
Report 4th quarter of 2020



WELCOME TO SOFTOX SOLUTIONS

Helping the World Fighting Infections

New ways of eradicating infections and fighting antimicrobial resistance



SoftOx Solutions AS is a biotech company listed on Euronext Growth Oslo with ticker 'SOFTX'. SoftOx Solutions AS was founded in 2012 and is headquartered in Oslo with subsidiaries in Malmö and Copenhagen.

SoftOx has developed a highly effective antimicrobial solution which eradicates and prevents biofilm, viral and antimicrobial infections. The technology is based on years of research and development in partnership with leading Nordic research institutes and is protected by patents.

Key figures for the SoftOx Solutions Group (SoftOx) as of 31.12.2020

Key figures (NOK 1,000)

	Q4 2020	Q4 2019	31.12.2020	31.12.2019
SoftOx Solutions Group				
Total operating revenue	596	233	9 839	4 099
Total operating expenses	22 588	6 928	61 203	25 969
Operating result	-21 992	-6 695	-51 364	-21 870
Net result before taxes	-20 469	-6 695	-49 714	-21 832
Net proceeds from equity issues	27 500	72 009	28 510	89 903
Net change in cash and cash equivalents	9 432	74 696	-41 194	74 759
Cash and cash equivalents at end of period	34 802	75 995	34 802	75 995
Outstanding shares, beginning of the period	7 829 900	4 626 000	7 751 000	2 488 500
Outstanding shares, end of the period	8 329 000	7 751 000	8 329 000	7 751 000
Employees, end of the period			21	11

Highlights for the 4th quarter of 2020

(figures in brackets apply to 2019)

- Year to date pre-tax results ended with a loss of NOK 49,7 million (loss of NOK 21,8 million). Results are characterized by high levels of activity in research and development in addition to preparatory work in both production and sales force ahead of the launch of our disinfectants in new markets
- SoftOx Solutions raised NOK 50 million through its private placement after the stock exchange close December 16th. The interest for the capital increase was high, and more than 100 percent oversubscribed. It is only the Tranche 1 of NOK 27,5 million that has been posted in 2020, Tranche 2 (NOK 22,5 million), a repair issue and an employee issue at the same subscription price will be executed in 2021
- Several new distributor agreements for our disinfection agents. One such agreement involves SoftOx Solutions' distributor Bonaventura Scandza and NorgesGruppen for the sale of SafeDes alcohol-free hand disinfectant
- The Swedish Chemicals Agency has evaluated and recommended approval of SoftOx disinfectant products for the Scandinavian markets. After hearing the Norwegian and Danish regulatory authorities, the final decision is expected delayed to late March

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- The additional safety studies for SIS in a minipig inhalation model confirmed mild changes to the respiratory epithelium when exposed with higher concentrations of SIS have been documented to be transient and fully reversible
 - SWIS 2 is approved by Regional Ethical Committee and ready for the start the clinical study

A statement from CEO Geir Almås

(Further details are also given later in the report)

Despite the delay in sales and some start-up problems in the production of our disinfection products in 2020, this has truly been an exciting quarter in the history of SoftOx.

Successful private placement demonstrates confidence in the market

In December, we carried out a new private placement which raised NOK 50 million. The placement was more than 100 % oversubscribed and closed in record time. This capital increase will contribute to further develop and finance ongoing and future clinical studies, including the ongoing respiratory track studies, where the company's goal is to start testing in humans early 2021, as well as general corporate purposes. The capital increase will allow SoftOx to intensify its activities related to the investment in its alcohol-free and skin-friendly hand sanitizers AntiVir™ and SafeDes™ towards several large markets in Europe. A repair issue will be arranged in Q1 to secure that the shareholders who did not join the private placement get the opportunity to participate and, in part, “repair” the dilution of ownership. A private placement directed to the employees will also be arranged on the same terms. This demonstrates that we have confidence in the market. We are on the right track, and this will give us the power we need for our future plans.

Cooperation with new distributors

In the last quarter, several new distributors began selling our disinfectants. It was especially gratifying when Norway's largest grocery chain NorgesGruppen with the Meny stores at the forefront chose to include SoftOx in their product range beginning in 2021. We have also established a distribution agreement with the sports chain XXL in all their stores in Norway, Sweden and Denmark. We are now experiencing increasing interest in our products. The market demands effective and skin-friendly disinfectant products. We feel confident that the market will respond, and we have a good story to tell simply because we have the best product.

