

A background image of a laboratory setting, featuring a microscope and a person wearing white gloves. The image is overlaid with a light blue tint.

# SCANDION ONCOLOGY



**INTERIM REPORT 01-JAN-2019 – 30-SEP-2019**

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Scandion Oncology A/S | 38613391 | [www.scandiononcology.com](http://www.scandiononcology.com)

# Interim report for the period 01-JAN-2019 – 30-SEP-2019

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*In this document, the following definitions shall apply unless otherwise specified: the “Company” or “Scandion Oncology” refers to Scandion Oncology A/S, CVR number 38613391.*

*Scandion Oncology is focused on developing cancer-fighting drugs that can block or circumvent drug resistance in cancer treatment. In preclinical studies, our candidate drug SCO-101 enhances the efficacy of standard cancer treatment when given in combination with the cancer drug and restores chemotherapy sensitivity in resistant cells. SCO-101 has successfully undergone four Phase I studies and will be dosed shortly in Phase II clinical trials in cancer patients with drug-resistant disease.*

**CEO, Nils Brünner**

## **Statement by the Board of Directors**

The Board of Directors provide their assurance that the interim report provides a fair and true overview of the Company's operations, financial position and results.

Copenhagen, November 21, 2019

The Board of Directors of Scandion Oncology A/S

<i>Peter Høngaard Andersen</i>	<i>Chairman of the Board</i>
<i>Joergen Bardenfleth</i>	<i>Vice-Chairman of the Board</i>
<i>Carl Borrebaeck</i>	<i>Member of the Board of Directors</i>
<i>Christian Vinding Thomsen</i>	<i>Member of the Board of Directors</i>
<i>Thomas Feldthus</i>	<i>Member of the Board of Directors</i>

## Key figures and selected financial posts

	01-JUL-2019 30-SEP-2019	01-JUL-2018 30-SEP-2018	01-JAN-2019 30-SEP-2019	01-JAN-2018 30-SEP-2018	01-JAN-2018 31-DEC-2018
DKK					
Net sales	-	-	-	-	-
Operating profit/loss	(7,030,270)	(1,295,891)	(14,226,261)	(4,357,361)	(9,934,585)
Profit/loss before taxes	(7,281,769)	(1,299,445)	(14,670,092)	(4,361,298)	(9,957,906)
Profit/loss for the period	(6,251,487)	(1,013,567)	(12,076,564)	(3,401,895)	(8,182,558)
Total assets	23,156,998	1,776,608	23,156,998	1,776,608	13,562,750
Equity ratio	0.91	(0.84)	0.91	(0.84)	0.93
Number of registered shares	19,052,241	7,463,207	19,052,241	7,463,207	11,907,651
Earnings per share	(0.33)	(0.14)	(0.63)	(0.46)	(0.85)

### Definitions

Equity ratio: Shareholders' equity as a proportion of total assets.

Earnings per share: Profit/Loss for the period divided by average number of shares.

### **Highlights during the period**

- On July 12<sup>th</sup>, Scandion Oncology announced that the rights issue in the Company was oversubscribed by 200%. Scandion Oncology is provided approx. 29.3 million SEK before issue costs. In addition, if all warrants are fully exercised, Scandion Oncology will in Q3, 2020, obtain additional 12.4 million SEK before issue costs.

### **Highlights after the period**

- On October 1<sup>st</sup>, Scandion Oncology announced that Peter Høngaard Andersen has accepted the role as Chairman of the Board. Jørgen Bardenfleth will continue as Vice Chairman of the Board.
- On October 1<sup>st</sup>, Scandion Oncology announced that the Company has submitted an application to the Danish Medicines Agency for permission to conduct a clinical Phase II study in patients with metastatic colorectal cancer.
- On October 1<sup>st</sup>, Scandion Oncology announced that the report on the in vivo animal data on antibiotic resistance and SOM-001 is extended until mid-Q4 2019 due to shortage in testing slots at the provider.
- On October 14<sup>th</sup>, Scandion Oncology announced that the European Patent Office ("EPO") has granted the company's patent application for SCO-101 when combined with chemotherapy. Patent is valid until May 2037.

