



HAMLET PHARMA

Q3

Interim report January – March 2020

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

Opening remarks

Hamlet Pharma can report significant progress during the third quarter of the financial year 2019-2020.

In February, the company raised 12.937 million SEK by issuing subscription warranties. In March, Hamlet Pharma received a major EU grant in strong international competition. The company was granted about 23 million SEK from the EIC Accelerator fund of the Horizon 2020 program. The EU grant is a significant quality stamp, confirming the company's achievements and future potential. The EU program is awarded to strengthen further clinical research, pharmaceutical development and company growth, including the recruitment of financial and business development expertise.

Significant research advances have been made and Hamlet Pharma has continued preparations to be ready to resume clinical trials, when national authorities and local hospital authorities give the green light for such activities.

We thank our share holders for their support and wish everyone continued good health and a nice summer. Improving human health is and remains our focus and we will continue to do our very best to develop new treatments for cancer patients.

Catharina Svanborg

Chairperson of the Board & CMO

Mats Persson

CEO

Significant events during the third quarter

FINANCIAL DEVELOPMENTS

Warranties

On February 3, 2020, Hamlet Pharma raised 12.937 million SEK by issuing subscription warranties in line with the resolution adapted by the Annual General Meeting (AGM) in 2018 and a board meeting decision from February 2019. The issuance costs were modest (KSEK 13).

EU grant to small and medium sized companies

As reported in a press release dated March 9th, 2020, Hamlet Pharma has been awarded a grant of € 2.2M from the EU's prestigious Horizon 2020 EIC Accelerator Fund. This grant indicates a very high level of confidence in the project entitled "Alpha 1H – A Unique Bladder Cancer Therapeutic, Acting with Great Precision". The funds will be paid incrementally during the project's 24-month duration.

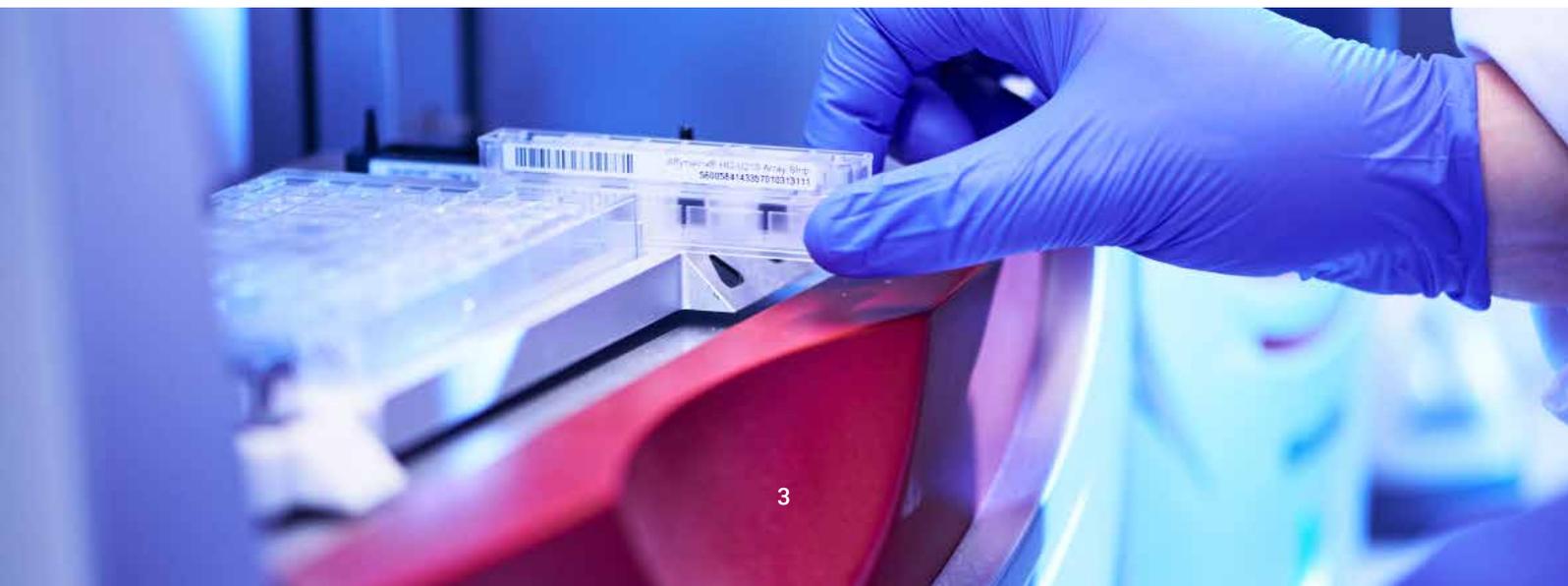
The award increases international visibility, placing Hamlet Pharma among the most promising new pharmaceutical companies in Europe. Moreover, the grant opens doors to the EU market and helps building our network with international companies. The EU program brings us closer to potential partners and enhances the focus on clinical research, pharmaceutical development and business development.

