bioXXmed AG

Germany / Healthcare
Primary Exchange: Frankfurt
Bloomberg: T5O GR
ISIN: DE000A0KFRJ1

Initiating coverage

RATING	**BUY**
PRICE TARGET	**€ 3.10**
Return Potential	82.4%
Risk Rating	High

CLOSE TO ACHIEVING APPROVAL OF LEAD PRODUCT

BioXXmed AG (former CytoTools) is a German holding company with a focus on the biotech and medtech sectors. BioXXmed's core holding in the company DermaTools GmbH is an attractive asset. DermaTools has completed development of its medical device candidate, DermaPro solution, and is preparing it for registration in Europe and the US. This product has the potential to significantly improve treatment of chronic wounds, particularly difficult-to-heal diabetic foot ulcers (DFU). In clinical trials, DermaPro has demonstrated statistically significant superior efficacy compared to standard of care (saline wound dressings). Results of a European multicentre, double-blind, randomised, comparative phase IIb study in 72 DFU patients showed that DermaPro delivered 67% wound area reduction vs 30.5% in the control group and complete wound closure in 38.2% of patients vs 23.7% in the control group receiving standard of care. The company is currently finalising marketable primary packaging and completing the upscaling of the manufacturing process and documentation required for DermaPro's certification according to ISO 13485 and registration as medical device. The goal is to obtain the CE-mark in Europe and 510(k) in the US. The company is also raising awareness of the product among specialists and potential distributors at wound care conferences. If DermaPro is approved and assuming the company can secure a marketing partner for commercialisation, we anticipate DermaTools will generate sales with DermaPro of >€25m in Europe and the US within 5 years of launch. We expect positive news flow on this product to trigger stock appreciation within the next 12-18 months. This news flow is likely to include filing and CE-registration in Europe, submission of the 510(k) application and FDA response in the US, announcement of a deal with (a) commercialisation partner(s) for the EU and potentially the US. We initiate coverage of BioXXmed with a Buy rating and a price target of €3.10.

Buy recommendation In our valuation, we focus on DermaTools, which is currently the only holding of significant value. Our sum-of-the-parts valuation model focusing on the lead product DermaPro yields a price target of €3.10, which represents a return potential of >80% from the current level. (p.t.o.)

FINANCIAL HISTORY & PROJECTIONS

	2020	2021	2022	2023E	2024E	2025E
Revenue (€ m)	0.04	0.04	0.01	0.01	0.00	0.00
Y-o-y growth	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
EBIT (€ m)	-1.84	-1.53	-0.82	-0.83	-0.88	-0.91
EBIT margin	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Net income (€ m)	-1.84	-4.06	-0.83	-0.82	-0.87	-0.91
EPS (diluted) (€)	-0.46	-1.01	-0.18	-0.16	-0.16	-0.15
DPS (€)	0.00	0.00	0.00	0.00	0.00	0.00
FCF (€ m)	-1.66	-1.69	-2.41	-1.36	-0.89	-0.93
Net gearing	n.a.	n.a.	n.a.	n.a.	-4.8%	-5.1%
Liquid assets (€ m)	1.57	0.00	1.84	0.49	1.01	1.08

RISKS

Risks to our price target include but are not limited to development, partnering, financial, and regulatory risks.

COMPANY PROFILE

BioXXmed AG (former Cytotools) is a German holding company with focus on the biotech/medtech sectors. BioXXmed's core holding in the company DermaTools GmbH has a medical device candidate, DermaPro, which is close to obtaining approval in Europe and potentially the US. This product has shown superior efficacy compared to standard of care in difficult-to-heal diabetic foot ulcers.

