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

# SCANDION ONCOLOGY

**HALF-YEAR REPORT 01-JAN-2019 – 30-JUN-2019**

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

# Half-year report for the period 01-JAN-2019 – 30-JUN-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 is now ready for 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 half-year report provides a fair and true overview of the Company's operations, financial position and results.

Copenhagen, August 22, 2019

The Board of Directors of Scandion Oncology A/S

<i>Joergen Bardenfleth</i>	<i>Chairman of the Board</i>
<i>Peter Høngaard Andersen</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

DKK	01-APR-2019	01-APR-2018	01-JAN-2019	01-JAN-2018	01-JAN-2018
	30-JUN-2019	30-JUN-2018	30-JUN-2019	30-JUN-2018	31-DEC-2018
Net sales	0	0	0	0	0
Operating profit/loss	(4,851,099)	(2,366,338)	(7,195,991)	(3,061,470)	(9,934,585)
Profit/loss before taxes	(4,952,214)	(2,366,721)	(7,388,323)	(3,061,853)	(9,957,906)
Profit/loss for the period	(3,876,732)	(1,693,196)	(5,825,077)	(2,388,328)	(8,182,558)
Total assets	7,807,992	1,319,603	7,807,992	1,319,603	13,562,750
Equity ratio	0.86	(0.37)	0.86	(0.37)	0.93
Number of registered shares	11,907,651	7,463,207	11,907,651	7,463,207	11,907,651
Earnings per share	(0.33)	(0.23)	(0.49)	(0.32)	(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

- Scandion Oncology announced that SCO-101 tablets have been successfully produced as a pilot production on June 26<sup>th</sup>. The Company expects to initiate its first clinical Phase II study with drug resistant cancer late 2019.
- Scandion Oncology announced on June 27<sup>th</sup> that the Company has identified the four clinical sites where the lead candidate drug SCO-101 will be tested in combination with chemotherapy in patients with metastatic and drug resistant colorectal cancer.
- Scandion Oncology announced on June 6<sup>th</sup> that the Company appointed Chairman and Vice-Chairman of its Board of Directors. Jørgen Bardenfleth continues as Chairman of the Board and Peter Høngaard Andersen will take the position as Vice-Chairman of the Board.
- Early April Scandion Oncology obtained EU Funding (SME Instruments Phase 1) for SCO-101 in drug resistant breast cancer patients.
- Scandion Oncology signed collaboration agreement with University of Copenhagen regarding co-development of a class of drug candidates that reverts anti-cancer drug resistance.
- Scandion Oncology received an “Intention to Grant” notice from the European Patent Office regarding its patent application covering SCO-101 in combination with specific topoisomerase I inhibitors to treat various cancers.

## Highlights after the period

- Scandion Oncology announces that the rights issue in the Company was oversubscribed by 200%. Scandion Oncology will be 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.
- Scandion Oncology releases first status on Dutch collaboration on SCO-101 (EU grant) regarding endocrine treatment of breast cancer cell lines.

## CEO Nils Brünner



We have now concluded the second financial quarter of 2019 and are able to look back on some important and commercially significant events for Scandion Oncology. We are continuing our path towards being able to offer patients with drug resistant cancer the SCO-101 drug together with the cancer drug that the patient has become resistant to. I would like to take this opportunity to comment on some of the significant highlights during the last quarter.

It is with great excitement that we can highlight some important events regarding the progress of our drug development during the last quarter. I am very pleased that we have identified our third drug, SCO-301, which complements our existing pipeline as it targets resistance against a large class of anti-cancer compounds that is not targeted by the SCO-101 or SCO-201. In April we announced the collaboration agreement with University of Copenhagen regarding co-development of SCO-301. This collaboration will further strengthen the commercial potential of our pipeline by resulting in new SCO-301 analogs with strong anti-cancer effects and improved commercial potential.

During the second quarter of 2019, Scandion Oncology conducted a rights issue in order to further increase the commercial potential of our drug candidates and to expand our drug pipeline. Since our IPO in 2018, we have continuously been able to scale up and accelerate our research and business efforts. In particular, we have reached all the milestones outlined at the IPO. We have also experienced increased interest from institutional and professional investors, which made us chose an offensive rights issue to enable our existing shareholders to take part in our exciting journey. We are very pleased for the significant interest in our rights issue, and I would like to take this opportunity to thank both our existing shareholders for their trust and welcome new shareholders who have chosen to invest in us. With the capital that we are now provided with, we look forward to continuing the planned activities. During the quarter we also obtained EU funding for SCO-101 in drug resistant breast cancer patients. We will also continue our soft funding strategy which is first to obtain smaller EU grants and then use these as stepping-stones for larger EU grants. We see granting of the SME Instruments phase I grant as an EU recognition of Scandion Oncology's business model and focus.