Conditional approval of our disinfectant products in the EU

We are now approaching approval from the EU on our disinfection product line. The Swedish Chemicals Agency (Kemi) has evaluated and recommended approval of SoftOx Solutions' disinfectant products for the Scandinavian markets, including AntiVir™, SafeDes and EffectDes. After hearing the Norwegian and Danish regulatory authorities, a final approval for Scandinavia is expected late March, after which approval in each EU market can be pursued on the local, country specific level. Preparations are already in progress for selected markets. This is an important milestone for SoftOx and brings us one step closer to the goal of becoming

a significant player within disinfection and hand hygiene. We can now prepare for mutual approval processes and launches in several European markets. With this conditional approval, we are now in a position where our hand disinfection product will be in line with the EU Biocidal Products Regulation and the EU Biocidal Products Directive, and we expect and hope that the Norwegian Institute of Public Health (FHI) now will carry out an update of the Hand Hygiene Guidelines to allow for hand disinfection products approved in accordance with the EU's new regulations.

Positive results from SoftOx Inhalation Solution (SIS)

When it comes to our R&D activities, we have further confirmed that SoftOx Inhalation Solution (SIS) is well tolerated and does not cause significant side effects in chosen therapeutic doses. Everything is now well prepared for further investigation and for us to prepare for the first-in-human clinical study starting in March. Now, our R&D department works intensively to move this process forward as quickly as possible. This could be a paradigm shift in how to treat all types of respiratory infections. It will contribute to reduced antibiotic use and will also be assessed in treatment of COVID-19 patients e.g. as first line defence to avoid any possible shutdowns in the future. A product like this can be an important supplement to vaccines and the medical armamentarium.

New partners on SoftOx Infection remover (SBE) development

One of the greatest achievements in Q4 was when The US Department of Defense (DoD) awarded SoftOx' approx. USD 2 million for the research and development of the SoftOx Biofilm Eradicator (SBE). SoftOx considers the funding and support from one of the world's leading research organizations as a great honour. This award gives us both the means and confirmation to continue this important work.

In summary, we are experiencing exciting times at SoftOx, both in product development and commercialization in Norway and internationally. We have confidence both in the market and from leading research organizations, we are experiencing increasing interest in our products, our R&D projects are showing promising results and soon our disinfectant products will be ready for the European market.

Operational update on development and operations in 2020

Research and product development

SoftOx Inhalation Solution (SIS):

SIS is undergoing development for the treatment of respiratory infections caused by viruses and bacteria. SIS is an aerosolized form of the SoftOx technology, designed to be safe and effective in the upper airways and in the lungs. Although there may be many indications for use, SoftOx has at the present time focused on the issue concerning the Corona pandemic and COVID-19 patients.

After presenting our preclinical evidence to the Danish Medicines Agency (October 2020), we obtained important feedback on our development plans, and we aim to bring SIS to market as soon as possible. During Q4-2020, we have advanced considerably in our preclinical research to establish safety and tolerability in relevant animal models. At the same time, we have gained even more evidence on the therapeutic concentrations. Altogether, this will be included in the scientific documentation to enable us to proceed with our first-in-human (FIH) study. We estimate the regulatory submission for phase 1 during Q1-2021.

SoftOx has obtained a “SkatteFUNN” grant specific to the SIS project from the Research Council of Norway (NFR) which includes all basic research that has already been completed in 2020.

SoftOx Biofilm Eradicator (SBE):

SBE functions as an infection remover in chronic wounds and is expected to have therapeutic effect by penetrating and killing microbes within biofilms. The formula shall penetrate deep into wound bed, yet it is non-toxic and safe to use. SBE kills antibiotic resistant bacteria and does not induce new resistance. Today's recommended solution, debridement removes only partly the bacterial infection and involves surgical removal of the wound bed. SBE represents an innovative treatment principle in how to prevent and treat biofilm infections in wounds.