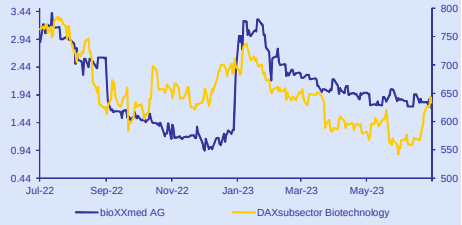
MARKET DATA

As of 7/28/2023

Closing Price	€ 1.70
Shares outstanding	5.14m
Market Capitalisation	€ 8.73m
52-week Range	€ 0.94 / 3.41
Avg. Volume (12 Months)	2,244

Multiples	2022	2023E	2024E
P/E	n.a.	n.a.	n.a.
EV/Sales	0.0	0.0	0.0
EV/EBIT	n.a.	n.a.	n.a.
Div. Yield	0.0%	0.0%	0.0%

STOCK OVERVIEW



COMPANY DATA

As of 31 Dec 2022

Liquid Assets	€ 1.84m
Current Assets	€ 1.95m
Intangible Assets	€ 0.00m
Total Assets	€ 21.61m
Current Liabilities	€ 0.00m
Shareholders' Equity	€ 21.42m

SHAREHOLDERS

Heidelberger Beteiligungsholding AG	19.7%
Delphi Unternehmensberatung AG	22.2%
Klocke Holding GmbH	7.1%
Freefloat and other	51.0%

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INVESTMENT CASE

Diabetic foot ulcer (DFU) care is an attractive market with high medical need Chronic wounds, particularly DFUs, are often very difficult to treat, and there is currently a high unmet medical need for newer, more efficient products. Diabetes is a major public health problem that is reaching epidemic proportions worldwide, with about 97m patients with diabetes in Europe and the US alone. There are an estimated 7.8m patients in Europe and the US who suffer from DFU – of which ~3m in Europe – and the DFU prevalence of 5-13% among diabetic patients is on the rise. The global DFU market was valued at USD 4.7bn in 2021 and is forecast to grow at a CAGR of 5.9% until 2030. The European DFU treatment market was estimated at USD 1.45bn in 2021 and is projected to expand at a CAGR of 5.4% until 2030 (sources: Zhang et al., 2016; CDC's National Diabetes Statistics Report for 2022, WHO, statistics from the International Diabetes Federation, Grand View Research).

DermaPro (active ingredient DPCOL / Indian brand name WOXheal) has achieved statistically significant superior efficacy to standard of care and is approved as a drug in India We believe DermaPro is a promising therapy for chronic wound healing and DFU in particular. BioXXmed licensed DermaPro to the Indian partner, Centaur Pharmaceuticals Pvt Ltd (Centaur). Following positive Indian phase II studies in 80 patients in which the product delivered 72% wound closure vs 60% in the control group, Centaur conducted phase III trials in 311 patients in India. WOXheal met the primary endpoint by achieving a superior statistically significant (p=0.0156) complete healing rate of 75.5% at the end of the 10-week treatment period; vs 62.0% in the standard of care group (source: Bal et al., 2022), representing a superior efficacy of DPCOL of 13.5 percentage points. The secondary endpoint was also met. DermaPro produced faster wound healing than standard therapy; its median time to wound closure was 42 days vs 56 days in the control group. Based on these solid data, WOXheal received Indian drug approval. Drugs typically require more robust and comprehensive efficacy data than medical devices which is the typical registration pathway that wound care products have largely taken around the world. Centaur is marketing the drug, although the sales level is low. Given that India is essentially a self-pay, price-sensitive market where most patients live in rural, hard-to-reach areas, we do not expect Centaur to generate significant royalties for BioXXmed in the coming years (FBe: <40-50k p.a.). Nevertheless, we are of the view Centaur has validated the positive efficacy profile of DermaPro.

Positive multicentre, double-blind, randomised, comparative phase IIb study in Europe also demonstrated statistically significant superiority of DermaPro against standard of care in DFU patients DermaPro's European clinical study showed positive safety and efficacy results in accordance with the primary endpoint. DermaPro achieved 67% wound closure overall (vs control: 30.5%) and complete wound closure in 38.2% of treated patients (vs control: 23.7%) in the total randomised patient population (Intention-To-Treat – ITT) of 72 patients. Moreover, in the patient population adjusted for protocol deviations (Per-Protocol-Set – PPS) of 53 patients, DermaPro delivered even stronger efficacy results, achieving complete wound closure in 41.7% of patients vs 20.7% in the control group (delta = 21 percentage points).

