# **INVESTMENT MEMORANDUM**



## SOFTOX WOUND & SKIN CARE AS

MAY 2025 (THIS IS NOT A PUBLIC OFFERING OR A PROSPECTUS)

SoftOx Wound & Skin Care AS

Bærum, Norway

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#### 1) Company background and unmet medical need

- i. SoftOx Wound & Skin Care AS (registration number: 921 773 668 and headquartered in Bærum, Norway) was earlier named SoftOx Disinfection AS and was a subsidiary of SoftOx Solutions AS. The name was changed before it was distributed as a dividend to the shareholders of SoftOx Solutions. The shareholders in SoftOx Solutions on the 23<sup>rd</sup> of December 2024 received one share in SoftOx Wound & Skin Care for each share held in SoftOx Solutions.
- ii. The early-stage financing of the company was secured by a group of investors, all shareholders in SoftOx Solutions AS, who through a guarantee agreement with the company have provided convertible loans. Part of this financing is now being converted to shares in the company. All shareholders not participating in the guarantee are invited to participate in a share issue with preemptive rights, on the same terms as for the guarantors' convertible loans.
- iii. SoftOx has developed new antimicrobials using buffered hypochlorous acid, addressing various tissue infections. The US FDA states that infections are a major challenge in wound care, requiring elimination for successful healing and noting no good solutions currently exist.
- iv. According to the International Wound Journal<sup>1</sup> the total wound care cost is estimated to be USD 300 billion worldwide. SoftOx offers a unique, patent-protected antimicrobial technology to treat wound infections effectively.

#### 2) Product development status

- Following regulatory changes, development of the medical device SoftOx Wound Irrigation Solution (SWIS) has been downgraded, and the focus is the drug SoftOx Biofilm Eradicator (SBE).
  - a. The first clinical trial of SBE confirmed its safety, tolerability, and dose-dependent antimicrobial and wound closure effects.
  - b. The trial included 28 patients with leg ulcers: 20 treated once in phase 1a, and 8 treated for five consecutive days in phase 1b.
  - c. Maximum effect was observed in the group treated twice daily for five days, showing a 98% reduction in bacterial burden and a 36% wound closure rate.
  - d. All treated groups showed positive wound closure outcomes, while the control group in phase 1a experienced negative development.
  - e. The performed studies also showed safety and tolerability on high doses of both Acetic acid and Hypochlorous acid.
  - f. Publication of the study results can be found in the medical wound journal "Advances in Wound Care" Link to the published article
- ii. Preclinical studies have indicated that the solution does not induce resistance or crossresistance to antibiotics.
- iii. In vitro studies have demonstrated a strong effect against biofilms and resistant microbes.

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<sup>&</sup>lt;sup>1</sup> https://doi.org/10.1111/iwj.14491

## SOFT-OX Wound & Skin Care

#### **Investment Memorandum**

- iv. Given its effectiveness against WHO-listed antibiotic-resistant microbes and biofilms, the company believes the product could also be approved as a topical solution for treating resistant wound infections.
- v. The company's patent-protected chemical solutions have adequate chemical stability in high doses when stored in compliance with regulatory requirements for drugs.

#### 3) Clinical development plan and regulatory pathway:

- i. The company is evaluating the opportunity to conduct a separate phase 2 clinical study in Ukraine to demonstrate its capability in treating wounds effectively in conflict areas, addressing issues with resistant bacteria in wounds. The study aims to have a shorter timeline than a normal phase 2 clinical study due to the emergency and may get partial funding from Western European allies. Ukraine's regulatory requirements are similar to those of the EU. The total cost is estimated to be EUR 1-2 million, and the timeline is approximately 1 year.
- ii. Based on data from Ukraine, the company has several potential next steps.
  - a. Execute a phase 3 study in Europe to get approval for the treatment of antimicrobial infections in surgical and trauma wounds.
  - b. With approval as an antimicrobial solution, the company shall perform clinical trials on different indications, to broaden the product's reach.
  - **c.** Conduct additional dose-finding studies to optimize wound closure in chronic wounds to achieve labelling for this purpose.