The timing of EU funding was very fortunate in view of the current uncertainty in many global financial markets. We are proud to say that Hamlet Pharma is financially stable, with no immediate need to raise further capital. We will follow the strategic plan for expansion of clinical research and product development programs, as well as business development and partnering.

CLINICAL AND SCIENTIFIC DEVELOPMENTS

The positive outcome of the clinical study in patients with bladder cancer has strengthened HAMLET Pharma's strategy to develop Alpha1H as a new stand-alone treatment in patients with early stage bladder cancer, also known as non-muscle-invasive bladder cancer (NMIBC). The EU funding will allow us to complete the dose escalation trial, start combination studies and design and plan the next development phase towards phase III. This will be done in close collaboration with our network of international Key Opinion Leaders.

Data from the bladder cancer study have been compiled into a manuscript and submitted for publication in March 2020. The results include preclinical and clinical data as well as a third party evaluation of the tumor effects. Advanced laboratory technology has been used to determine the molecular effects of Alpha1H on tumor tissues, changes in the expression of genes and proteins and other variables. We expect feedback from the journal within a few months.





Hamlet Pharma has received permission from the Czech authorities to perform a dose-escalation trial to help define the optimal dose for further clinical trials. The dose-escalation approach was based on studies in animal models of bladder cancer, where increasing doses of Alpha1H were shown to markedly increase the therapeutic effects, without a parallel increase in toxicity for healthy tissues. The paper describing this study has been recently accepted for publication in the International Journal of Cancer.

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. Combination treatment is widely used in cancer therapy to increase efficacy and reduce the amount of side effects. Therefore, these findings broaden the potential use of Alpha1H in patients with bladder cancer. The plan is to include combination therapy of Alpha1H with Epirubicin in the ongoing clinical trial as one more treatment option, in addition to the analysis of Alpha1H alone.

PHARMACEUTICAL DEVELOPMENT

In partnership with external Contract Manufacturing Organizations (CMOs), Hamlet Pharma is developing a drug formulation of Alpha1H suitable for phase III clinical studies and commercialization. The objective is to achieve bedside efficacy, a longer shelf life and a formulation suitable for new indications.

BUSINESS DEVELOPMENT

The EU grant has highlighted the importance of developing issues of business development and commercialization. Part of the EU funding is specifically allocated to promoting company growth. Hamlet Pharma is recruiting dedicated experts in business development, financing and marketing to join our team. Through the EU organization, Hamlet Pharma will be supported by international coaches with the aim to connect the company to potential licensing partners and to develop pricing and reimbursement strategies.

EFFECTS OF COVID 19

The COVID-19 pandemic has negatively affected many companies, including those involved in R&D activities. The European Medicines Agency (EMA) has acknowledged the impact of COVID-19 on the health care system and on clinical trials. For instance, travel restrictions and confinements of trial participants may occur and the availability of trial staff may be altered. Hamlet Pharma is following the development in close contact with the clinical partners and is preparing to initiate the clinical studies as soon as possible.

Significant events after the third quarter

LICENSING OF BAMLET FOR NON-PHARMACEUTICAL DEVELOPMENT

Alpha-lactalbumin from cow's milk binds oleic acid and forms BAMLET (Bovine alpha-lactalbumin made lethal to tumor cells). This bovine alpha-lactalbumin complex kills tumor cells and may be of interest for future drug development in the Hamlet Pharma portfolio. The ownership of the BAMLET patents therefore resides with Hamlet Pharma.

