
Report1st quarter 2019



Biofilm eradication

Fighting Chronic Wounds and Antimicrobial Resistance

SoftOx Solutions AS ("SoftOx") is a medtech company listed on the Merkur list, Oslo Stock Exchange with the ticker "SOFTOX-ME". SoftOx Solutions AS was founded in 2012 and is headquartered in Oslo, Norway, with subsidiaries in Malmö and Copenhagen.

SoftOx aims to develop a non-toxic and highly efficient antimicrobial technology, which eradicates and prevents biofilm infections, and is founded on the basis of extensive years of research and product development with leading Nordic research institutes.

Highlights for the 1st quarter of 2019

- First clinical study of SoftOx Wound Irrigation Solutions (SWIS) in humans at Bispebjerg University Hospital in Copenhagen is ongoing. The study is progressing with a slight delay, with more than 50% of the patients enrolled, and is expected to be completed in Q3-2019
- Negotiations are ongoing with a potential distributor for our hand disinfectant in the Scandinavian market.
- The European Union is undergoing regulatory transition, regarding approval of medical devices (MDR) which will be implemented from 1st of May 2020. The company's assigned Notified Body has not been accredited as of yet to evaluate new applications according to new regulations, yet simultaneously stopped accepting applications in accordance with previous (MDD) requirements. In line with this, Softox may experience delays in the registration process of Softox Wound Irrigation Solution in Europe.
- The planned share issue (spring 2019) will now take place in autumn 2019, in accordance with delays in the clinical development process.

Key figures

	1Q19	1Q18	2 018
SoftOx Solutions Group			
Total revenue and other income	1 290	0	4 323
Total operating expenses	5 568	4 168	21 609
Operating result	-4 278	-4 168	-17 286
Net result before taxes	-4 252	-4 175	-17 466
Net proceeds from equity issues	17 894	0	600
Net cash flow	7 034	-6 030	-15 862
Cash and cash equivalents at end of period	8 270	11 069	1 237
Outstanding shares, beginning of the period (1, 2)	3 778 650	2 488 500	2 488 500
Outstanding shares, end of the period (1, 2)	4 626 000	3 758 650	3 778 650
Employees, end of the period	10	7	10

(1) The share issue in 4Q17 was registered in 1Q18

(2) Adjusted for share split 1:50 in July 2018

Operational review

Product development

The development of the SoftOx Wound Irrigation Solution (SWIS) and SoftOx Biofilm Eradicator (SBE) is progressing according to plan, with a short delay of three months in the first clinical study for SoftOx Wound Irrigation Solution as described above. The intended use for SWIS is to prevent infections in acute wounds, and the intended use for SBE is to fight established biofilm infections in chronic wounds. Both products are intended to either reduce or replace the use of antibiotic treatment on skin-related infections.

Major milestones

SoftOx' first-in-man clinical investigation (SWIS-01) was initiated at the Wound Healing Department at Bispebjerg University Hospital in November 2018 and is continuously progressing. Information about the study can be found at www.clinicaltrials.gov.

The company's drug candidates (SBE) have undergone the first study in animals (minipigs) at the Research Technology Center (RTC) in Italy. The results indicate an encouraging safety and local tolerance profile. The maximum tolerated dose has not been reached, indicating that higher dosages may be applied to yield optimal benefits: risk ratio for future human studies.

In late December of 2018 SoftOx submitted an application for SoftOx- disinfection- product-family according to the new 2019 Biocidal Products Regulations (BPR) for market approval in the Norwegian, Swedish and Danish market from 2019.

SoftOx aims to launch a hand- disinfection-product in cooperation with a distributor in the local Nordic market during 2019.

Negotiations with the potential distribution partner are ongoing.

The European Union's new regulation regarding approval of new medical devices will be implemented from 1st of May 2020. The company's assigned Notified Body has not been yet accredited to evaluate new applications according to new regulations, yet simultaneously stopped accepting applications in accordance with previous (MDD) requirements. In line with this, Softox may experience delays in the registration process of Softox Wound Irrigation Solution in Europe. It is also possible that additional changes in regard to product documentation may contribute to further delays. That said, we continue to have close discussions around this topic and how to streamline it, with our assigned Notified Body.

Further information is expected in January 2020.

Organizational information

The Company, including daughter companies, has eleven employees at the end of the fourth quarter (two on part-time basis), for a total of 10 FTE's.

Upcoming risk next three months

Since both the clinical study and the distribution agreement are slightly delayed, the company has decided to delay the planned share issue until autumn 2019.

Conducting clinical trials has inherent risks.

The company has sought to minimize such risks through its design as well as various compliance measures and by adhering to applicable standards, including Good Clinical Practice. We are confident that with the ongoing progression of our study, we will have results available in the Q3 2019 report.

The Company is negotiating a distribution agreement for SoftOx- Hand -Disinfectant for the Nordic market. Negotiations are progressing in line with expectations outside of the minor delays (as commonly associated with such a process.)

Financial review

Financial figures in this report are unaudited figures for the SoftOx Solution Group.

Other operating revenues in the first quarter of 2019 consist mostly of accrued grants from the Norwegian Research Council under the BIA program and Skattefunn.

Personnel expenses increased to KNOK 2,561 in the first quarter of 2019, compared to KNOK 1,406 in the same period of 2018, due to the planned increase in staff in the parent company and the Danish subsidiary.

Other operating expenses increased to KNOK 2,728 in the first quarter of 2019, compared to KNOK 2,551 in the same period of 2018 due to general expansion of operations.