The final audited report (published on Euronext Growth, Oslo 16.12.2020) from the toxicity study (GLP standard) over 28 days has been received during Q4-2020. This study, performed at the European Research Biology Center (ERBC) in Pomezia, Italy, aimed to examine the company's SBE product candidates with regard to tolerance and toxicity in mini pigs (which is the chosen animal model for toxicological studies of damaged skin for drug testing and is also the animal model recommended by the regulatory authorities). As previously reported, even at the highest concentrations, no adverse local or systemic effects of the test solutions were observed, and the product candidates can therefore be regarded as safe. With the final report at hand, we have achieved an important milestone documentation-wise, and the results are very encouraging. The study provides a solid foundation for further development of SBE in human patients with infected chronic wounds.

An important prerequisite for further product development is public funding. SoftOx has already received a grant from the Research Council of Norway (NFR) which has been vital to the basic research that has already been completed. In addition, SoftOx has received a grant of USD 2 million issued on behalf of the Naval Medical Research Center (NMRC) under the Medical Technology Enterprise Consortium (MTEC), a biomedical technology consortium that collaborates under a transaction agreement (OTA) with the US Army Medical Research and Development Command (USAMRDC). Together, these grants will move the project forward to Proof of Concept (PoC) in humans in which most of the costs are expected to be covered by the stated contributors. Further studies, if needed depending on classification, is planned to be based on the results achieved in POC and hopefully financed in cooperation with future

partners. SoftOx and NMRC/MTEC have already started on the collaboration and are working to reach our aggressive milestones and timelines ahead.

In addition, SoftOx is already working on “next generation” products which are designed to give the product new and enhanced attributes. This also includes parts of a doctoral research project, which is partially financed by the Research Council of Norway and in partnership with the Department of Pharmacy at the University of Oslo.

SoftOx Wound Irrigation Solution (SWIS):

SWIS is intended for acute and chronic wounds and was developed to rinse wounds to prevent infections and biofilm formation. The medical device uses a lower concentration and gives a softer sting when applied to wounds. SWIS is safe to use and non-toxic to host cells/tissue. The current recommended treatment solution for acute wounds is saline water, which holds 80% market share. Based on the clinical results achieved in the pilot study the goal of SWIS is to replace today's wound wash products with a product equal risk profile and profound antimicrobial effect.

SoftOx Wound Irrigation Solution (SWIS), the company's first medical device, has seen good progress. The clinical study (SWIS-02), which is to confirm the results of the first pilot study (SWIS-01), is approved by both the Danish Medicines Agency and the Danish Research Ethics Committees (VEK). The clinical study started late November 2020 and has already recruited 20% of the total number subjects by the end of December 2020. The study is being performed at the recognised wound treatment centre at Bispebjerg University Hospital in Copenhagen. Given the ongoing lockdown by the Danish government, this situation are affecting the recruitment pace of the study. Due to the nature of the ongoing COVID-19 pandemic the company cannot predict how long the lockdown will last.

In parallel with the completion of the clinical study, the company's quality system continues to be developed to satisfy the requirements for CE marking.

Animal health

The activities related to animal health have been delayed due to the outbreak of the ongoing COVID-19 pandemic. A small study on companion animal wounds, which was postponed last year due to the stated reasons, is expected to be reactivated in Q2-2021 and conclude in Q4-2021. In the long term, animal health will continue to be an important part of the SoftOx research activities.

Market trends, sales and distribution

Market trends

The company's long-term ambition is to establish a new category of highly effective and skin-friendly hand disinfection products. We want to establish SoftOx as the preferred choice of

alcohol-free disinfectants, especially in the segment of users who experience that today's hand disinfectant products dry out and damage the skin. This is a well-known problem for health professionals. As a result of increased use and attention around hand disinfection due to the COVID-19 pandemic, it has become even more relevant. Particularly vulnerable groups such as children, young people, the elderly and people with sensitive, damaged skin or eczema need a safe and skin-friendly alternative to alcohol.

National guidelines currently prioritize disinfectant products with alcohol. SoftOx is working to ensure that new products with documented effect, safety and skin friendliness are at least equated with current products, and SoftOx has a close dialogue with the authorities in all the Nordic domestic markets in this regard. The World Health Organization (WHO) has also acknowledged the need for alcohol-free solutions in their updated guidelines on hand disinfection. This growing awareness along with the approval from Kemi and the expected updated guidelines from FHI will pave the way for the product introduction on a Pan-European level, in addition to the local level. The Norwegian Minister of Health has previously confirmed that the hand hygiene guidelines will be updated accordingly when new knowledge is made available.