BioXXmed will pursue a medical device registration strategy in Europe and the US Missteps on the risky path of developing DermaPro as a drug led to the dismissal of the previous management and the initiation of civil action against them for alleged irregularities in the exercise of their office. The new CEO, Dr Rosen, undertook a professional reassessment and change of strategy. The company switched from a drug to a medical device registration pathway saving significant time and money for repeating a required pivotal trial. According to management, the solid positive data generated thus far is sufficient to support a CE-mark in Europe and 510(k) clearance in the US. The company is currently

completing dossiers and expects to submit and obtain European CE-mark approval by YE 2024. Given the greater complexity of the 510(k) submission in the US and the company's lack of initial contact with the FDA to confirm that the European/Indian data are sufficient, we are cautious in our assumptions for this country. We anticipate potential approval in the US in H1 2025 (BioXXmed guidance: mid-2024).

Potential marketing partnerships will be the key to DermaPro's success – we expect DermaTools to generate >€25m in sales five years after launch The DFU market is crowded and highly competitive. It is crucial that BioXXmed secure (a) committed medical device partner(s) to commercialise the product in Europe and the US. Unfortunately, the prior management failed to engage key opinion leaders (KOLs) in the development process to support the partnering process and promote the product to the scientific/professional wound care community. Management is currently catching up and presenting its solid study results (double-blind, two-arm studies against standard of care vs peers who typically have single-arm studies) at international wound care conferences. Based on the positive clinical data, we have assumed that BioXXmed will be capable of closing a deal for DermaPro with (a) medical device partner(s) in H1 2024, allowing a market launch among self-pay customers in H1 2025 in Europe and H2 2025 in the US (BioXXmed guidance: H2 2024).

We initiate coverage of BioXXmed with a Buy rating and a price target of €3.10 In our view, BioXXmed's holding in the subsidiary DermaTools is a valuable asset. DermaTools has a medical device candidate, DermaPro, which has the potential to provide with a better treatment option for DFU patients. We expect positive news flow on this product, particularly on the registration and potential partnerships for Europe and the US, to trigger stock appreciation within the next 12-18 months.

SWOT ANALYSIS

STRENGTHS

- **Lead product DermaPro has already demonstrated statistically significant efficacy in a multi-centre, double-blind, randomised, comparative phase IIb study in patients with diabetic foot ulcer (DFU) in Europe** The European DFU trial, including 72 patients, delivered a statistically significant superior efficacy compared to standard of care (saline wound dressing) including 67% wound area reduction vs 30.5% in the control group and complete wound closure in 38.2% of patients vs 23.7% in the control group.
- **DermaPro is close to the marketing stage in Europe and potentially the US** With DermaPro on the verge of receiving approval as a medical device for the treatment of DFU in Europe and potentially the US, BioXXmed's core holding DermaTools owns a promising late-stage product for DFU treatment with superior performance to the current standard of care (i.e. wound dressing) which could start generating revenues in 2025 (BioXXmed guidance: H2 2024).
- **DermaPro was validated through successful drug approval for DFU in India** In a pivotal phase III study with 311 patients DermaPro demonstrated a superior statistically significant (p=0.0156) complete healing rate of 75.5% compared to 62.0% in the standard therapy group. With the Indian partner Centaur who orchestrated DermaPro's clinical development, approval as a drug and market launch in India, the company has derisked, validated and added value to the product.

WEAKNESSES

- **Lack of opinion leaders supporting the lead product DermaPro** Despite the attractive efficacy data that DermaPro achieved in clinical trials, the former management did not make sufficient effort to build relationships with key opinion leaders (KOLs) who would know the product and promote its use. This may limit the company's ability to win a strong wound care marketing partner and create awareness of the product among the wound care specialist community to drive product adoption.
- **Holding structure and one holding company** As a holding company, BioXXmed provides poor earnings visibility, since the holdings are not consolidated in its financial statements. Moreover, the company has only one valuable holding, DermaTools, and limited funds to invest in additional holdings.
- **Small size compared to competitors active in the wound care market** With a market cap of approx. €9m BioXXmed and its core holding DermaTools are very small compared to giant wound care peers such as 3M (US), Smith & Nephew (US), Mölnlycke Health Care (Sweden), Convatec Group (UK), Medtronic PLC (Ireland), Cardinal Health (US), Baxter International, Inc. (US), among others. BioXXmed thus lacks financial and marketing strength and fully depends on potential marketing partners.