In addition, based on its origin in cow's milk, the Bamlet molecule may have beneficial health effects that would be useful for nutritional or other non-pharmaceutical purposes. This potential cannot be realized by Hamlet Pharma, whose mission is to focus solely on the development of pharmaceuticals. Hamlet Pharma has therefore decided to out-license Bamlet for non-pharmaceutical use. In this process, the importance of the partner's commitment, unique knowledge and experience regarding the Bamlet molecule was emphasized. Linnane Pharma was identified as a suitable partner, fulfilling these criteria.

On May 12th, 2020, Hamlet Pharma signed a patent licensing agreement with Linnane Pharma for the development of Bamlet for non-pharmaceutical purposes. The agreement stipulates that Hamlet Pharma retains the rights to develop Bamlet as a pharmaceutical but licenses to Linnane Pharma the rights to develop Bamlet for other, non-pharmaceutical use. The agreement requires Linnane Pharma to pay to Hamlet

Pharma a royalty at the rate of 10 % on Linnane Pharma's future gross income emanating from the licensed patent rights in the form of product sales, signing fees, option fees, milestones, royalties or similar. Linnane Pharma cannot sublicense without Hamlet Pharma's approval. The agreement is valid for long as the patents protecting the use of Bamlet are valid.

Linnane is a majority shareholder in Hamlet Pharma and SelectImmune and is a research and development hub handling novel discoveries and developments. In this case, Linnane will be responsible for securing the considerable resources that will be required in order get this opportunity ready for commercialisation.

The patent licensing agreement supports Hamlet Pharma's strategy to focus solely on the development of drugs against various cancer types, specifically the clinical development of the drug candidate Alpha1H. Linnane Pharma, through its unique knowledge of the science behind BAMLET, its applications, production and product profiling, is well positioned to effectively realise BAMLET's non-pharmaceutical potential.

Related transaction

Linnane Pharma is the parent company of Hamlet Pharma and owns 50,19 % of the shares.

Figures

THIRD QUARTER (JAN 1, 2020–MAR 31, 2020)

- Revenue for the third quarter totaled KSEK 0 (0)
- Loss before tax amounted to KSEK -6,231 (-4,116)
- Loss after tax amounted to KSEK -6,231 (-4,116)
- Loss per share* was SEK -0.1853 (-0.1301)

NINE MONTHS (JUL 1, 2019–MAR 31, 2020)

- Revenue for the first nine months totaled KSEK 0 (0)
- Loss before tax amounted to KSEK -16,961 (-10,438)
- Loss after tax amounted to KSEK -16,961 (-10,438)
- Loss per share* was SEK -0.5044 (-0.3301)
- At March 31, 2020, the equity/assets ratio** was 75.9 (86.5) %

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 (31,624,899), respectively, where 33,624,899 is the number of shares outstanding at March 31, 2020. The comparative figure in parentheses was the number of shares at March 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 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 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.

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 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 trial in patients with bladder cancer. During the third quarter increased costs for the production of Alpha1H from Polypeptide, to be used for future clinical studies, were taken. 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 nine months was KSEK -16,961 (-10,438).
Loss before tax for the third quarter was KSEK -6,231 (-4,116).

Financial position

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

At the end of the third quarter, the equity/assets ratio was 75.9 (86.5) %, and the Company's cash and cash equivalents were KSEK 21,028 (16,340).

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 third quarter.

The share

At March 31, 2020, the number of shares totaled 33,624,899. 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 totaling 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 series of subscription warrants. The issuance costs of a modest KSEK 13, generating KSEK 12,937 net. In February 2020, the Company received another KSEK 12,950 from redemption of the second series of subscription warrants. The issuance costs of also a modest KSEK 13, generating another KSEK 12,937 net.