SoftOx expects that the market for disinfectants will continue to grow in 2021 because of the ongoing COVID-19 pandemic. The gradual opening of society as a result of vaccination efforts will most likely add further focus to infection control measures, and thus keep the use of disinfectants at a high level in the long term.

We are experiencing a growing interest in our effective and skin-friendly products in the market, and we expect this segment to gradually increase its market share. SoftOx has therefore decided to stick to the long-term strategy of building the foundation for the category of "high-efficiency and skin-friendly disinfection" and establish a separate category of skin-friendly hand disinfectants, with SoftOx as the preferred solution, rather than maximizing the short-term sales of AntiVir™ in a saturated alcohol-based market.

Sales and distribution

In order to operate in line with the new European guidelines and after a dialogue with the Norwegian Environment Agency, SoftOx decided to withdraw and change the label on the products sold before the EU change took effect. The practical consequence is that SoftOx chose to call back products for approximately NOK 1,9 million to ensure correct labelling. The amount is larger than first estimated due to a higher batch of goods that we did not expect to be returned. This decision has reduced revenues in Q4-2020.

To secure competitiveness and broad distribution, SoftOx introduced AntiVir™, SafeDes Hand Disinfectant™ and EffectDes® Surface Disinfectant to the Norwegian market in Q2-2020. In the second half of 2020, the company has worked intensively to expand its network of distributors in several market segments. We have also been working extensively to establish relations and increase product knowledge with important key customers in various market segments.

By the end of 2020, we have built a solid foundation on the distributor side: MILAS for the kindergarten segment; Bonaventura for groceries, pharmacies and specialty stores; AssistCo for sports and sports medicine; Brødrene Dahl for the industrial segment; Wittusen and Jensen for the office segment and the Red Cross Auxiliary Corps for infection control are worth mentioning.

Through AssistCo, SoftOx hand disinfection has been launched in the sports chain XXL in Norway, Sweden and Denmark and is on its way into additional sports chains in Norway in Q1-2021. Through Bonaventura, SoftOx has been accepted into NorgesGruppen's grocery chain Meny, in addition to a voluntary listing in the grocery chains Spar and Bunnpris, which includes a total of more than 700 grocery stores in Norway. These new distribution agreements give us increasing confidence that the market will respond with significant sales in 2021.

Our primary focus is on the health care sector, where we have an upcoming hospital tender (HINAS) for the infection disease control category. The tender is again postponed and is expected to be announced in February 2021 for the first time with a separate category for alcohol-free hand disinfection.

At SoftOx, we look at the past year as a launch year for the first product based on the innovative SoftOx technology. In the years to come, we believe that our technology will form the basis for a number of innovations that that will make important contributions in "Helping the World Fighting Infections".

In this launch year, we faced some challenges, but also many victories. Naturally, entering an established market and market infrastructure come with some start-up problems and a lot of lessons. The COVID-19 pandemic hit us with full force in the spring of 2020, and we managed to launch 6 months in advance of the original plan. Many had possibly too optimistic expectations regarding sales and speed of market penetration, but we experienced long-lasting negotiations with distributors and delays in large tenders with public customers. We also faced a significant delay in the update of the hand hygiene guidelines from the Norwegian Institute of Public Health (FHI).

In retrospect, we are still satisfied. The COVID-19 pandemic has created a larger market for disinfectants for many years to come. We know that we have a skin-friendly and superior product. We have established a new sales and marketing strategy with many exciting distribution agreements in place for 2021. The needed production capacity is in place to meet the market demand. The company is also well prepared to launch in new markets as soon as we get the expected EU approval.

Organizational information

SoftOx has used 2020 to build a solid and robust organization both when it comes to R&D activities, sales and marketing in addition to administration and control functions.

Significant risk factors for the company

- The rise of COVID-19 infection and the lockdown of society entails a risk for the entire value chain in the company – from delivery of goods, illness among employees in production, quality control and development and delivery of goods as well as our R&D teams
- Research studies always involve an inherent risk of being delayed and not delivering results as expected
- Lack of approval of applications for conducting clinical studies and products
- Further delays by the authorities in updating their recommendations related to hand disinfection in the Nordic countries

Financial matters

Financial figures for the SoftOx Solution Group are not audited (figures in brackets are comparable figures for 2019).