## CEO Nils Brünner



The third quarter has now passed, and we have reached a number of important milestones, which have brought Scandion Oncology and its drug candidates forward.

During the quarter, the production of SCO-101 was successfully completed at Cambrex in Sweden and the SCO-101 powder was shipped to Solural, Denmark, where the final tablets were produced. Solural is now ready to deliver the tablets to the hospital departments where the patients will be treated. As planned, we will initiate our first clinical phase II study in Q4 2019.

Scandion Oncology's pipeline of drug candidates is based on excellent scientific work and we believe that our drug candidates have great potential to successfully overcome chemotherapy-resistant cancer. A huge area, which, with positive results and subsequent commercialization, will generate significant value for the company and pave the way for more effective treatment of cancer patients with drug resistant disease. We are now in an exciting period and in the position of initiating our first clinical phase II study. On October 1<sup>st</sup>, we submitted our application to the Danish Medicines Agency for permission to conduct a clinical phase II study in patients with metastatic and drug resistant colorectal cancer. The clinical phase II study will be conducted in two parts. Provided that we soon receive permission from the Danish Medicines Agency and the Regional Danish Ethical committees, the study is initiated in fourth quarter 2019, the data from the first part are expected in Q2 2020 and the final study report will be released in H1 2021. We have optimized trial design and included clinical validation of several predictive biomarkers. The future use of predictive biomarkers will ensure that SCO-101 treatment is administrated only to patients who will respond to the drug e.g. a personalized medicine concept.

We have made progress regarding SOM-001 and are now awaiting the final results from the animal testing: Mice are inoculated with antibiotic resistant bacteria and then treated with control substance or SOM-001 and its analogues.

We recently achieved a very important milestone when we obtained patent approval for SCO-101 from the European Patent Office. For the company, the granting of this first patent is extremely important as it provides

Scandion Oncology with the necessary protection and thereby value when selling SCO-101 to a larger pharma company. By passing this important milestone, Scandion Oncology is one step closer to commercializing SCO-101.

Finally, I was very pleased to announce Peter Høngaard Andersen as the new Chairman of the Board of Scandion Oncology. Peter Høngaard Andersen brings a vast experience in building and running life sciences companies that we can benefit greatly from at Scandion Oncology. I also want to take this opportunity to thank Jørgen Bardenfleth, who has done a terrific job as Chairman. He has led Scandion Oncology through its important first two years with great success.

We are now continuing the work with our drug candidates and look forward to the coming months. I would like to thank all the employees for their solid work and our shareholders for their continued confidence in our operations.

*Nils Brünner*

*CEO*

*Scandion Oncology A/S*

## **About Scandion Oncology**

Scandion Oncology is a clinical stage II biotech company founded in 2017 with the purpose of addressing one of the greatest and most important challenges in modern oncology – the effective treatment of cancer, which is or has become resistant to the prescribed anti-cancer drugs. Scandion Oncology's innovative drug, SCO-101, has in preclinical studies shown that it can reverse resistance against some of the most commonly used anti-cancer drugs.