#### 4) Wound care market and commercial potential

- i. The total market for wound care products is estimated at USD 22 billion with a compound average growth rate (CAGR) of 7%.
- **ii.** The estimated material cost of total wound care cost is estimated to be approximately 7,5 %, where remaining costs are mainly personnel costs, but also the cost of facilities and other costs.
- iii. Excite International's study on SoftOx found that improved wound healing for venous leg ulcer (VLU) patients in the US could save between USD 1,307 to USD 6,555 per patient. The antimicrobial effect alone is valued at USD 732 per VLU patient. With about 2 million VLU patients in the US, total savings could range from USD 2 to 15 billion. The cost of the treatment of VLU is estimated to be approximately 15% of the US wound care market. The US accounts for approximately 40% of the global wound care market.

#### 5) Commercialization strategy

- i. With a focus on addressing significant unmet medical needs and targeting sales to doctors and hospitals, the company may utilize local distributors for distribution in the EU and US, while licensing its technology in other relevant areas globally.
- ii. The active substance of a second-generation SBE will be produced in Europe and distributed globally. The final product is nearly the same as the first generation, but with significantly improved shelf life.

#### 6) Intellectual property and patents



#### **Investment Memorandum**

i. SoftOx Solutions AS and SoftOx Wound & Skin Care AS have collectively filed over 100 patents globally and have been granted 75 key patents as of March 2025. These key patents are filed in the US, Europe, MENA, Asia, and South America. The contract between the two companies regulates shared ownership, granting each company licensed access to the other's intellectual property within its specific area. SoftOx Solutions AS is authorized to explore the use for mucosa, while SoftOx Wound & Skin Care can focus on wounds, skin, surfaces, and plants.

#### 7) Shareholders

The 20 largest shareholders in the company as of 21.05.2025:

#	Share %	Name
1	13,6 %	PRO AS
2	12,3 %	J G INVEST AS
3	8,1 %	OSLO NÆRINGSUTVIKLING AS
4	6,7 %	HAREFRØKEN INVEST AS
5	5,1 %	MYRLID AS
6	4,4 %	BONICAAS
7	4,1 %	ALMHAUG BOLIG AS
8	2,5 %	Danske Bank A/S
9	2,4 %	STIFTELSEN UNI
10	2,4 %	LOYD AS
11	1,9 %	AUBERT INVEST AS
12	1,8 %	INGEBORG VICTORIA AASVOLD ALMÅS
13	1,8 %	ROBIN EVEN HAMMER
14	1,7 %	NORDNET LIVSFORSIKRING AS
15	1,6 %	WL-02 HOLDING AS
16	1,5 %	HOLTA & CO AS
17	1,3 %	GH HOLDING AS
18	1,3 %	GEMALLO AS
19	1,2 %	Nordnet Bank AB
20	1,0 %	The Bank of New York Mellon

Total number of shares in the company: 1 951 253 942

A daily updated share register is available for Scandinavian investors at the Public Shareholder Register.



#### 8) Guarantee agreement

- i. According to a guarantee agreement of November 2024 between certain guarantors and SoftOx Solutions AS related to SoftOx Wound & Skin Care, a plan for developing the wound care business is aimed for by 2026 to finance a phase 2/3 SBE study in the US or EU. The guarantee secures NOK 10 million in 2025 to cover the cost of the work up till February 2026.
- **ii.** The guarantee agreement states that shareholders who are not guarantors have the right to invest an amount of NOK 6 million into the company on equal terms as for the guarantors.
- iii. In order to finance the phase 2/3 SBE clinical study, the company has engaged a consulting firm to assist in exploring the opportunity to list the company, either on Nasdaq New York or another relevant market. Other financing alternatives and shareholders' exit will also be evaluated.

