares totaled 31,624,899. 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.

Issue of new shares and subscription warrants

On February 1, 2019, the Board of Hamlet Pharma AB decided to implement a private placement of shares with subscription warrants that would generate proceeds of approximately MSEK 36 for the Company if fully exercised.

The Company's share capital was increased by SEK 30,000 by issuing 1,000,000 shares. The Board's decision also means that a maximum of 2,000,000 subscription warrants will be issued, entitling the holders to subscribe for a maximum of 2,000,000 shares. If the subscription warrants are exercised, the Company's share capital will increase by a further maximum of SEK 60,000. The new shares will not carry the right to a dividend until the first record date after the shares have been registered with Euroclear Sweden AB.

In February 2019, the Company implemented the adopted new issue totalling KSEK 10,350, with issuance costs of a modest KSEK 12, generating KSEK 10,338 net. In October 2019, the Company received KSEK 12,950 from redemption of the first serie of subscription warrants. No issue costs were paid, making the entire sum available to the company. A second series of subscription warrants scheduled for January/February, can potentially generate an additional KSEK 12,950.

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.

Review

This interim report has not been audited.

Financial calendar

Annual General Meeting for the 2018/19 fiscal year	November 21, 2019
Interim report for Q2, 2019/20	February 28, 2020
Interim report for Q3, 2019/20	May 22, 2020

Income statement

SEK	2019-07-01 2019-09-30	2018-07-01 2018-09-30	2018-07-01 2019-06-30
Net sales	0	0	0
Operating income	**0**	**0**	**0**
Other external costs	-2,284,314	-2,484,422	-14,514,793
Employee benefit expenses	-427,507	-428,497	-2,213,402
Depreciation of tangible assets	-9,000	-78,756	-315,024
Other operating expenses	-22,677	12,329	-59,524
Operating Profit/Loss	**-2,743,498**	**-2,979,346**	**-17,102,743**
Financial items	0	-615	-242
Profit/Loss before tax	**-2,743,498**	**-2,979,961**	**-17,102,985**
Tax on loss for the period	0	0	0
Profit/Loss after tax	**-2,743,498**	**-2,979,961**	**-17,102,985**

Balance sheet

ASSETS, SEK	2019-09-30	2018-09-30	2019-06-30
Non-current assets			
Property, plant and equipment	72,000	317,268	81,000
Total Non-current assets	**72,000**	**317,268**	**81,000**
Current assets			
Other receivables	452,876	308,918	485,463
Prepaid expenses	514,420	480,861	101,205
Cash and bank balances	5,040,696	12,366,037	10,617,570
Total current assets	**6,007,991**	**13,155,816**	**11,204,238**
TOTAL ASSETS	**6,079,991**	**13,473,084**	**11,285,238**

EQUITY & LIABILITIES, SEK	2019-09-30	2018-09-30	2019-06-30
Restricted equity			
Share capital	948,747	918,747	948,747
Statutory reserve	20,000	20,000	20,000
Total restricted equity	**968,747**	**938,747**	**968,747**
Non-restricted equity			
Share premium reserve	59,033,909	48,725,414	59,033,909
Retained earnings	-51,968,760	-34,865,775	-34,865,775
Profit/Loss for the period	-2,743,498	-2,979,961	-17,102,985
Total non-restricted equity	**4,321,650**	**10,879,678**	**7,065,148**
Total equity	**5,290,397**	**11,818,425**	**8,033,895**
Current liabilities			
Accounts payable	396,735	696,829	2,251,704
Other liabilities	81,370	99,130	246,041
Accrued expenses	311,489	858,701	753,598
Total current liabilities	**789,594**	**1,654,659**	**3,251,343**
TOTAL EQUITY & LIABILITIES	**6,079,991**	**13,473,084**	**11,285,238**

Cash flow statement

SEK	2019-07-01 2019-09-30	2018-07-01 2018-09-30	2018-07-01 2019-06-30
Operating activities			
Profit/Loss after financial items	-2,743,498	-2,979,961	-17,102,985
Adjusted for non-cash items, etc.	9,000	78,756	315,023
Cash flow from operating activities before changes in working capital	**-2,734,498**	**-2,901,205**	**-16,787,961**
Cash flow from changes in working capital			
Change in current receivables	-380,628	-83,646	119,465
Change in current liabilities	-2,461,749	-110,548	1,486,135
Cash flow from operating activities	**-5,576,874**	**-3,095,399**	**-15,182,360**
Investing activities			
Acquisition of tangible assets	0	0	0
Cash flow from investing activities	**0**	**0**	**0**
Financing activities			
New share and subscription warrant issues	0	0	10,350,000
Issuance costs	0	0	-11,505
Cash flow from financing activities	**0**	**0**	**10,338,495**
Cash flow for the period	**-5,576,874**	**-3,095,399**	**-4,843,865**
Cash and cash equivalents at the beginning of the period	**10,617,570**	**15,461,436**	**15,461,436**
Cash and cash equivalents at the end of the period	**5,040,696**	**12,366,037**	**10,617,570**

Equity

Equity (SEK)	Share capital	Statutory reserve	Non-restricted reserves	Profit/Loss for the period	Total
Opening balance July 1, 2019	**948,747**	**20,000**	**24,168,133**	**-17,102,985**	**8,033,895**
Transfer of prior year's loss - Preliminary	0	0	-17,102,985	17,102,985	0
Profit/Loss for the period, Q1	0	0	0	-2,743,498	-2,743,498
Equity September 30, 2019	**948,747**	**20,000**	**7,065,148**	**-2,743,498**	**5,290,397**

Malmö, November 8, 2019

Catharina Svanborg
Chairperson of the Board

Bengt Westermark
Board member

Christer Köhler
Board member

Helena Lomberg
Board member

Mats Persson
CEO

HAMLET PHARMA

For further information:

Hamlet Pharma AB

Mats Persson, CEO
Tel: +46 (0)40-12 25 00
E-mail: mats.persson@hamletpharma.com

Catharina Svanborg, Professor, MD
Tel: +46 (0)40-12 25 05
E-mail: catharina.svanborg@hamletpharma.com