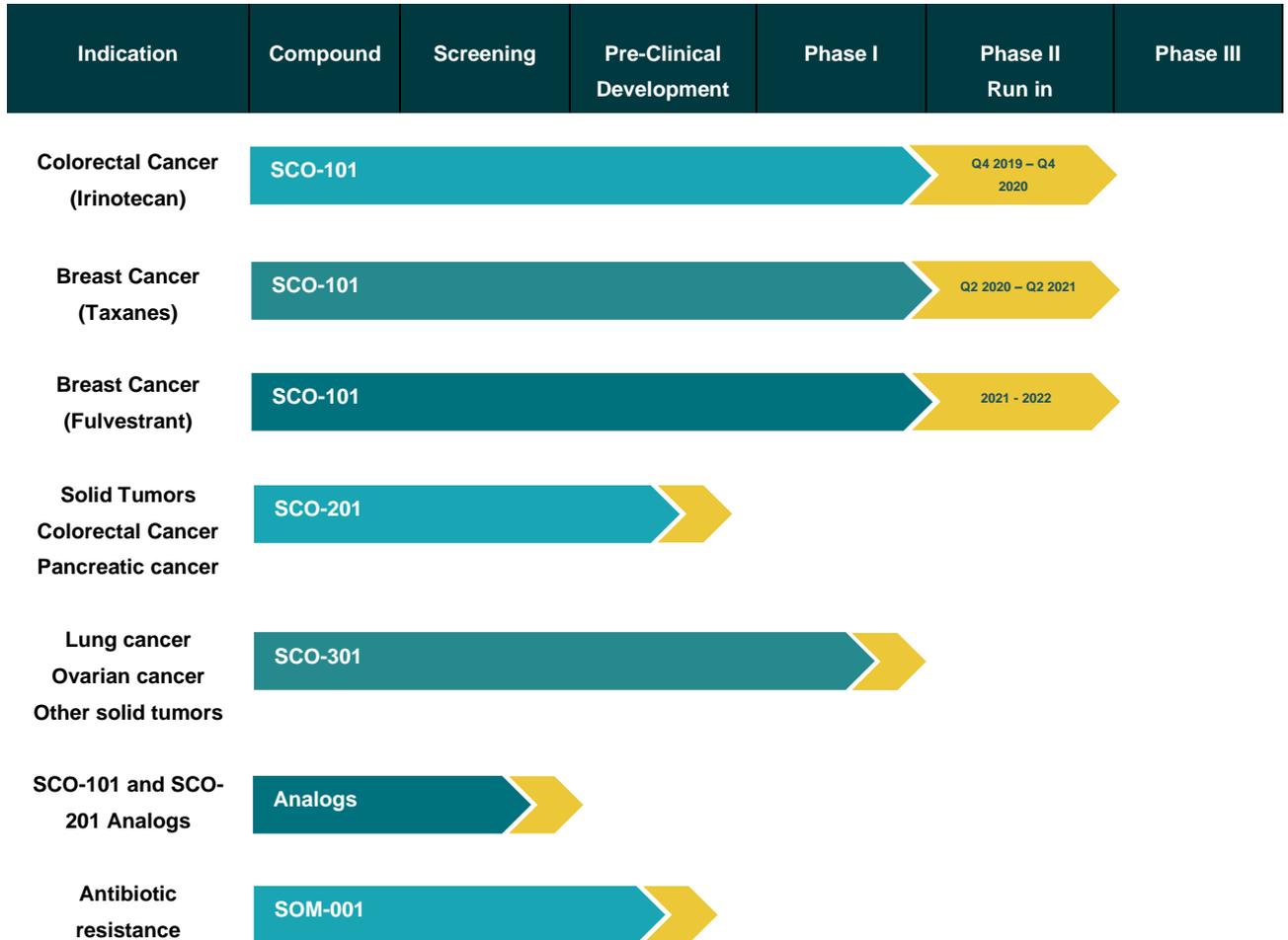
About half of all cancer patients with metastatic disease fail their cancer treatment – largely due to the cancer either being resistant already from the time of the primary diagnosis, or that the cancer acquires resistance during anti-cancer treatment. As a result, the cancer continues to grow despite treatment and after a period of time the patient may lose his/her life to the cancer disease. Therefore, drug resistance is a major treat to cancer patients and a burden on the health and medical care systems. It also presents a significant commercial opportunity for Scandion Oncology.

### **Positive Phase I results for SCO-101**

The candidate drug SCO-101 has been tested in four Phase I studies comprising a total of 92 healthy subjects. SCO-101 is provided as tablets and can as such be taken at home. Overall, the Phase I studies showed that SCO-101 was safe and well tolerated with an excellent pharmacokinetic profile. Based on this positive clinical phase I data, Scandion Oncology has now submitted an application to the Danish Medical Agency for a Phase II clinical trial in patients with chemotherapy-resistant metastatic colorectal cancer.

### Figure 1. Pipeline – Multiple assets targeted several forms of drug resistance

Scandion Oncology has a pipeline consisting of SCO-101, SCO-201 and SCO-301 all of which have been shown to reverse anti-cancer drug resistance in cancer cell lines. Since these compounds/drugs target different resistance mechanisms, Scandion Oncology’s pipeline when fully developed is estimated to cover approximately 60% of all types of chemotherapy.



