



**HAMLET** PHARMA

# Q3

**Interim report July 2018-March 2019**

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

# Significant events in the third quarter

During the period, the Company delivered significant results.

## 1. New capital injection

On February 1, 2019, the Board decided to implement a private placement of shares, to generate an initial contribution of approximately MSEK 10, with an option to inject an additional MSEK 25 into the Company by exercising subscription warrants until Q1 2020. The decision is in line with a resolution adopted by the Annual General Meeting (AGM) on November 22, 2018, which authorized the Board to seek new funding. The capital injection will enable Hamlet Pharma to continue its operations, start new clinical activities and develop the Alpha1H candidate into a new drug.

## 2. Bladder cancer trial

In the third quarter, we were focused on the continued recruitment of patients to include the 40 patients defined in the protocol. The doctors and staff involved in the trial are doing a fantastic job. Our plan, as previously communicated, is to end the clinical trial in June. We are therefore in a very labor-intensive period and performing continuous assessments of the samples that form the basis of the clinical trial analysis. By working pro-actively, we are hoping to have materials ready for a prompt analysis of the results following the last subject, last visit.

## 3. Follow-up of long-term effects

On February 7, the Company announced that the Czech regulator had approved an extension of the ongoing trial whereby patients would be tracked for an additional two years after an initial evaluation. Such an evaluation is highly important for understanding the long-term effects of our Alpha1H drug candidate. In the ongoing trial, patients are treated for one month and the effects are studied in conjunction with the administration of Alpha1H. Now that we have received the regulator's approval, we will be studying any long-term effects and comparing the test group treated with Alpha1H with the control group that received a placebo. The patients will be examined at various times throughout the two-year period, and any relapses will be reported and recorded. Patients who have participated in the trial are benefited by a thorough long-term follow-up after the completion of their trial treatment.

## 4. Continued Alpha1H manufacturing for clinical trials

On March 8, the Company announced the conclusion of an agreement with PolyPeptide Laboratories Holding (PPL) AB regarding the manufacture of a new batch of the peptide (Alpha1H) for forthcoming large-scale clinical trials. PPL is a world-leading contract manufacturer of peptides and peptide-related molecules, and certified by authorities in several countries. This means that the Good Manufacturing Practices (GMP) for drugs have been met. With higher available volumes of the agent, the Company will be able to conduct a dose-finding trial in patients with bladder cancer and then commence the planning of larger trials. New batches will also make it possible to study new cancer indications.

## **5. Patents**

We are continuing to expand the Company's patent portfolio with a clear strategy for protecting our intellectual property and a commercially relevant focus for our patent applications. During the quarter, our research made progress in terms of the patent application for nutraceuticals – or dietary supplements. As previously communicated, this patent has been granted in Europe and we are hoping to achieve the same success in the US.

Patents have already been granted for recombinant HAMLET in 11 other countries around the world, with one patent pending in Canada. We have also filed a patent application in the US for the prevention of gastrointestinal (GI) cancer.

## **6. Media and international focus**

Hamlet Pharma has initiated a partnership with an international communications agency to support the Company's English-language website and to increase Hamlet Pharma's global presence through its network.

Following the Company's press release announcing the end date for the ongoing bladder cancer trial (April 16), The Times published an article on breast milk, Alpha1H and cancer. An interview with BBC Science & Nature was published as a BBC Science & Nature Podcast and the interview is available on the BBC Science Focus website. An interview in The Daily Mail, which has previously followed our research, led to a new article.

A number of major news media also expressed an interest in following the results of the bladder cancer trial, including BBC News, The Daily Telegraph, The Guardian and The Independent. It is gratifying to see how attention from the international press is growing and how the Company's progress is increasingly attracting media interest.

On 8 April, Hamlet Pharma also presented the company at the Women's Night of the Swedish Shareholders' Association in Stockholm, Sweden. Follow this link to view the presentation:

<https://youtu.be/vy4qUTw41Co>

The Company has also received media attention in Sweden, most recently in an analysis carried out by the digital service SvD Børsplus on May 6, 2019.

