HAMLET PHARMA

Q2

Interim report October – December 2019

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

Opening remarks

Financial
During the second quarter of the fiscal year 2019/2020 the company raised KSEK 12,937 by issuing subscription warrants in line with the resolution adapted by the AGM 2018 and board meeting decision from February 2019.

Clinical and scientific developments
The company released further data from the ongoing clinical study in patients with early stage bladder cancer, also known as non-muscle-invasive bladder cancer (NMIBC). This patient group represents 70% of new bladder cancer diagnoses and affects 1.6 million patients in Europe. Current NMIBC treatments are suboptimal and often associated with significant side-effects resulting in a high tumour recurrence rate (approximately 70%). The data generated from our clinical study strengthens Hamlet Pharma's strategy to develop Alpha1H as a new stand-alone treatment in patients with bladder cancer. The results, which include analyses of available clinical data, have been prepared in a manuscript, which will be submitted shortly.

New indications for Alpha 1H
Hamlet Pharma has also initiated a toxicology study to evaluate the safety of Alpha1H infusion into the brain. As this is technically challenging, extensive laboratory testing has been performed in order to ensure accuracy and safety. Severe brain tumors such as glioblastomas are often resistant to current therapies and recurrence rates remain high. Therefore, there is an urgent need for more efficient treatment options. Hamlet Pharma is planning to start clinical studies in brain tumor patients after completion of the necessary preparations including the toxicology study and approvals from relevant authorities and
ethics committees.

Outlook 2020
Important strategic questions are being addressed and additional resources are being allocated to business development and other key areas. 2020 will be a very important year to define new horizons for the company, to accelerate drug development for bladder cancer and other cancer indications and to put Hamlet Pharma in a position where contacts with potential licencing partners can be initiated.

We would like to thank our shareholders for their confidence in the company and our colleagues and partners whose efforts to develop the company are crucial to our success.

Catharina Svanborg
Chairperson of the Board & CMO

Mats Persson
CEO

Significant events during the second quarter

On October 7, 2019, Hamlet Pharma raised KSEK 12,937 by issuing subscription warrants in line with the resolution adapted by the AGM 2018 and board meeting decision from February 2019. The agreement from February 2019 also enables the Company to generate an additional capital of KSEK 12,937 by issuing subscription warrants during February 2020 (see below under 'Significant events following the second quarter'). For more information, please also see below under 'New share issues and subscription warrants'.

On October 11, 2019, the Company released further data from the clinical study in patients with bladder cancer. The objective of the phase I/II trial was to investigate the safety and efficacy of Alpha1H versus placebo.

SAFETY ANALYSES
Consistent with the results from animal toxicity studies, no side effects related to the Alpha1H treatment were registered, indicating that instillations of 1.7 mM of Alpha1H into the bladder can be regarded as safe.

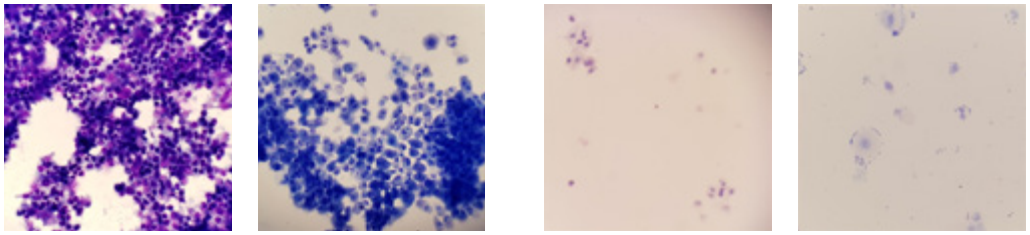
ADVERSE EVENTS (AEs)

No. of AEs	**Alpha1H** (n=20)	**Placebo** (n=20)	**Total** (n=40)
Drug-related AEs	0	-	0
Serious AEs	0	1	1
AE resulting in discontinuation	0	0	0