**Figure 2. Clinical phase II study in patients with metastatic colorectal cancer**



\* In the dose-escalation part it is not possible to exactly know the number of patients needed to be treated in order to reach the Maximum Tolerated Dose. However, we have a predetermined maximal dose of SCO-101 to be administered meaning that we will not exceed 18 patients.

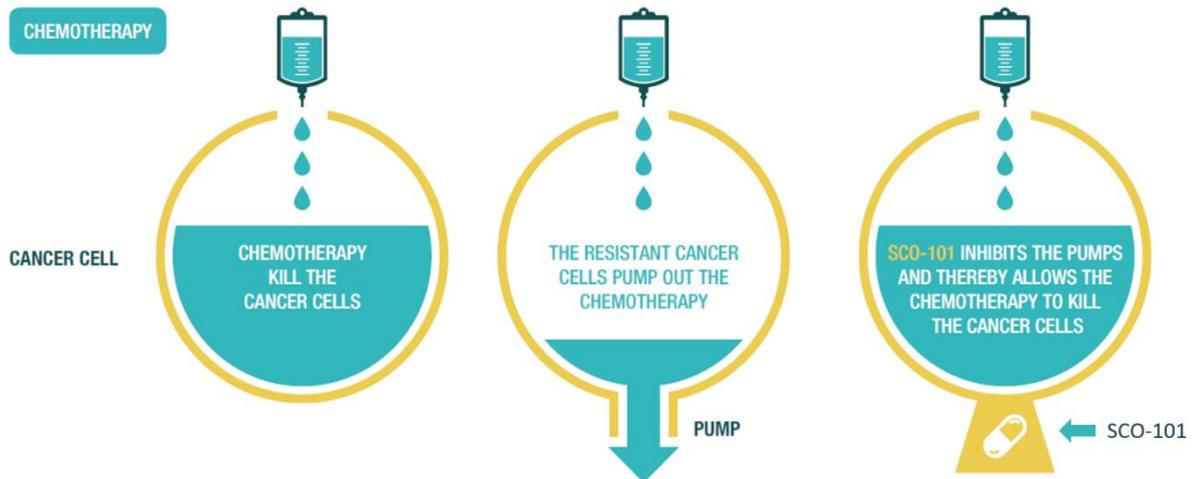
\*\*6 patients from the previous run-in study are included here. Scandion Oncology will need 2 or more responders in order to have Proof of Concept. This means that Scandion will as a maximum include 25 patients but expects to have 2 responders at an earlier time-point.

In the application to the Danish Medical Agency, Scandion Oncology asks for permission to initiate the first clinical phase II study with SCO-101. This study has two parts where the first part will prove safety and tolerability when combining SCO-101 with chemotherapy. Patients will be treated with dose escalation of SCO-101 in combination with standard dose of chemotherapy. At each dose 3 patients will be included. At the last dose escalation of SCO-101 additional three patients (a total of 6 patients) will be treated. Scandion Oncology expects to enrol between 12-18 patients in this first part. The data from the first part will form the basis for defining the Recommended Dose for Phase II (RDP2), which means the dose of SCO-101 to be used in the second part of the phase II study in combination with the standard dose of chemotherapy, and will provide the first indication of efficacy (the last 6 patients will receive the RDP2 of SCO-101). In the second part of the Phase II study an additional 15-25 patients will be enrolled and treated with the RDP2. Upon inclusion, patients are scanned before treatment start and then every 8 weeks during treatment. SCO-101 will be given as a daily oral treatment the first four days and then at the fifth and sixth day the patients will receive chemotherapy in combination with SCO-101. From day 7-14, the patients will be without treatment (drug holiday). These 14 days constitute one treatment cycle. Patients will continue these treatment cycles until progression of their cancer is observed. After finalizing treatment of the last patient, all data from the study will be compiled and presented. Scandion Oncology plans to release interim data after the first part of the study and will further use the phase II study to validate its predictive biomarkers.