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 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	2020-01-01 2020-03-31	2019-01-01 2019-03-31	2019-07-01 2020-03-31	2018-07-01 2019-03-31	2018-07-01 2019-06-30
Net sales	0	0	0	0	0
Operating income	0	0	0	0	0
Other external costs	-5,744,276	-3,601,442	-15,599,632	-8,779,588	-14,514,793
Employee benefit expenses	-466,653	-425,970	-1,348,608	-1,432,874	-2,213,402
Depreciation of tangible assets	-9,000	-78,756	-27,000	-236,268	-315,024
Other operating income	0	0	24,714	10,314	0
Other operating expenses	-1,415	-9,657	0	0	-59,524
Operating Profit/Loss	-6,221,344	-4,115,826	-16,950,525	-10,438,416	-17,102,743
Financial items	-9,995	-100	-10,361	258	-242
Loss before tax	-6,231,339	-4,115,926	-16,960,886	-10,438,158	-17,102,985
Tax on loss for the period	0	0	0	0	0
Loss after tax	-6,231,339	-4,115,926	-16,960,886	-10,438,158	-17,102,985

Balance sheet

ASSETS, SEK	2020-03-31	2019-03-31	2019-06-30
Fixed assets			
Tangible assets	54,000	159,756	81,000
Total fixed assets	54,000	159,756	81,000
Current assets			
Other receivables	1,027,316	333,225	485,463
Prepaid expenses	223,459	155,908	101,205
Cash and bank balances/financial investments	21,028,266	16,339,989	10,617,570
Total current assets	22,279,041	16,829,122	11,204,238
TOTAL ASSETS	22,333,041	16,988,878	11,285,238
EQUITY & LIABILITIES, SEK	2020-03-31	2019-03-31	2019-06-30
Restricted equity			
Share capital	1,008,747	948,747	948,747
Statutory reserve	20,000	20,000	20,000
Total restricted equity	1,028,747	968,747	968,747
Non-restricted equity			
Share premium reserve	84,848,309	59,033,909	59,033,909
Retained earnings	-51,968,760	-34,865,775	-34,865,775
Loss for the period	-16,960,886	-10,438,158	-17,102,985
Total non-restricted equity	15,918,662	13,729,975	7,065,148
Total equity	16,947,409	14,698,722	8,033,895
Current liabilities			
Accounts payable	4,099,080	1,546,110	2,251,704
Other liabilities	91,113	80,755	246,041
Accrued expenses	1,195,439	663,290	753,598
Total current liabilities	5,385,632	2,290,155	3,251,343
TOTAL EQUITY & LIABILITIES	22,333,041	16,988,878	11,285,238

Cash flow statement

SEK	2020-01-01 2020-03-31	2019-01-01 2019-03-31	2019-07-01 2020-03-31	2018-07-01 2019-03-31	2018-07-01 2019-06-30
Operating activities					
Loss after financial items	-6,231,339	-4,115,926	-16,960,886	-10,438,158	-17,102,985
Adjusted for non-cash items, etc.	9,000	78,756	27,000	236,268	315,024
Cash flow from operating activities before changes in working capital	-6,222,339	-4,037,170	-16,933,886	-10,201,890	-16,787,961
Cash flow from changes in working capital					
Change in current receivables	-129,037	118,409	-664,107	217,000	119,465
Change in current liabilities	2,820,219	746,601	2,134,289	524,948	1,486,135
Cash flow from operating activities	-3,531,157	-3,172,160	-15,463,704	-9,459,942	-15,182,361
Financing activities					
New share and subscription warrant issues	12,950,000	10,350,000	25,900,000	10,350,000	10,350,000
Issuance costs	-12,800	-11,505	-25,600	-11,505	-11,505
Cash flow from financing activities	12,937,200	10,338,495	25,874,400	10,338,495	10,338,495
Cash flow for the period	9,406,043	7,166,335	10,410,696	878,553	-4,843,866
Cash and cash equivalents at the beginning of the period	11,622,223	9,173,654	10,617,570	15,461,436	15,461,436
Cash and cash equivalents at the end of the period	21,028,266	16,339,989	21,028,266	16,339,989	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
Subscription warrants	30,000		12,907,200		12,937,200
Loss for the period, Q3				-6,231,339	-6,231,339
Equity March 31, 2020	1,008,747	20,000	32,879,548	-16,960,886	16,947,409

Malmö, May 22, 2020

Catharina Svanborg
Chairperson of the Board

Bengt Westermark
Board member

Christer Köhler
Board member

Helena Lomberg
Board member

Rolf Carlsson
Board member

Mats Persson
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HAMLET PHARMA

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