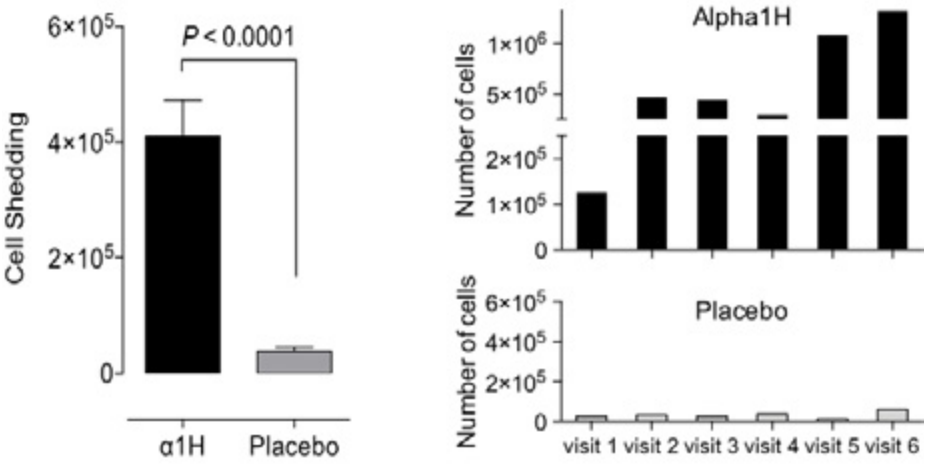
TREATMENT EFFICACY
For several variables, Alpha1H demonstrated a clear and significant effect compared to the placebo group. Some patients treated with Alpha1H secreted whole tumour fragments, indicating efficacy of Alpha1H compared with placebo. Alpha1H also induced cell death in the tumour through apoptosis, which is a process by which tissues remove dead cells without damage to the healthy tissue. These findings support the mechanisms of action for Alpha1H demonstrated in the laboratory experiments and in animal studies.

Alpha1H triggers 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). The cell shedding response was seen each time the patients received Alpha1H (Visit 1-6) but not in the placebo group. A similar increase was observed for tumor fragments, which were released into the urine of patients receiving Alpha1H (P<0.0001).

Alpha1H | Placebo

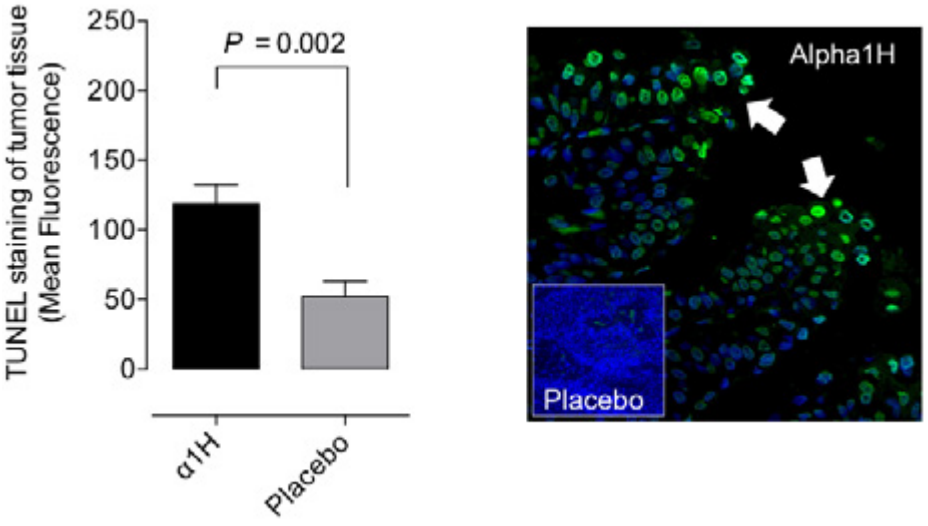


Left panels: Cell shedding into the urine showing a large number of cells (blue) in two samples from the treatment group. ***Right panels:*** Low cell shedding in the placebo group.