## **7. Board of Directors**

On March 19, 2019, we announced the sudden passing of Board member Dr Bengt Furberg. Since the AGM on November 22, 2018 decided that the Board would consist of five members without any deputies, there is now one vacant Board position.

## Figures

### THIRD QUARTER (1 JAN 2019-31 MAR 2019)

- Revenue for the third quarter totaled KSEK 0 (0)
- Loss before tax amounted to KSEK -4,116 (-5,297)
- Loss after tax amounted to KSEK -4,116 (-5,297)
- Loss per share\* was SEK -0.1301 (-0.1730), and SEK -0.1224 after dilution

### NINE MONTHS (1 JUL 2018-31 MAR 2019)

- Revenue for the nine month period totaled KSEK 0 (0)
- Loss before tax amounted to KSEK -10,438 (-12,873)
- Loss after tax amounted to KSEK -10,438 (-12,873)
- Loss per share\* was SEK -0.3301 (-0.4203), and SEK -0.3104 after dilution
- At March 31, 2019, the equity/assets ratio\*\* was 86.5% (84.3)

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 March 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 March 31, 2018.

\*\* Equity divided by total capital.

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## New capital injection

The AGM on November 22, 2018 authorized the Board to seek new funding. On February 1, 2019, the Board decided to implement a private placement of shares, to generate an initial contribution of KSEK 10,338 net, with an option to inject an additional MSEK 25 into the Company by exercising subscription warrants until Q1 2020. The share issue was registered on February 15 at the Swedish Companies Registration Office. The issue will enable Hamlet Pharma to continue its operations, and to run the project to develop the Alpha1H candidate into a new drug.



## Comments

Hamlet Pharma is working intensively to evaluate the sample material collected in the Phase I/II trial in patients with bladder cancer before the trial ends. The Company is also preparing for the continued development of Alpha1H into a drug for bladder cancer and other types of cancer. New research findings are also broadening the patent portfolio, as well as Hamlet Pharma's ability to design strategies for new drug candidates alongside the development of Alpha1H.

We are extremely grateful for the invaluable expertise contributed by our Board members, employees and partners. We are grateful for our shareholders' trust and are looking forward to the analysis of the trial and the exciting challenges ahead.

**Catharina Svanborg and Mats Persson**

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

## Hamlet Pharma AB

Hamlet Pharma, whose shares are traded on Spotlight Stock Market, is a company 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 agent 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 tumor 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 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 an effect 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

In the first nine months of the financial year, 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, and to implementation of the clinical trial in bladder cancer patients. The research led to new patent applications during the financial year. 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. 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 three quarters was KSEK -10,438 (-12,873). In the third quarter of the financial year, sales amounted to KSEK 0 (0) and loss before tax was KSEK -4,116 (-5,297).

## Financial position

In the third quarter, the Company issued new shares totaling KSEK 10,350, with issuance costs of a modest KSEK 12, which generated KSEK 10,338 net. The share issue was registered on February 15 at the Swedish Companies Registration Office. In addition, the Board decided to issue subscription warrants. Read more about subscription warrants below.

At the end of the quarter, the equity/assets ratio was 86.5% (84.3). The Company's cash and cash equivalents amounted to KSEK 16,340 (20,365) at the end of the quarter.

## Cash flow and investments

The new share issue described above generated net proceeds of KSEK 10,338 for the Company. 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 nine months.

## The share

At March 31, 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.

## 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 approximately MSEK 36 in proceeds for the Company if fully exercised. The decision comprises 1,000,000 shares, 1,000,000 subscription warrants of series 2019 and 1,000,000 subscription warrants of series 2020 (units) with the following terms.

Each unit comprises one share\*, one subscription warrant that may be exercised between September 30-October 4, 2019 and one subscription warrant that may be exercised between January 27-31, 2020. The right to subscribe for units will be offered to the following people, who also subscribed for all units in accordance with the decision.