Profit and loss statement

In 2020 the company's revenue for hand disinfectants and surface disinfectants reached approx. NOK 3,7 million. As predicted in previous reports, sales in Q4-2020 were lower than expected at just below minus NOK 1,3 million due to the withdrawal of products because of wrong labelling. In addition, just above NOK 6 million (NOK 4 million) has been recognised as income in connection with funding from The Research Council of Norway and Department of Defence. Compared to 2019, income has increased by approx. 140 % this year.

Salary costs were NOK 18,9 million (NOK 11,2 million), an increase of 69 % compared to the previous year. This increase is mainly due to several employees in the production, sales and administration departments, which is planned to contribute to boosting business further.

Other operating costs have increased to NOK 39,6 million (NOK 13 million) in 2020. For Q4-2020, the cost is approx. NOK 13,4 million (NOK 2,9 million) compared to NOK 9 Million (NOK 4 million) in Q3-2020. The increase related to last year is due to several factors among others construction and facilitation of the company's production and sale force and increased activity for R&D projects which have met several important milestones in 2020. More than 65 % of operating expenses in 2020 are related to R&D activities

SoftOx continues to build up its organization for future growth and development, and pre-tax results ended with a loss of NOK 49,7 million (loss of NOK 21,8 million).

Cash flow and consolidated balance sheet

Of the capitalized assets, the company has activated its IP and patent cost worth NOK 6 million. These are capitalized patent costs in the Swedish subsidiary, which get depreciated over 5 years. Deferred tax assets stand at NOK 18,2 million, corresponding to the year of 2019, adjusted for tax in Sweden. Tax calculations will be performed at the end of the year on revised figures.

Production has been initiated and investments of approx. NOK 4 million have been capitalized. This mainly applies to production facilities that have been put into operation. Due to low sales in Q3 and Q4, stocks have been built up to a value of approx. NOK 3 million at the same time as receivables have increased with NOK 3,3 million.

In December, SoftOx raised NOK 50 million through its private placement. The private placement is divided into two tranches: tranche 1 consists of 500,000 shares and tranche 2 with 409 090 shares. It is only the first tranche of NOK 27,5 million that has been posted by year end. The second tranche was approved by company's General Assembly (GA) January 4th, 2021. At the GA, a repair issue up to NOK 10 million was also approved. The repair issue is scheduled to be implemented in Q1-2021.

Outlook

- Progressing work on the development of each individual project
 - o SoftOx Wound Irrigation Solution (SWIS) – complete the clinical study (SWIS-02) and quality system for medical devices. Establish GMP production and submit an application to the *Notified Body* for CE certification
 - o SoftOx Biofilm Eradicator (SBE) –achieve regulatory approval and launch a Phase I study of patients with chronic wounds
 - o SoftOx Inhalation Solution (SIS) – excellent progress of preclinical safety studies in compliance with the advice of the regulatory authorities. Aim to submit and obtain approval of first-in-human study
- The company's work to boost sales to achieve a positive cash flow
- Submission of tenders for HINAS (hospital tender for the national agreement) announcement where the tender will introduce a separate category for alcohol-free hand disinfection
- Product launch to the consumer segment via AssistCo into the sports segment (Sport1, Stadion Sport) and Bonaventura into grocery chain NorgesGruppen's members Meny, Spar and Bunnpris Q1/2021
- Get disinfectants approved outside the Nordic region to launch the products in selected markets
 - Selecting markets in Northern Europe incl. Germany and in Asia is considered high priority

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- Receive final confirmation from The Swedish Chemical Agency regarding the EU approval of SoftOx disinfectants after questions and comments from Danish Environmental Protection Agency and the Norwegian Environment Agency have been replied and the final decision settled
 - Resume activities in animal health
 - Establishment of a network of partners and distributors in Norway, Sweden, Denmark and Germany will be an important activity for the next 6-12 months — experience can be utilized at launches in other countries

Declaration by the Board

We confirm, to the best of our knowledge, that the unaudited, summarised Q4 accounts for the period 1 January to 31 December 2020 have been prepared in accordance with accounting standards for the group and that the information contained in these accounts gives a true and fair view of the group's assets, liabilities, financial position and profits as a whole, and that the Q4 report provides a true and fair view of the information specified in Section 5-6, fourth paragraph, of the Norwegian Securities Trading Act.