Finally, I am very pleased that we were able to announce that Solural Pharma ApS has successfully finalized a pilot scale drug product of SCO-101 in accordance with our time plan. This is yet another important milestone and we are now preparing a Clinical Trial Application for our first Phase II clinical trial with SCO-101. In late June, we were also able to announce that we have identified four clinical sites to take part in the planned Phase II clinical trial with SCO-101. This is a very important milestone in the quest to prove that SCO-101 can revert resistance to chemotherapy in colorectal cancer patients. When the trial is successful, it will have significant importance for the thousands of patients who have no treatment options due to treatment-resistance. We are very grateful for the commitment of the four sites and look forward to this collaboration. The first patients to enter the trial are expected to be included in December 2019. I want to thank our associates for their hard work, and we look forward to the upcoming months of work with the development processes.

All in all, this underlines our commercial strategy to bring our products to market without any delays. Scandion's products will increase the chance of cancer patients to have a better outcome than possible today. This is the driving force of the entire Company and thus is why time to market is crucial.

*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 their 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.

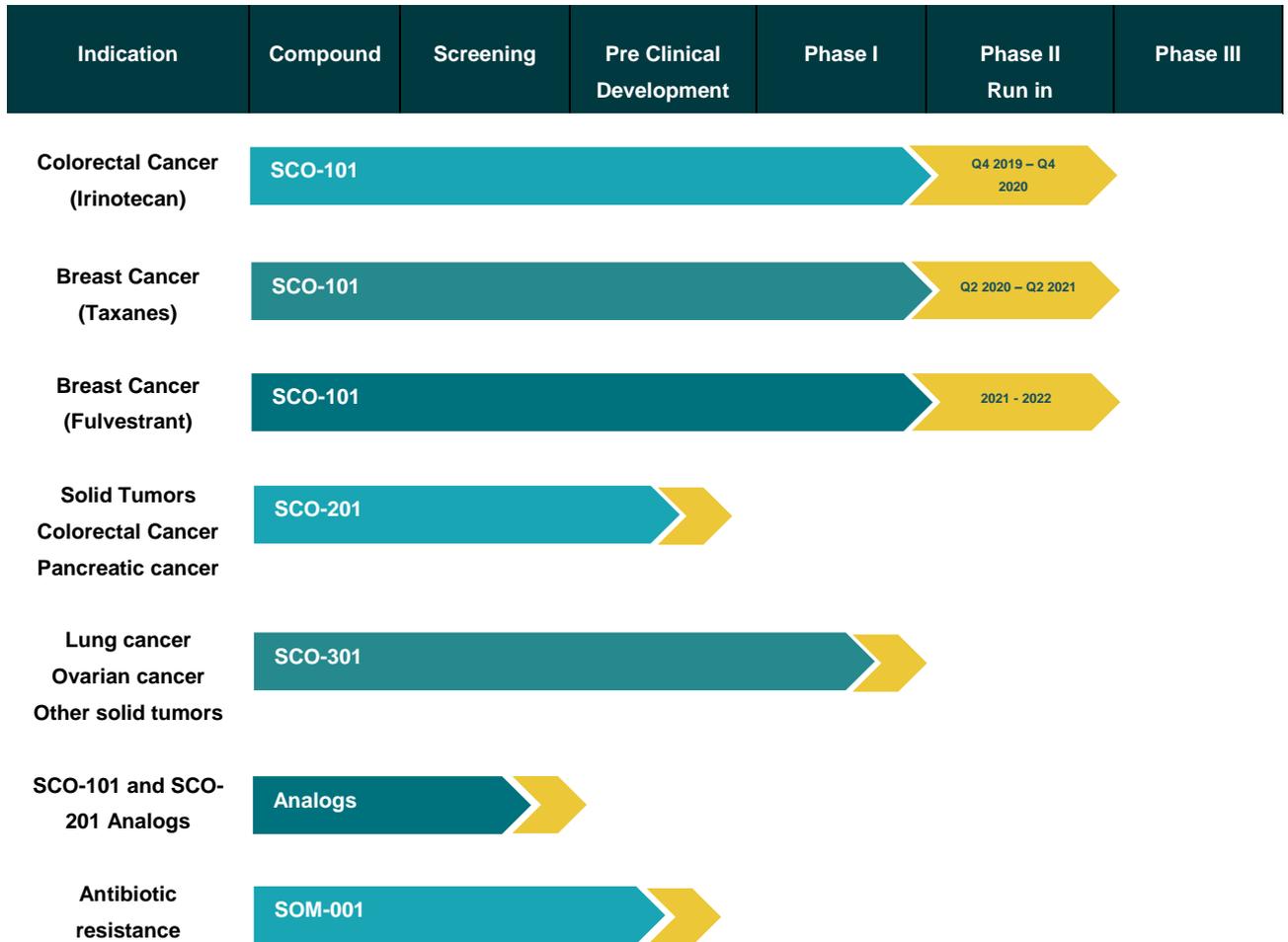
A little less than half of all cancer patients with metastatic disease fail their cancer treatment – largely due to the cancer either being resistant already from the time of the primary diagnosis, or that the cancer acquires resistance during anti-cancer treatment. As a result, the cancer continues to grow despite treatment and after a period of time the patient will eventually lose his/her life to the cancer disease. Therefore, drug resistance is a major burden on health and medical care systems and 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 these positive clinical phase I data, Scandion Oncology is now preparing an application to the Danish Medical Agency for a Phase II clinical trial in patients with chemotherapy-resistant 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.