#### 9) Risk factors

- i. **Volatility and Market Risks:** Share prices may fluctuate significantly due to factors beyond the company's control, potentially resulting in a loss for investors. Market trends and past performance do not guarantee future results.
- ii. **Dilution Risk:** Issuing new shares to raise capital may dilute existing shareholders' ownership, impacting dividends, voting rights, and share value.
- iii. **Foreign Shareholder Restrictions:** Shareholders outside Norway, especially in the U.S., may face participation restrictions in rights issues due to differing regulations.
- iv. **Financial Risks:** These include interest rate risks affecting returns on cash, currency fluctuations impacting on foreign transactions, low credit risk due to limited receivables, and continuous liquidity monitoring to maintain financial flexibility.

#### v. Operational Risks:

- a. **Research and Development:** Developing MedTech and pharmaceutical products involves significant risks in clinical trial outcomes and timing. The company mitigates these by adhering to best practices and collaborating with specialized Clinical Research Organizations and international partners.
- b. **Commercial Risks:** Challenges include time, costs, competition, regulatory approvals, and patent protection. Strategic partnerships provide financial and R&D support to mitigate these risks.
- c. **Partnerships and Collaboration Risks:** Success relies on strong partnerships with suppliers, clinical trial parties, distributors, and key customers. The company employs a partner strategy to align with like-minded partners at various development stages and relies on a solid distribution network for sales.
- vi. **Intellectual Property Rights:** Protecting intellectual property is critical and involves maintaining patent protection and avoiding third-party infringements. The company collaborates with Withers Bergman, securing patents globally.



vii. **Legal Risks:** The company remains vigilant against potential legal challenges that could arise from ongoing or unforeseen disputes, regulatory changes, or other legal requirements impacting its operations.

#### 10) Share issues and use of proceeds

- i. In addition to the referred guarantee amounting to NOK 10 million, additional funds of NOK 10 million are needed for
  - Filing for NASDAQ Capital Market NY listing or other relevant markets NOK 6 million.
    - i. Post-filing, the company expects to be able to secure funding from other investors to secure IPO and listing.
  - **b.** Cost for planning and securing financing of studies in Ukraine NOK 4 million.
- ii. Subject to approval in the company's General Assembly on 22<sup>nd</sup> May 2025:
  - **a.** NOK 6 000 000 already financed through convertible loans related to the guarantee will be converted to 1 200 000 000 shares at a share price of NOK 0,005 per share.
  - b. NOK 6 608 675,89 share issue is being offered to the shareholders, ref 8) b), at a share price of NOK 0,005. Shareholders who are not part of the guarantee agreement have the first right to subscribe.
    - i. Subscription period: from 22<sup>nd</sup> of May 2025 until 19<sup>th</sup> of June 2025 at 16:00 CEST, unless terminated earlier by the Board, but not before 5<sup>th</sup> of June 2025 at 16:00 CEST. If the maximum amount is subscribed by entitled shareholders by the 5<sup>th</sup> of June 2025 at 16:00 CEST, no further subscriptions will be permitted. If the maximum amount is not subscribed, guarantors and others may participate, with priority given to shareholders, including guarantors.
    - ii. Minimum subscription: NOK 10 000,00.
    - iii. Allocation: If shareholders entitled to subscribe have subscribed for shares exceeding the maximum amount, the shares will be distributed proportionally among subscribers in accordance with section 10-4 (1) and (3) of the Private Limited Companies Act.
    - iv. Payment deadline: No later than the 27th of June 2025.
    - v. The company is entitled to dispose of the amount before the capital increase is registered in accordance with section of dispose of the Private Limited Companies Act.
    - vi. The subscription shall be made on a separate subscription form. The subscription form is available at www.sow.no.
    - vii. Subscriptions may be made by email to <a href="mailto:post@sow.no">post@sow.no</a> by the 5<sup>th</sup> of June 2025, at 16.00 CEST.
  - **c.** The Board of Directors will be granted authorization to increase the company's share capital by up to NOK 780 000, and by setting aside the shareholders' preemptive right according to section 10-4 of the Private Limited Companies Act.



### **Investment Memorandum**

### **11 Contact Information**

For inquiries, email post@sow.no