OPPORTUNITIES

- **Growing chronic wound care market** Wound care is still an underdeveloped market, with a considerable share of the market yet to adopt innovative advanced therapies. The European diabetic foot ulcer market is projected to grow at CAGR of 5.4% until 2030.
- **We expect DermaPro's value-enhancing registration as a medical device with a CE mark in Europe and 510(k) pathway in the US in 2025** BioXXmed/DermaTools even anticipate completing product registration as a medical device by mid-2024 in the US and by YE 2024 in Europe. Moreover, the company also aims to close a deal(s) for the commercialisation of the product in both regions in H1 2024. These milestones will add substantial value to the company.
- **Registration and partnership with Centaur in India may generate additional, although modest, revenue potential** By entering the Indian market via a partnership, BioXXmed/DermaTools will benefit from drawing on Centaur's sales force, which already has an established presence in clinicians' offices. However, India has a highly competitive, self-pay market which limits sales potential.
- **Expansion in further attractive holdings in the dermatology/wound care market** Management is currently evaluating new and innovative projects in dermatology and wound care which could expand its portfolio. For this purpose, it intends to raise €5-10m in additional funds.

THREATS

- **Production, registration and commercialisation risk** Despite DermaPro's proven superior efficacy, as a newcomer there is still a substantial risk that the company may fail to achieve CE-mark approval and particularly 510(k) clearance from the FDA. The main active ingredient, DPOCL, is produced by DermaTools. Manufacturing risks are chiefly related to DermaTools' reliance on third parties for downstream manufacturing of the product. In particular we see commercial and partnering risk, as the company is highly dependent on securing strong commercial partners able to successfully market and sell its product. In our view, this is BioXXmed's most challenging task.
- **Competitive risks** The self-payer chronic wound care and diabetic foot markets are very competitive and dominated by large peers who aggressively market their products. The dominant peers have strong marketing muscle which may prevail despite the possibly lower efficacy of their products compared to DermaPro. This makes it challenging for new players such as BioXXmed to get into the market.
- **Financing risks** The company will need to raise funds to finance operations beyond 2024, to secure DermaTools operations beyond Q1 2024 and to expand its holding portfolio. A difficult financing environment, negative news on its core holding DermaTools, CE-mark / 510(k) registration, partnership and launch of its lead products DermaPro could impede raising more capital.

VALUATION

We have assessed BioXXmed's fair value based on a sum-of-the-parts methodology (SOTP). We believe this is the most appropriate valuation method for the company because it reflects the implicit risk-adjusted value of every programme in the R&D pipeline. Development risks, including clinical, regulatory and marketing risks, are considered, as are market size and the expected timing of cash flows post-approval for each project.

At present BioXXmed has only one valuable holding, DermaTools, which in turn owns one valuable asset, DermaPro. We have used a risk-adjusted NPV model for the lead programme DermaPro in the one key development-stage indication, diabetic foot ulcer (DFU). We believe that DermaPro also has value in further chronic wound indications. However, BioXXmed my still need to conduct additional small clinical trials to expand the indication, embedding development risk. We thus regard it as upside to our valuation.

During the forecasting process, we adjusted our sales projections and resulting cash flows for estimated success probabilities to obtain risk-adjusted expected values. We base our probability coefficients on statistical sector studies, such as DiMasi et al., and on our own estimates. In this instance, we have derived an 75% probability of success in the DFU indication in the EU (clear CE mark medical device registration pathway, potential marketing partner(s) still to be found) and a 35% success probability in the DFU indication in the US (510k medical device registration pathway, unclear if the FDA accepts solely European & Indian clinical data, potential marketing partner(s) still to be found).

Additionally, using First Berlin methodology, which takes company-specific risk factors into account, we have derived a cost of equity (COE) of 16.5% for BioXXmed. Based on a debt ratio of 0.0%, we arrive at a WACC estimate of 16.5%, which we have used to discount projected cash flows. Including proforma net cash of €4.2m, we value BioXXmed at €19.4m, which implies a fair value of €3.10 per share on a proforma fully diluted basis.