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



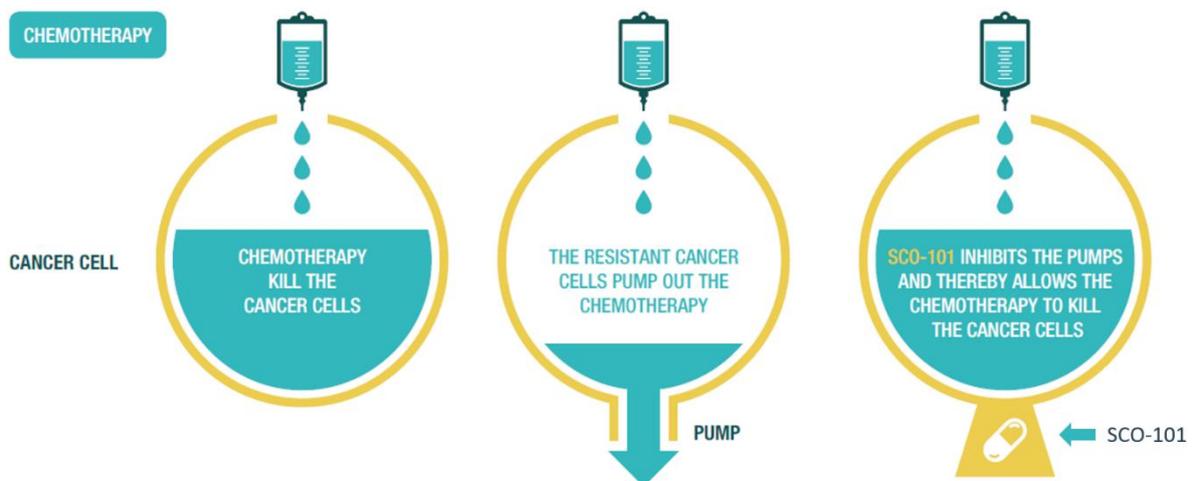
\* 6 patients from the previous run-in study (12 patients) are included here.

Scandion Oncology’s first clinical phase II study with SCO-101 will have a first part, which includes 12 patients to 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 enroll a total of 12 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 in combination with standard dose of chemotherapy to be used in the second part of the phase II study. In the second part of the study, an additional 9 patients will be enrolled and treated with the RDP2. Since the last 6 patients in the first part of the study also received the RDP2, these 6 patients will be included in the calculations of the data from the second part of the study. This means that a total of 15 patients (6+9) will have received the RDP2. Patients are scanned before treatment start and then every 8 weeks during treatment. The first part of the phase II study will provide the first indication of efficacy (the last 6 patients will receive the RDP2 of SCO-101). Scandion Oncology will also use the first part of the phase II study to validate its predictive biomarkers. 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 treatment until progression. After finalizing treatment of the last patient, all data from the study will be compiled and presented.

## 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 can 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, resistant cells may 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. Scandion Oncology estimates that the use of SCO-101 to combat drug resistance to cancer drugs will open up a new and important market segment for the major pharmaceutical and biotechnology companies.