Oslo, February 8th 2021

SIGNED

Melvin Teigen, Chairman of the Board

SIGNED

Kari Myren, Board Member

SIGNED

Claus Seeberg, Board Member

SIGNED

Olav Jarlsby, Board Member

SIGNED

Geir Hermod Almås, CEO

Profit and loss statement				
Accounts for fourth quarter and year to date 2020				
SoftOx Solutions Group				
<i>NOK 1,000</i>	Q4 2020	Q4 2019	YTD 2020	YTD 2019
Other operating revenues	596	233	9 839	4 099
Total operating revenues	596	233	9 839	4 099
Personnel expenses	7 940	3 153	18 869	11 197
Other operating expenses	13 424	2 902	39 631	13 071
Depreciation	1 223	873	2 703	1 701
Depreciation, goodwill				
Total operating expenses	22 588	6 928	61 203	25 969
Operating result	-21 992	-6 695	-51 364	-21 870
Net financial items	1 523	0	1 650	38
Net result before taxes	-20 469	-6 695	-49 714	-21 832
Tax				5 842
Net result after tax				-16 336

Statement of financial position	31.12.2020	31.12.2019
SoftOx Solutions Group		
<i>NOK 1,000</i>		
Other intangible assets	6 143	4 928
Deferred tax asset	18 218	18 135
Goodwill from acquisition of subsidiary		
Total intangible assets	24 361	23 063
Production equipment	3 909	242
Total fixed assets	3 909	242
Non-current assets	28 270	23 304
Inventory	2 970	0
Total inventory	2 970	
Other receivables	8 961	5 664
Total receivables	8 961	5 664
Cash and cash equivalents	34 802	75 996
Current assets	46 733	81 660
Total assets	75 002	104 965

Share capital	167	155
Other paid in equity	116 735	89 713
Total paid in equity	116 902	89 868
Other equity	-52 992	-3 399
Total equity	63 910	86 469
Other long term debts	0	114
Other non-current liabilities	0	114
Public duties payable	151	659
Shareholder loans	0	3 101
Other current liabilities	5 145	3 622
Accounts payable	5 797	10 999
Total current liabilities	11 093	18 382
Total liabilities	11 093	18 496
Total equity and liabilities	75 002	104 965

Cash flow statement	Q4 2020	Q4 2019	31.12.2020	31.12.2019
SoftOx Solutions Group				
<i>NOK 1,000</i>				
Cash flow from operating activities				
Net result before taxes	-20 469	-6 695	-49 714	-22 178
Tax paid			0	0
Depreciation	1 223	873	2 703	1 701
Change in current assets	1 775	2 662	-6 090	518
Change in current liabilities	1 060	8 707	-7 289	9 397
Net cash flow from operating activities	-16 410	5 547	-60 390	-10 562
Cash flow from investment activities				
Investments in non-current assets	6	-3 201	-7 668	-3 201
Net cash flow from investment activities	6	-3 201	-7 668	-3 201
Cash flow from financing activities				
Proceeds from equity issues	26 125	70 500	27 135	88 394
Other financing activities	0	1 814	-114	114
Translation differences	-289	36	-157	14
Net cash flow from financing activities	25 836	72 350	26 864	88 521
Net change in cash and cash equivalents	9 432	74 696	-41 194	74 759
Cash and cash equivalents at beginning of period	25 370	1 300	75 995	1 237
Cash and cash equivalents at end of period	34 802	75 995	34 802	75 995

Statement of changes in equity				
SoftOx Solutions Group				
<i>NOK 1,000</i>				
	Q4 2020	Q4 2019	YTD 2020	YTD 2019
Equity at end of prior period	58 365	17 238	86 468	14 409
Share issues	27 500	75 995	28 510	88 393
Loss for the period	-20 469	-6 695	-49 714	-16 336
Other changes in equity	-1 486	-70	-1 354	2
Equity at end of period	63 910	86 468	63 910	86 468

Notes to the half-year accounts for the SoftOx Solutions Group

Note 1 Accounting principles

The accounts for the SoftOx Solutions Group have been prepared according to Norwegian Accounting Act and generally accepted accounting principles for small companies.