### **Mechanisms of Action**

Scandion Oncology has filed patents on the mechanisms of action of SCO-101 when restoring sensitivity to anti-cancer drugs. One mechanism of action of SCO-101 is inhibition of so-called drug efflux pumps (Figure 3). These pumps are located in the membrane of the cells. In resistant cancer cells, the pumps can be 100-1000-fold upregulated and the cancer cells thereby protect themselves against the toxic anti-cancer drugs by pumping the drugs out of the cells before the drugs can kill the cancer cells. Another Mechanism of Action of SCO-101 is inhibition of a specific kinase in cells. By blocking this kinase and its down-stream signalling, we have shown that resistant cells become sensitive to the anti-cancer drugs again.

**Figure 3: Drug resistant cancer cells may upregulate drug efflux pumps and thereby pump out chemotherapy leading to resistance.**



Due to SCO-101 being “First in Class” with new mechanisms of action, Scandion Oncology has already experienced a significant interest from a number of Pharma companies. In addition, chemotherapy continues to be the primary medical treatment modality to fight cancer, and chemotherapy is expected to remain the primary treatment option for the next many years. Immuno-oncological drugs, such as checkpoint inhibitors, are also expected to be utilized in combination with chemotherapy. However, it is estimated that only 20-30% of cancer patients will benefit from the new immuno-oncology drugs, leaving a majority of the patients for chemotherapy or endocrine treatment. Moreover, the combination of check-point inhibitors with chemotherapy will only work if the cancer cells are sensitive to the chemotherapy- and this could be a good reason to add a drug like SCO-101 to the combination treatment. Scandion Oncology estimates that the use of SCO-101 to combat drug resistance to cancer drugs will open a new and important market segment for the major pharmaceutical and biotechnology companies.

## **Business model**

Scandion Oncology was planning to initiate negotiations with major pharma partners after completion of phase II, involving either an out-licensing or co-development agreement of SCO-101. However, as the interest from Pharma companies has been larger than expected, Scandion Oncology will intensify business development activities already early 2020 to identify a future partner for further development of SCO-101. A partnership with a Pharmaceutical company could involve jointly entering into a Phase IIb or III clinical trial with SCO-101, or acquisition of the Scandion Oncology assets eventually leading to an acceleration towards FDA and EMA approval. Either of these options would be a commercial opportunity for Scandion Oncology paving the way for several of the novel compounds in the pipeline of the company, as well as strengthen Scandion Oncology's position in the oncology market.

## Shareholders

The table below presents the 25 largest shareholders (based on nominee accounts) in Scandion Oncology as per Sept 30, 2019.

Name	Number of shares	Votes & capital (%)
Saniona AB	3,473,577	18.23
Avanza Pension	1,904,571	10.00
Nordnet Pensionsförsäkring AB	1,790,775	9.40
Jan Stenvang *	1,421,516	7.46
Nils Brünner**	1,160,435	6.09
Christian René Tang-Jespersen	524,588	2.75
Göran Ofsén	480,000	2.52
Kim Arvid Nielsen	476,765	2.50
Lioneagle ApS***	288,565	1.51
Lars Björkström	231,088	1.21
JPM Chase NA	216,994	1.14
Morten Fadum Nissen	181,105	0.95
Hans Love Ingvard Carlsson	178,306	0.94
Bank Of New York Mellon SA NV / Jyske Bank	143,901	0.76
Bolvig Ejendomme ApS	141,880	0.74
Cecél Kolz	137,900	0.72
Bank Of New York Mellon SA NV	135,814	0.71
Tomas Tymark	135,000	0.71
Martin Svantesson	110,530	0.58
Maor Bracha	106,000	0.56
Tellus Midas	105,000	0.55
CB Ocean Capital AB****	104,035	0.55
Skandia	99,362	0.52
Mads Bjerre-Petersen	95,040	0.50
Other	5,409,494	28.40
<b>Total</b>	<b>19,052,241</b>	<b>100.00</b>

\* CSO, Jan Stenvang.

\*\* CEO, Nils Brünner.

\*\*\* Vice-Chairman of the Board Joergen Bardenfleth.

\*\*\*\* Member of the Board Carl Borrebaeck.