<b>Eligible for subscription</b>	<b>Number of units</b>
Östen Carlsson	200,000
Erik Lindbärg	350,000
Tobias Persson Rosenqvist	350,000
Kristian Kierkegaard	100,000

The subscription price is SEK 10.35 per unit. The subscription price corresponds to the volume-weighted average price of the Company's share during the ten trading days prior to the decision. The subscription warrants will be issued without consideration but may only be subscribed for as part of a unit. One subscription warrant series 2019 entitles the holder to subscribe for one new share at a subscription price of SEK 12.95 from September 30-October 4, 2019. One subscription warrant series 2020 entitles the holder to subscribe for one new share at a subscription price of SEK 12.95 from September 27-October 31, 2020. The subscription period ends on February 1, 2019. The subscribed units must be paid for within ten days of subscribing.

The Board's decision means that the Company's share capital will increase by a maximum of SEK 30,000 by issuing a maximum of 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.

### **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**

Year-end report for 2018/19	August 30, 2019
Interim report for Q1, 2019/20	November 8, 2019
Annual General Meeting for 2018/19	November 21, 2019

# Income statement

SEK	Jan 1, 2019- 31 Mar 2019	Jan 1, 2018- 31 Mar 2018	Jul 1, 2018- 31 Mar 2019	Jul 1, 2017- 31 Mar 2018	Jul 1, 2017- 30 Jun 2018
Net sales	0	0	0	0	0
Other operating income	0	0	0	0	0
<b>Operating income</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>
Other external costs	-3,601,442	-4,866,897	-8,779,588	-11,955,177	-14,574,525
Employee benefit expenses	-425,970	-413,241	-1,432,874	-779,400	-1,291,233
Depreciation of tangible assets	-78,756	-9,000	-236,268	-27,000	-315,023
Other operating expenses	-9,657	-7,410	10,314	-109,832	-116,487
<b>Operating loss</b>	<b>-4,115,826</b>	<b>-5,296,548</b>	<b>-10,438,416</b>	<b>-12,871,409</b>	<b>-16,297,267</b>
Financial items	-100	-469	258	-1,753	-1,753
<b>Loss before tax</b>	<b>-4,115,926</b>	<b>-5,297,017</b>	<b>-10,438,158</b>	<b>-12,873,162</b>	<b>-16,299,020</b>
Tax on loss for the period	0	0	0	0	0
<b>Loss after tax</b>	<b>-4,115,926</b>	<b>-5,297,017</b>	<b>-10,438,158</b>	<b>-12,873,162</b>	<b>-16,299,020</b>

# Balance sheet

<b>ASSETS, SEK</b>	31 Mar 2019	31 Mar 2018	30 Jun 2018
<b>Fixed assets</b>			
Tangible assets	159,756	126,000	396,024
<b>Total fixed assets</b>	<b>159,756</b>	<b>126,000</b>	<b>396,024</b>
<b>Current assets</b>			
Other receivables	333,225	864,196	421,738
Prepaid expenses	155,908	252,419	284,395
Cash and bank balances/financial investments	16,339,989	20,364,967	15,461,436
<b>Total current assets</b>	<b>16,829,122</b>	<b>21,481,582</b>	<b>16,167,569</b>
<b>TOTAL ASSETS</b>	<b>16,988,878</b>	<b>21,607,582</b>	<b>16,563,593</b>
<b>EQUITY &amp; LIABILITIES, SEK</b>	31 Mar 2019	31 Mar 2018	30 Jun 2018
<b>Restricted equity</b>			
Share capital	948,747	918,747	918,747
Statutory reserve	20,000	20,000	20,000
<b>Total restricted equity</b>	<b>968,747</b>	<b>938,747</b>	<b>938,747</b>
<b>Non-restricted equity</b>			
Share premium reserve	59,033,909	48,725,414	48,725,414
Retained earnings	-34,865,775	-18,566,755	-18,566,755
Loss for the period	-10,438,158	-12,873,162	-16,299,020
<b>Total non-restricted equity</b>	<b>13,729,975</b>	<b>17,285,497</b>	<b>13,859,638</b>
<b>Total equity</b>	<b>14,698,722</b>	<b>18,224,244</b>	<b>14,798,385</b>
<b>Current liabilities</b>			
Accounts payable	1,546,110	2,435,137	830,213
Other liabilities	80,755	19,533	55,417
Accrued expenses	663,290	928,668	879,577
<b>Total current liabilities</b>	<b>2,290,155</b>	<b>3,383,338</b>	<b>1,765,207</b>
<b>TOTAL EQUITY &amp; LIABILITIES</b>	<b>16,988,878</b>	<b>21,607,582</b>	<b>16,563,593</b>