## **Business model**

At the completion of Phase II the business model of Scandion Oncology is to out-license SCO-101 to a partner that has the ability to develop and market SCO-101 on the world market. This would be a tremendous commercial but realistic opportunity for Scandion Oncology and would pave the way for several of the novel compounds in the pipeline, further strengthen Scandion Oncology's position in the oncology space. Another possibility is that Scandion Oncology enters into a partnership with a pharmaceutical company to complete a Phase III clinical trial with SCO-101, leading to FDA and EMA approval, which would even further increase the value of SCO-101.

## Shareholders

The table below presents the 25 largest shareholders (based on nominee accounts) in Scandion Oncology as per June 30, 2019 i.e. before completion of the Rights issue.

Name	Number of shares	Votes & capital (%)
Saniona AB	3,473,577	29.17
Jan Stenvang *	1,481,516	12.44
Nils Brünner**	1,136,045	9.54
Nordnet Pensionsförsäkring AB	853,770	7.17
Kim Arvid Nielsen	476,765	4.00
Avanza Pension	400,813	3.37
Christian René Tang-Jespersen	327,869	2.75
Bank of New York Mellon SA NV	191,020	1.60
JPM Chase NA	146,152	1.23
I/S P. Bolvig	141,880	1.19
Göran Ofsén	136,000	1.14
Lioneagle ApS***	130,030	1.09
Morten Fadum Nissen	113,191	0.95
Tomas Tymark	91,000	0.76
Christian Holger Mörch	84,316	0.71
CB Ocean Capital AB****	79,645	0.67
Jimmie Landerman	78,144	0.66
Sparekassen Kronjylland	71,800	0.60
Mats Lagerdahl	59,432	0.50
Alan K.Hueg	57,863	0.49
Morten Riise-Knudsen	45,641	0.38
Christer Gavuzzi	45,000	0.38
Petronella Fritz	42,000	0.35
Skandia	41,768	0.35
Anderson Bridge Company ApS	41,025	0.34
Others	2,161,389	18.17
<b>Total</b>	<b>11,907,651</b>	<b>100.00</b>

\* CSO, Jan Stenvang.

\*\* CEO, Nils Brünner.

\*\*\* 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 June 30, 2019, the number of shares was 11,907,651. All shares have equal rights to the Company's assets and results.

## **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 half-year 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 second quarter 2019 is DKK thousand -4,851 (-2,366) and for the first half year 2019 is DKK thousand -7,196 (-3,061).

External expenses for the second quarter 2019 are DKK thousand -3,872 (-2,145) and staff costs are DKK thousand -1,110 (-221). External expenses for the first half year 2019 are DKK thousand -5,374 (-2,776). External expenses and staff costs are consisting of costs of manufacturing of product, patent expenses and business expenses.

Costs and losses for the second quarter 2019 and for the first half year 2019 are in line with plans and expectations. Activities and therefore also costs have increased both in second quarter 2019 and for the first half year 2019 compared with second quarter 2018 and for the first half year 2018 as financing of SEK 26 million in fourth quarter 2018 has been performed. In addition, a rights issue has been performed in July 2019 with a proceed of SEK 29 million before issue costs securing financing beyond 2019.

## Balance Sheet

Total assets as of June 30, 2019 are DKK thousand 7,808 (1,320) of which cash is DKK thousand 3,160 (327). Current liabilities as of June 30, 2019 are DKK thousand 1,063 (1,805) consisting primarily of ordinary trade payables.

Equity as of June 30, 2019 is DKK thousand 6,745 (-486).

## Cash Flow

Cash flow from operating activities for the first half year 2019 is a cash outflow of DKK thousand -4,471 (-1,761). Operating cash flow for the first half year 2019 is explained by the operating loss of DKK -7,196 thousand (-3,061) during the period and a decrease in working capital. The decrease in working capital is primarily due to prepayment of production of SCO-101 at Cambrex AB, Sweden from 2018 that have been utilised in the first half year 2019.

Cash as of June 30, 2019 is DKK thousand 3,160 (327).