## **The share**

The shares of Scandion Oncology A/S were listed on Spotlight Stock Market on November 8, 2018. The short name/ticker is SCOL and the ISIN code is DK0061031895. As per September 30, 2019, the number of shares was 19,052,241. All shares have equal rights to the Company's assets and results. At the Rights Issue June/July 2019 Scandion Oncology issued 2,381,530 warrants of series TO. The short name/ticker of the Warrants is SCOL TO 1 and the ISIN code is DK0061144078.

## **Operational risks and uncertainties**

The risks and uncertainties that Scandion Oncology's operations are exposed to are related to factors such as development, competition, capital requirements, currencies and interest rates. For a more detailed description of risks and uncertainties, please read the prospectus published in June 2019. During the current period, no significant changes in risk factors or uncertainties have occurred. The documents are available on the Scandion Oncology website ([www.scandiononcology.com](http://www.scandiononcology.com)).

## **Auditor's review**

The interim report has not been reviewed by the Company's auditor.

## **For further information, please contact**

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# Financial Review

## Income Statement

Operating loss for the third quarter 2019 is DKK thousand -7,030 (-1,296) and for the nine months of 2019 is DKK thousand -14,226 (-4,357).

External expenses for the third quarter 2019 are DKK thousand -5,974 (-1,257) and staff costs are DKK thousand -1,056 (-39). External expenses for the nine months of 2019 are DKK thousand -11,348 (-4,033). External expenses comprise manufacturing costs, clinical expenses, patent expenses and business expenses.

Costs and losses for the third quarter 2019 and for the nine months of 2019 are in line with plans and expectations. Activities and therefore also costs have increased both in third quarter 2019 and for the nine months of 2019 compared with third quarter 2018 and for the nine months of 2018.

## Balance Sheet

Total assets as of September 30, 2019 are DKK thousand 23,157 (1,777) of which cash is DKK thousand 18,028 (544). Current liabilities as of September 30, 2019 are DKK thousand 1,971 (3,276) consisting primarily of ordinary trade payables.

Equity as of September 30, 2019 is DKK thousand 21,186 (-1,499).

## Cash Flow

Cash flow from operating activities for the nine months of 2019 is a cash outflow of DKK thousand -10,259 (-2,344). Operating cash flow for the nine months of 2019 is explained by the operating loss of DKK -14,226 thousand (-4,357) during the period and a decrease in working capital.

Cash as of September 30, 2019 is DKK thousand 18,028 (544).

## Financial Calendar

February 20, 2020

Q4 2019 and Year-end report

## Income Statement

DKK	01-JUL-2019 30-SEP-2019	01-JUL-2018 30-SEP-2018	01-JAN-2019 30-SEP-2019	01-JAN-2018 30-SEP-2018	01-JAN-2018 31-DEC-2018
<b>Gross loss</b>	<b>(5,974,489)</b>	<b>(1,257,347)</b>	<b>(11,218,040)</b>	<b>(4,032,933)</b>	<b>(7,385,008)</b>
Staff costs	(1,055,782)	(38,544)	(3,008,221)	(324,428)	(2,549,577)
<b>Operating profit/loss</b>	<b>(7,030,270)</b>	<b>(1,295,891)</b>	<b>(14,226,261)</b>	<b>(4,357,361)</b>	<b>(9,934,585)</b>
Financial costs	(251,499)	(3,554)	(443,831)	(3,937)	(23,321)
<b>Profit/loss before taxes</b>	<b>(7,281,769)</b>	<b>(1,299,445)</b>	<b>(14,670,092)</b>	<b>(4,361,298)</b>	<b>(9,957,906)</b>
Tax on profit/loss for the year	1,030,282	(285,878)	2,593,528	959,403	1,775,348
<b>Profit/loss for the period</b>	<b>(6,251,487)</b>	<b>(1,013,567)</b>	<b>(12,076,564)</b>	<b>(3,401,895)</b>	<b>(8,182,558)</b>
Proposed distribution of profit					
Retained earnings	(6,251,487)	(1,013,567)	(12,076,564)	(3,401,895)	(8,182,558)