On 31.03.19 the Group had cash and cash equivalents of KNOK 8,270.

On 31.03.19 the Group had deferred tax assets of KNOK 12,264, which reflects the deferred tax assets at year end 2018. Tax calculations will be done on final (audited) full year figures.

On 31.03.19 the Group had other intangible assets of KNOK 2,956, consisting of mainly the capitalized patent expenses in the Swedish subsidiary.

In the first quarter of 2019, the Group had a cash flow of KNOK 7,034, including net cash flow from share issues and other financing activities of KNOK 15,854.

Outlook

The Company's plans for the upcoming twelve months include:

- Finalizing the first-in-man pilot study on SWIS and starting the final pivotal clinical investigation.
- Registration of SoftOx- Hand - Disinfectant
- Finalizing negotiations with Antibac.
- Completing preclinical toxicology and max dose studies on SBE drug candidates.

No other substantial financial events have been affecting the Company's P&L after 31.03.2019.

Declaration

We declare that to the best of our knowledge the accounts for the 1st quarter of 2019 have been prepared in accordance with current accounting standards for the Group and that the disclosures in the accounts provide a true and fair view of the Company's and the Group's assets, liabilities, financial position and results as a whole and that the quarterly report, including a description of the most important risk and uncertainty factors facing the Group, gives a true and fair view of the development, results and position of the entity and the Group.

Oslo, 27th of June 2019

SIGN

Lars Johan Frigstad, Chairman

SIGN

Kristian Almås, Director

SIGN

Olav Trygve Jarlsby, Director

SIGN

Kari Grønås, Director

SIGN

Dag Vangsnes, Director

SIGN

Geir Hermod Almås, CEO

Profit and loss statement

SoftOx Solutions Group

NOK 1,000

	1Q19	1Q18	2018
Other operating revenues	1 290	0	4 323
Total operating revenues	1 290	0	4 323
Personnel expenses	2 561	1 406	8 183
Other operating expenses	2 728	2 551	12 311
Depreciation	278	211	1 115
Depreciation, goodwill	0	0	0
Total operating expenses	5 568	4 168	21 609
Operating result	-4 278	-4 168	-17 286
Net financial items	26	-6	-179
Net result before taxes	-4 252	-4 175	-17 466
Tax			4 534
Net result after tax			-12 932

Statement of financial position	1Q19	1Q18	2018
SoftOx Solutions Group			
<i>NOK 1,000</i>			
Other intangible assets	2 956	2 536	3 343
Deferred tax asset	12 264	7 745	12 305
Goodwill from acquisition of subsidiary	0	0	0
Total intangible assets	15 220	10 281	15 648
Production equipment	281	411	327
Total fixed assets	281	411	327
Total non-current assets	15 501	10 692	15 975
Other receivables	6 247	3 497	6 182
Total receivables	6 247	3 497	6 182
Cash and cash equivalents	8 270	11 069	1 237
Current assets	14 517	14 566	7 419
Total assets	30 018	25 258	23 393
Share capital	93	75	76
	0	0	0
Other paid in equity	35 647	47 452	17 771
	0	0	0
Total paid in equity	35 740	47 527	17 846
Other equity	-7 924	-25 098	-3 438
Total other equity	-7 924	-25 098	-3 438
Total equity	27 816	22 429	14 409
Public duties payable	531	104	706
Shareholder loans	0	0	2 000
Other current liabilities	1 038	652	1 868
Accounts payable	633	2 073	4 411
Total current liabilities	2 202	2 829	8 985
Total liabilities	2 202	2 829	8 985
Total equity and liabilities	30 018	25 258	23 393

Cash flow statement	1Q19	1Q18	2018
SoftOx Solutions Group			
<i>NOK 1,000</i>			
Cash flow from operating activities			
Net result before taxes	-4 252	-4 175	-17 466
Tax paid	0	0	0
Depreciation	278	211	1 115
Change in current assets	-64	-701	-3 386
Change in current liabilities	-4 782	-1 362	2 794
Net cash flow from operating activities	-8 821	-6 027	-16 943
Cash flow from investment activities			
Investments in non-current assets	0	0	-1 444
Net cash flow from investment activities	0	0	-1 444
Cash flow from financing activities			
Proceeds from equity issues	17 894	0	600
Other financing activities	-2 000	0	2 000
Translation differences	-39	-3	-75
Net cash flow from financing activities	15 854	-3	2 525
Net change in cash and cash equivalents	7 034	-6 030	-15 862
Cash and cash equivalents at beginning of period	1 237	17 098	17 098
Cash and cash equivalents at end of period	8 270	11 069	1 237

Statement of changes in equity				
SoftOx Solutions Group				
<i>NOK 1,000</i>	Share capital	Other paid in equity	Other equity	Total equity
Balance at 01.01.2018	50	30 263	-3 466	26 846
Loss for the period		-12 929	-3	-12 932
Share issues	26	574		600
Other changes in equity		-137	32	-105
Balance at 31.12.2018	76	17 770	-3 437	14 409
	0	0	0	0
Balance at 01.01.2019	76	17 770	-3 437	14 409
Loss for the period			-4 175	-4 175
Share issues	17	17 877		17 894
Other changes in equity	0		-312	-312
Balance at 31.03.2019	93	35 647	-7 924	27 816

Notes to the Quarterly Financial Statement

The financial statements of SoftOx Solutions Group for 1st quarter 2019 and 2018 are presented in accordance with the Norwegian Accounting Act and generally accepted accounting principles for small-size companies.