Table 1: "Sum-of-the-parts" valuation model

Compound	Project[1)]	Present Value	Patient Pop (K)	Treatment Cost (€)	Market Size (€M)	Market Share (%)	Peak Sales (€M)	PACME Margin[2)] (%)	Discount Factor (%)	Time to Market (years)
DermaPro	Diabetic foot wounds - EU	€ 14.5M	3,000K	80	240.0M	4%	8.5M	50%	16.5%	1.5
DermaPro	Diabetic foot wounds - US	€ 13.2M	4,800K	100	480.0M	4%	17.2M	50%	16.5%	2.0
PACME PV		€ 27.6M			720.0M		25.7M			
Costs PV[4)]		€ 5.2M								
NPV		€ 22.4M								
Woxheal royalties PV		€ 0.0M								
Fair Value of 100% Holding		€ 22.4M								
Fair Value of 67.60% Holding		€ 15.2M								
Net cash (proforma)		€ 4.2M								
Fair Value BioXXmed		€ 19.4M								
Share Count (proforma)		6,268K								
Price Target		€ 3.10								

1) A project typically refers to a specific indication or, where necessary or relevant, a combination between indication and geographic market

2) PACME (Profit After Costs and Marketing Expenses) reflects the company's profit share on future revenues.
This share may be derived in the form of royalties (outsourced marketing/manufacturing) or operating EBITDA margin (in-house model), or some mix of both (depending on the specific parameters of partnership agreements)

3) Remaining patent life after the point of approval

4) Includes company-level R&D, G&A, Financing Costs and CapEx; COGS and S&M are factored into the PACME margin for each project

Source: First Berlin Equity Research

Risks Using our ten-factor risk analysis, we have set a High-risk rating for BioXXmed. The main risk factors that we have identified are development & regulatory, financing, securing committed marketing partners, and competition.

PRODUCTS – DETAILED ANALYSIS

Estimation of price, sales potential and product value

DermaPro in diabetic foot ulcer (DFU) patients in Europe DFUs are complex chronic wounds occurring in patients with diabetes. These wounds are commonly located on the bottom of the foot and chiefly result from arterial problems and diabetic neuropathy (damage of the peripheral nerves). The prevalence of DFUs among diabetes patients in Europe has been estimated at 5.1% (source: Zhang et al., 2016), which equates to about 3m DFU patients in the region. Despite significant advances in wound care, we see a substantial unmet medical need. Many wounds cannot be treated optimally, even with the most modern products, and 14-24% of DFU patients require a major or minor lower limb amputation due to severe gangrene (Liao et al., 2022). We therefore believe that innovative products with superior efficacy and cost/benefit performance have good chances of penetrating the market.

We have conservatively assumed an average ex-factory therapy price per treatment course of 8-10 weeks per year of €80 (or a retail price of about €230). We note that comparable antibacterial wound dressing treatments have retail prices of about €300-400 for an 8-10 week treatment course (e.g. UrgoStart wound dressing).

Due to the ageing of the population and growing numbers of diabetes cases, we have assumed that the DFU patient population will grow at a CAGR of 3% by 2040. We anticipate that BioXXmed will out-license the product either to a large medical device partner or to small regional players on a country-by-country base. The partner(s) will be responsible for commercialisation and bear the marketing expenses. We expect DermaPro to achieve a penetration rate of 4%, leading to peak sales of €8m five years after market launch. We project a potential EU CE-mark approval by YE 2024 and market launch in H1 2025.

Table 2: Assumed parameters for DermaPro in DFU patients in Europe

DermaPro - Europe	Present Value	Patient Pop	Treatment Cost	Market Size	Market CAGR	Market Share	Peak Sales	PACME Margin	Discount Factor
Parameters	€14.5M	3,000K	€80	€240M	3%	4%	€8M	50%	16.5%

Source: First Berlin Equity Research

Considering that DPOCL is not a complex compound and its contract manufacturer may be capable of easily synthesising and producing the product, we have assumed that DermaTools would be able to generate a profit margin (PACME margin) of 50%. These assumptions are in accordance with the metrics we have observed in the industry.