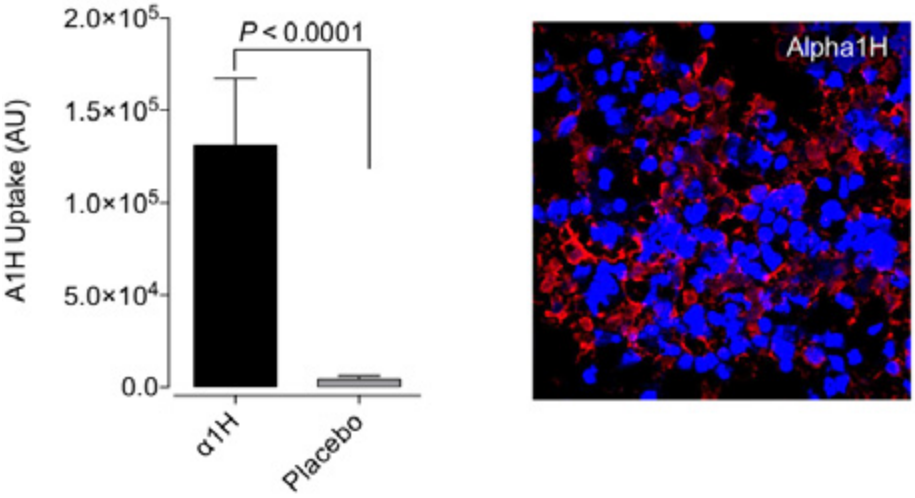
Left panel: Statistic analysis of cell shedding in the treatment and placebo groups.
Right panels: Examples of cell shedding in the treatment group, versus the placebo group. Data obtained at each visit to the clinic (visits 1-6).

Alpha1H triggers cell death in the tumor (apoptosis)
To examine how the tumor responds to Alpha1H, biopsies were obtained from the tumor at the time of surgery. Cell death in the tumor 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.



Left panel: Statistic analysis of cell death in tumor samples from the treatment and placebo groups.
Right panel: Examples of apoptotic cell death (green color) in one tumor sample compared to placebo.

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



Left panel: Statistic analysis of Alpha1H uptake in tumor cellsfrom the treatment and placebo groups.
Right panel: Alpha1H staining in one tumor sample (red color) from the treatment group. Cell nuclei are shown in blue.

The results reveal clear differences between the Alpha1H and placebo groups, supporting the safety and therapeutic efficacy of Alpha1H.

DOSE-ESCALATION STUDY
Positive results in an animal model of bladder cancer have convincingly shown that the treatment effect of Alpha1H increases with the dose. Hamlet Pharma is therefore extending the clinical trial program to include a dose escalation part. The Czeck authority SUKL, has approved dose-escalation as an extention of the ongoing study.

The necessary and technically challenging production of larger volumes of Alpha1H have been successful and the formulation for the dose escalation study is now complete. The final quality controls are ongoing to ensure compliance with current guidelines. Due to technical issues during the production, this process has been somewhat delayed. The clinic in Prague has been initiated and is ready to include patients, as soon as the study medication is released by the manufacturer.

ANIMAL TOXICOLOGY FOR BRAIN CANCER
On December 18, 2019, the company initiated a GLP study to evaluate if intracerebral infusion of Alpha1H has any toxic effects in the treatment of brain tumors. It is anticipated that Alpha1H will be infused intracerebrally for at least one week in humans in order to evaluate its effects on the disease, either alone or in combination with other drugs. To assess the risk of side effects in clinical studies, it is necessary to first determine whether infusions of Alpha1H cause any adverse effects in animals and a toxicology study will therefore be performed by Adlego Biomedical. Adlego has previously performed the toxicology studies of Alpha1H in preparation of the ongoing Phase I/II clinical trial in bladder cancer patients.

Significant events following the second quarter

On February 3, 2020 the company generate an additional capital of KSEK 12,937 by issuing subscription warrants. The funding is in line with a resolution adopted by the Annual General Meeting (AGM) on November 22, 2018.

On February 5, 2020 the company announced a new, pre-clinical discovery showing that Alpha1H also improves the therapeutic efficacy of other cancer drugs such as Mitomycin C and Epirubicin. By combining Alpha1H with low doses of these chemotherapeutic agents, an increase in treatment efficacy was observed in a cancer model in mice. The findings suggest that in addition to acting as a cancer drug on its own, Alpha1H may be used in combination with chemotherapy, to further improve therapeutic efficacy.