## Financial Calendar

November 21, 2019	Quarterly statement Q3, 2019
February 20, 2020	Q4 2019 and Year-end report

## Income Statement

	01-APR-2019 30-JUN-2019	01-APR-2018 30-JUN-2018	01-JAN-2019 30-JUN-2019	01-JAN-2018 30-JUN-2018	01-JAN-2018 31-DEC-2018
<b>Gross loss</b>	<b>(3,741,087)</b>	<b>(2,144,888)</b>	<b>(5,243,551)</b>	<b>(2,775,586)</b>	<b>(7,385,008)</b>
Staff costs	(1,110,012)	(221,450)	(1,952,439)	(285,884)	(2,549,577)
<b>Operating profit/loss</b>	<b>(4,851,099)</b>	<b>(2,366,338)</b>	<b>(7,195,991)</b>	<b>(3,061,470)</b>	<b>(9,934,585)</b>
Other financial expenses	(101,115)	(383)	(192,332)	(383)	(23,321)
<b>Profit/loss before tax</b>	<b>(4,952,214)</b>	<b>(2,366,721)</b>	<b>(7,388,323)</b>	<b>(3,061,853)</b>	<b>(9,957,906)</b>
Tax on profit/loss for the year	1,075,482	673,525	1,563,246	673,525	1,775,348
<b>Profit/loss for the year</b>	<b>(3,876,732)</b>	<b>(1,693,196)</b>	<b>(5,825,077)</b>	<b>(2,388,328)</b>	<b>(8,182,558)</b>

## Balance sheet in comparison

DKK	30-JUN-2019	30-JUN-2018	31-DEC-2018
Deposits	65,526	34,578	34,578
<b>Fixed asset investments</b>	<b>65,526</b>	<b>34,578</b>	<b>34,578</b>
<b>Fixed assets</b>	<b>65,526</b>	<b>34,578</b>	<b>34,578</b>
Other receivables	214,456	122,038	240,210
Income tax receivable	3,338,594	833,806	1,775,348
Prepayments	1,029,005	2,059	3,850,494
<b>Receivables</b>	<b>4,582,055</b>	<b>957,903</b>	<b>5,866,052</b>
<b>Cash</b>	<b>3,160,411</b>	<b>327,123</b>	<b>7,662,120</b>
<b>Current assets</b>	<b>7,742,466</b>	<b>1,285,026</b>	<b>13,528,172</b>
<b>Assets</b>	<b>7,807,992</b>	<b>1,319,603</b>	<b>13,562,750</b>

## Balance sheet in comparison

DKK	30-JUN-2019	30-JUN-2018	31-DEC-2018
Share capital	875,212	548,546	875,212
Additional paid in capital	20,890,289	2,367,058	20,890,289
Retained earnings	(15,020,472)	(3,401,164)	(9,195,394)
<b>Equity</b>	<b>6,745,029</b>	<b>-485,560</b>	<b>12,570,107</b>
Trade payables	716,782	88,863	715,602
Other payables	346,181	1,716,300	277,041
<b>Current liabilities other than provisions</b>	<b>1,062,963</b>	<b>1,805,163</b>	<b>992,643</b>
<b>Liabilities other than provisions</b>	<b>1,062,963</b>	<b>1,805,163</b>	<b>992,643</b>
<b>Equity and liabilities</b>	<b>7,807,992</b>	<b>1,319,603</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-JUN-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	-	-	-	-
Profit/loss for the period	-	-	(5,825,077)	(5,825,077)
<b>Equity end of period</b>	<b>875,212</b>	<b>20,890,289</b>	<b>(15,020,472)</b>	<b>6,745,029</b>

## Cash flow statement

	01-JAN-2019 30-JUN-2019	01-JAN-2018 30-JUN-2018	01-JAN-2018 31-DEC-2018
<b>DKK</b>			
Operating profit/loss	(7,195,991)	(3,061,470)	(9,934,585)
Working capital changes	2,917,562	1,301,306	(3,317,540)
<b>Cash flow from ordinary operating activities</b>	<b>(4,278,428)</b>	<b>(1,760,164)</b>	<b>(13,252,125)</b>
Financial income paid	(192,332)	(383)	(23,321)
<b>Cash flow from operating activities</b>	<b>(4,470,761)</b>	<b>(1,760,547)</b>	<b>(13,275,446)</b>
Acquisition of fixed asset investments	(30,948)	-	-
<b>Cash flow from investing activities</b>	<b>(30,948)</b>	<b>-</b>	<b>-</b>
Cash increase of capital	-	450,000	19,299,897
<b>Cash flow from financing activities</b>	<b>-</b>	<b>450,000</b>	<b>19,299,897</b>
<b>Increase/decrease in cash and cash equivalents</b>	<b>(4,501,709)</b>	<b>(1,310,547)</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>3,160,411</b>	<b>327,123</b>	<b>7,662,120</b>
Change in working capital			
Increase/decrease in receivables	2,847,243	5,159	(3,801,167)
Increase/decrease in trade payables etc.	70,319	1,296,147	483,627
	<b>2,917,562</b>	<b>1,301,306</b>	<b>(3,317,540)</b>



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