DermaPro in DFU patients in the US In the US, DFU prevalence is as high as 13% of diabetic patients, which based on 37.3m existing diabetic patients translates into 4.8m estimated DFU patients (sources: Zhang et al., 2016; CDC National Diabetes Statistics Report for 2022). The price level of wound care treatments in the US is in general at least 30-50% higher than in Europe. We have thus conservatively assumed an average ex-factory therapy price per 8-10 week treatment course per year of €100 (or a retail price of about €290). Similarly to Europe, we project that the DFU segment will increase at a CAGR of 3% until 2040.

We assume that the company will negotiate the licensing of the product's US marketing rights in parallel to the European rights with potential medical device partners, also a PACME margin of 50% upon commercialisation. Given that the US 510(k) is more complex

and the company has not yet had any contact with the FDA to discuss filing details and clarify the registration pathway, we assume more conservative timelines than BioXXmed's guidance. We thus project a potential medical device approval in H1 2025 (BioXXmed guidance: mid-2024) and market launch in H2 2025 (BioXXmed guidance: H2 2024). Based on an anticipated penetration rate of 4%, we conservatively expect DermaTools to achieve peak sales after five-year launch with DermaPro of € 17m.

Table 3: Assumed parameters for DermaPro in DFU patients in the US

DermaPro - US	Present Value	Patient Pop	Treatment Cost	Market Size	Market CAGR	Market Share	Peak Sales	PACME Margin	Discount Factor
Parameters	€13.2M	4,800K	€100	€480M	3%	4%	€17M	50%	16.5%

Source: First Berlin Equity Research

We project Indian sales and corresponding royalties to be very low Based on the poor revenue track record of the Indian partner Centaur Pharmaceuticals Pvt Ltd (Net royalties to BioXXmed of €12k in 2022 after €9k in 2021 under the 50% royalty share agreement with DermaTools), and considering that India is largely a self-pay, price-sensitive market where most patients live in rural, difficult to reach areas, we do not expect Centaur to generate significant sales in the country. Centaur's sales force is chiefly focused on metropolitan areas and the largest cities in India. Moreover, Centaur funded all phase II and phase III clinical trials in India required for the approval of DermaPro as a drug. We therefore estimate that DermaTools has negotiated low-mid single-digit royalties with Centaur for distribution in India and Africa. At present, we anticipate that DermaTools' royalties will stay at <€40-50k p.a. during the next few years.

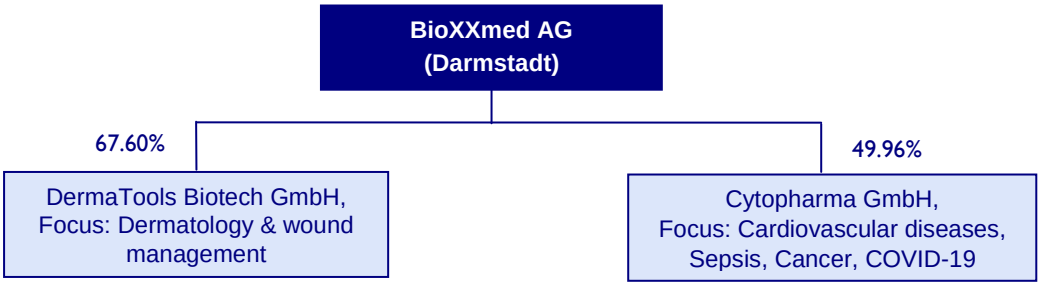
COMPANY PROFILE

OVERVIEW

Holding company with one core dermatology & wound care subsidiary BioXXmed AG (formerly known as CytoTools AG) is a biomedical holding company focusing on the therapeutic area of dermatology and wound care. BioXXmed was founded in 2000 by Dr Mark-Andre Freyberg (CEO, Founder) and Dr Dirk Kaiser (CRO, Co-founder) as a spin-off of the biotechnology faculty at Darmstadt Technical University. The motivation was to capitalise on their core technology and expertise within apoptosis inhibition. In 2004 management set up the subsidiary DermaTools Biotech GmbH to further develop dermatologic applications of the company's programmes; BioXXmed now holds 67.6% of DermaTools. This subsidiary owns the most promising development programme, DermaPro®, for the treatment of chronic wounds focusing initially on diabetic foot ulcer (DFU) patients.