## Balance sheet in comparison

DKK	30-SEP-2019	30-SEP-2018	31-DEC-2018
Deposits	101,431	34,578	34 578
Other receivables long term	1,775,348	959,403	-
<b>Fixed asset investments</b>	<b>1,876,779</b>	<b>993,981</b>	<b>34,578</b>
<b>Fixed Assets</b>	<b>1,876,779</b>	<b>993,981</b>	<b>34,578</b>
Other receivables	390,003	65,211	240,210
Income tax receivable	2,593,528	160,281	1,775,348
Prepayments	268,305	12,975	3,850,494
<b>Receivables</b>	<b>3,251,836</b>	<b>238,467</b>	<b>5,866,052</b>
Cash	18,028,383	544,160	7,662,120
<b>Current assets</b>	<b>21,280,219</b>	<b>782,627</b>	<b>13,528,172</b>
<b>Assets</b>	<b>23,156,998</b>	<b>1,776,608</b>	<b>13,562,750</b>
<b>Equity and liabilities</b>			
Share capital	1,400,340	548,546	875,212
Share premium	41,057,611	2,367,058	20,890,289
Retained earnings	(21,271,958)	(4,414,731)	-9,195,394
<b>Equity</b>	<b>21,185,992</b>	<b>(1,499,127)</b>	<b>12,570,107</b>
Loan	-	800,000	-
Trade payables	973,771	651,811	715,602
Other payables	997,235	1 823,924	277,041
<b>Current liabilities other than provisions</b>	<b>1,971,006</b>	<b>3,275,735</b>	<b>992,643</b>
<b>Equity and liabilities</b>	<b>23,156,998</b>	<b>1,776,608</b>	<b>13,562,750</b>

## Equity

2018 DKK	Contributed capital	Share premium	Retained earnings	Total
Equity beginning of year	540,065	1,925,539	(1,012,836)	1,452,768
Increase of capital	335,147	18,964,750	-	19,299,897
Profit/loss for the year	-	-	(8,182,558)	(8,182,558)
<b>Equity end of year</b>	<b>875,212</b>	<b>20,890,289</b>	<b>(9,195,394)</b>	<b>12,570,107</b>

01-JAN-2019 – 30-SEP-2019 DKK	Contributed capital	Share premium	Retained earnings	Total
Equity beginning of year	875,212	20,890,289	(9,195,394)	12,570,107
Increase of capital	525,127	20,167,322	-	20,692,449
Profit/loss for the period	-	-	(12,076,564)	(12,076,564)
<b>Equity end of period</b>	<b>1,400,340</b>	<b>41,057,611</b>	<b>(21,271,958)</b>	<b>21,185,992</b>

## Cash flow statement

DKK	01-JAN-2019 30-SEP-2019	01-JAN-2018 30-SEP-2018	01-JAN-2018 31-DEC-2018
Operating profit/loss	(14,226,261)	(4,357,361)	(9,934,585)
Working capital changes	4,410,759	2,017,788	(3,317,540)
<b>Cash flow from ordinary operating activities</b>	<b>(9,815,502)</b>	<b>(2,339,573)</b>	<b>(13,252,125)</b>
Financial income paid	(443,831)	(3,937)	(23,321)
<b>Cash flows from operating activities</b>	<b>(10,259,333)</b>	<b>(2,343,509)</b>	<b>(13,275,446)</b>
Acquisition of fixed asset investments	(66,853)	-	-
<b>Cash flows from investing activities</b>	<b>(66,853)</b>	<b>-</b>	<b>-</b>
Cash increase of capital	20,692,449	450,000	19,299,897
Loan	-	800,000	-
<b>Cash flows from financing activities</b>	<b>20,692,449</b>	<b>1,250,000</b>	<b>19,299,897</b>
<b>Increase/decrease in cash and cash equivalents</b>	<b>10,366,263</b>	<b>(1,093,509)</b>	<b>6,024,451</b>
Cash and cash equivalents beginning of period	7,662,120	1,637,670	1,637,670
<b>Cash and cash equivalents end of period</b>	<b>18,028,383</b>	<b>544,160</b>	<b>7,662,120</b>
Change in working capital			
Increase/decrease in receivables	3,432,396	51,070	(3,801,167)
Increase/decrease in trade payables etc.	978,363	1,966,718	483,627



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