These new findings broaden the potential to use Alpha1H in bladder cancer and other cancer indications. Combination therapy is widely used in cancer patients, to increase efficacy and reduce the amount of side effects. A preliminary statement from the Czech authority, SUKL, indicated that it will be possible to include combination therapy as one more variable in the ongoing bladder cancer study, in addition to the analysis of Alpha1H alone.

Figures

SECOND QUARTER (OCT 1, 2019-DEC 31, 2019)
– Revenue for the second quarter totalled KSEK 0 (0)
– Loss before tax amounted to KSEK -7,986 (-3,342)
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– Loss per share* was SEK -0.2448 (-0.1091), and SEK -0.2375 after dilution

FIRST HALF (JUL 1, 2019-DEC 31, 2019)
– Revenue for the first half totalled KSEK 0 (0)
– Loss before tax amounted to KSEK -10,730 (-6,322)
– Loss after tax amounted to KSEK -10,730 (-6,322)
– Loss per share* was SEK -0.3289 (-0.2064), and SEK -0.3191 after dilution
– At December 31, 2019, the equity/assets ratio** was 80.0 (84.6)%

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

* Profit/loss after tax for the period divided by 32,624,899 (30,624,899) and 33,624,899 shares, respectively, where 32,624,899 is the number of shares outstanding at December 31, 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 December 31, 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 51,72% 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 PhaseI/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. Alpha1H has been granted patents in both Europe and the US.

Revenue and earnings

During the second 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 production of the drug candidate Alpha1H for the ongoing clinical trial in patients with bladder cancer. The team at Lund University is also responsible for the 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 the ongoing GLP study in mice and the ongoing clinical trial in patients. Loss before tax for the first half was KSEK -10,730 (-6,322). Loss before tax for the second quarter was KSEK -7,986 (-3,342).

Financial position

The Company have issued the first serie of subscription warrants in October. This brought the Company KSEK 12,950. The issuance costs of a modest KSEK 13, generating KSEK 12,937 net.

Further, The Company also have issued the second serie of subscription warrants in February 2020, after the second quarter. This also brought the Company KSEK 12,950. The issuance costs were KSEK 13, again generating KSEK 12,937 net.

At the end of the second quarter, the equity/assets ratio was 80.0% (84.6)%, and the Company's cash and cash equivalents were KSEK 11,622 (9,174).

For more information, please 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 second quarter.

The share

At December 31, 2019, the number of shares totalled 32,624,899. 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.

New share issue 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. The issuance costs of a modest KSEK 13, generating KSEK 12,937 net. The second series of subscription warrants, after the second quarter, generated an additional KSEK 12,937 net in February 2020.

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

Interim report for Q3, 2019/2020	May 22, 2020
Year-end report for 2019/2020	August 28, 2020
Annual Report for 2019/2020	November 5, 2020
Interim report for Q1, 2020/2021	November 12, 2020
Annual General Meeting for 2019/2020	November 26, 2020

Income statement

SEK	2019-10-01 2019-12-31	2018-10-01 2018-12-31	2019-07-01 2019-12-31	2018-07-01 2018-12-31	2018-07-01 2019-06-30
Net sales	0	0	0	0	0
Operating income	**0**	**0**	**0**	**0**	**0**
Other external costs	-7,571,042	-2,693,724	-9,855,356	-5,178,146	-14,514,793
Employee benefit expenses	-454,448	-578,407	-881,955	-1,006,904	-2,213,402
Depreciation of tangible assets	-9,000	-78,756	-18,000	-157,512	-315,024
Other operating expenses	48,807	7,644	26,130	19,972	-59,524
Operating Profit/Loss	**-7,985,683**	**-3,343,243**	**-10,729,181**	**-6,322,590**	**-17,102,743**
Financial items	-366	973	-366	358	-242
Profit/Loss before tax	**-7,986,049**	**-3,342,270**	**-10,729,547**	**-6,322,231**	**-17,102,985**
Tax on loss for the period	0	0	0	0	0
Profit/Loss after tax	**-7,986,049**	**-3,342,270**	**-10,729,547**	**-6,322,231**	**-17,102,985**