# Cash flow statement

SEK	Jan 1, 2019- 31 Mar 2019	Jan 1, 2018- 31 Mar 2018	Jul 1, 2018- 31 Mar 2019	Jul 1, 2017- 31 Mar 2018	Jul 1, 2017- 30 Jun 2018
<b>Operating activities</b>					
Loss after financial items	-4,115,926	-5,297,017	-10,438,158	-12,873,162	-16,299,020
Adjusted for non-cash items, etc.	78,756	9,000	236,268	27,000	315,023
<b>Cash flow from operating activities before changes in working capital</b>	<b>-4,037,170</b>	<b>-5,288,017</b>	<b>-10,201,890</b>	<b>-12,846,162</b>	<b>-15,983,997</b>
<b>Cash flow from changes in working capital</b>					
Change in current receivables	118,409	-492,459	217,000	-700,695	-290,213
Change in current liabilities	746,601	1,658,797	524,948	1,552,040	-66,091
<b>Cash flow from operating activities</b>	<b>-3,172,160</b>	<b>-4,121,679</b>	<b>-9,459,942</b>	<b>-11,994,817</b>	<b>-16,340,301</b>
<b>Investing activities</b>					
Acquisition of tangible assets	0	0	0	0	-558,047
<b>Cash flow from investing activities</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>-558,047</b>
<b>Financing activities</b>					
New share and subscription warrant issues	10,350,000	0	10,350,000	0	0
Issuance costs	-11,505	0	-11,505	0	0
<b>Cash flow from financing activities</b>	<b>10,338,495</b>	<b>0</b>	<b>10,338,495</b>	<b>0</b>	<b>0</b>
<b>Cash flow for the period</b>	<b>7,166,335</b>	<b>-4,121,679</b>	<b>878,553</b>	<b>-11,994,817</b>	<b>-16,898,348</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>9,173,654</b>	<b>24,486,648</b>	<b>15,461,436</b>	<b>32,359,784</b>	<b>32,359,784</b>
<b>Cash and cash equivalents at the end of the period</b>	<b>16,339,989</b>	<b>20,364,969</b>	<b>16,339,989</b>	<b>20,364,967</b>	<b>15,461,436</b>

# Equity

Equity (SEK)	Share capital	Statutory re- serve	Non-restricted re- serves	Profit/loss for the period	Total
<b>Opening balance July 1, 2018</b>	<b>918,747</b>	<b>20,000</b>	<b>30,158,659</b>	<b>-16,299,020</b>	<b>14,798,385</b>
Transfer of prior year's profit/loss			-16,299,020	16,299,020	0
Profit/loss for the period, Q1				-2,979,961	-2,979,961
Profit/loss for the period, Q2				-3,342,271	-3,342,271
New share issue	30,000		10,308,495		10,338,495
Profit/loss for the period, Q3				-4,115,926	-4,115,926
<b>Equity at March 31, 2019</b>	<b>948,747</b>	<b>20,000</b>	<b>24,168,133</b>	<b>-10,438,157</b>	<b>14,698,723</b>

**Malmö, May 17, 2019**

Catharina Svanborg  
**Chairperson of the Board**

Bengt Westermark  
**Board member**

Christer Köhler  
**Board member**

Helena Lomberg  
**Board member**

Mats Persson  
**CEO**



**HAMLET** PHARMA

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