Balance sheet

ASSETS, SEK	2019-12-31	2018-12-31	2019-06-30
Non-current assets			
Property, plant and equipment	63,000	238,512	81,000
Total Non-current assets	**63,000**	**238,512**	**81,000**
Current assets			
Other receivables	743,793	379,015	485,463
Prepaid expenses	377,945	228,527	101,205
Cash and bank balances	11,622,223	9,173,654	10,617,570
Total current assets	**12,743,960**	**9,781,196**	**11,204,238**
TOTAL ASSETS	**12,806,960**	**10,019,708**	**11,285,238**

EQUITY & LIABILITIES, SEK	2019-12-31	2018-12-31	2019-06-30
Restricted equity			
Share capital	978,747	918,747	948,747
Statutory reserve	20,000	20,000	20,000
Total restricted equity	**998,747**	**938,747**	**968,747**
Non-restricted equity			
Share premium reserve	71,941,109	48,725,414	59,033,909
Retained earnings	-51,968,760	-34,865,775	-34,865,775
Profit/Loss for the period	-10,729,547	-6,322,231	-17,102,985
Total non-restricted equity	**9,242,801**	**7,537,407**	**7,065,148**
Total equity	**10,241,548**	**8,476,154**	**8,033,895**
Current liabilities			
Accounts payable	1,980,607	544,761	2,251,704
Other liabilities	81,370	176,489	246,041
Accrued expenses	503,436	822,304	753,598
Total current liabilities	**2,565,412**	**1,543,554**	**3,251,343**
TOTAL EQUITY & LIABILITIES	**12,806,960**	**10,019,708**	**11,285,238**

Cash flow statement

SEK	2019-10-01 2019-12-31	2018-10-01 2018-12-31	2019-07-01 2019-12-31	2018-07-01 2018-12-31	2018-07-01 2019-06-30
Operating activities					
Profit/Loss after financial items	-7,986,049	-3,342,271	-10,729,547	-6,322,231	-17,102,985
Adjusted for non-cash items, etc.	9,000	78,756	18,000	157,512	315,023
Cash flow from operating activities before changes in working capital	**-7,977,049**	**-3,263,515**	**-10,711,547**	**-6,164,719**	**-16,787,961**
Cash flow from changes in working capital					
Change in current receivables	-154,443	182,237	-535,070	98,591	119,465
Change in current liabilities	1,775,818	-111,105	-685,930	-221,653	1,486,135
Cash flow from operating activities	**-6,355,673**	**-3,192,383**	**-11,932,548**	**-6,287,781**	**-15,182,360**
Investing activities					
Acquisition of tangible assets	0	0	0	0	0
Cash flow from investing activities	**0**	**0**	**0**	**0**	**0**
Financing activities					
New share and subscription warrant issues	12,950,000	0	12,950,000	0	10,350,000
Issuance costs	-12,800	0	-12,800	0	-11,505
Cash flow from financing activities	**12,937,200**	**0**	**12,937,200**	**0**	**10,338,495**
Cash flow for the period	**6,581,527**	**-3,192,383**	**1,004,652**	**-6,287,781**	**-4,843,865**
Cash and cash equivalents at the beginning of the period	**5,040,696**	**12,366,037**	**10,617,570**	**15,461,436**	**15,461,436**
Cash and cash equivalents at the end of the period	**11,622,222**	**9,173,654**	**11,622,222**	**9,173,654**	**10,617,570**

Equity

Equity (SEK)	Share capital	Statutory reserve	Non-restricted reserves	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			-17,102,985	17,102,985	0
Loss for the period, Q1				-2,743,498	-2,743,498
Subscription warrants	30,000		12,907,200		12,937,200
Loss for the period, Q2				-7,986,049	-7,986,049
Equity December 31, 2019	**978,747**	**20,000**	**19,972,348**	**-10,729,547**	**10,241,548**

Malmö, February 28, 2020

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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HAMLET PHARMA

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