Over time the company investigated further application fields for its technology in cardiovascular diseases, cancer, sepsis and latest COVID-19. BioXXmed spun off these activities into the subsidiary CytoPharma GmbH holding a minority stake of 49.96%. However, these non-core, early-stage research programmes were risky, lacked proper financing and did not bear much fruit. BioXXmed's latest management assessment in August 2022 concluded that CytoPharma's programmes are unlikely to be licensable at the current pre-clinical stage; in addition, nearly all patents were about to expire. They are also not attractive enough to warrant any further investment by BioXXmed in CytoPharma. BioXXmed AG has been listed on the Open Market of the Frankfurt Stock Exchange as an Entry Standard company since December 2006.

Figure 1: BioXXmed AG structure



Source: First Berlin Equity Research, BioXXmed AG

Old management and founder team highly questioned by unhappy investors DermaTools' lead programme DermaPro could be developed in two different ways, either as a drug or as a medicinal product, also known as a medical device (CE mark). The management and founder team of Dr Freyberg and Dr Kaiser chose the drug pathway, which is substantially more risky, lengthy and expensive. Unfortunately, after over 18 years of development and >€26m spent, the drug candidate is many years away from a potential drug registration, and patents are close to expiration (November 2024). Overall, management has in our view underperformed during the drug development process with substantially longer than expected development timelines, failures (e.g. the manufacturing glitch by its external contract manufacturer which led to a failure of both European phase III trials on diabetic foot and open leg ulcer in 2015), lack of financial discipline and transparency as well as poor communication. The last European phase III trial setback, which caused a significant time and money loss due to the need to repeat the study, led to a massive loss of investors' trust. From 2016, the largest investor group Balaton AG/Heidelberger Beteiligungsholding AG/Delphi Unternehmensberatung AG, currently with a >40% shareholding, pursued management change. This was a challenging task that lasted until the AGM in September 2021, when the majority of shareholders elected a new

Supervisory Board which included the lawyer Arne Björn Segler as the new Chairman and Ralph Bieneck, a member of the Executive Board of Heidelberger Beteiligungsholding (Balaton), as his deputy. The former Board members Dr Freyberg and Dr Kaiser were dismissed and Dr Bruno Rosen was appointed as a new Management Board Member (CEO). A legal battle started to dismiss the old management from the Board of the core subsidiary DermaTools. In March 2022, a settlement by contractual agreement, including the replacement of Dr Freyberg with the experienced clinical development manager Dr Reinhold Gahlmann as second Managing Director and the commitment to invest a minimum of €1.5m in DermaTools, gave BioXXmed and its new management control of this asset. A later audit of BioXXmed revealed indications of significant irregularities in the management of the company. In December 2022, the company filed civil action against the former Supervisory Board / Executive Board members under §47 and §93 of the German Stock Corporation Act (AktG) at the Darmstadt Regional Court.

New CEO launched deep strategic changes Under the leadership of Dr Rosen BioXXmed completed a capital increase of €4.4m in May 2022 by placing 1.1m new shares at a subscription price of €3.95. €2.0m of this has been invested in DermaTools, thereby increasing BioXXmed's stake to the current 67.6%. These funds should be sufficient to fund DermaTool's operations into Q1 2024, complete DermaPro's dossier and the quality management (QM) certifications required for the registration application. Following a professional reassessment of the development and marketing situation, management launched a new strategy which chiefly included switching from a drug to a medical device registration pathway. According to management, the positive data generated so far would be sufficient to support a CE mark registration in Europe and 510(k) in the US. Management also implemented cost-cutting measures, which included moving to a cheaper office, stopping paying for unneeded patents and negotiating a settlement of its ongoing expensive litigation with its contract manufacturer (DermaTools sued them in 2016).

BioXXmed still aims to raise further funds to sharpen DermaPro's market profile and to expand its dermatology/wound care portfolio Besides implementing measures to strengthen DermaTools' competitive profile, management is currently evaluating new and innovative projects in Dermatology which would expand its portfolio. For this purpose, it intends to raise €5-10m in additional funds.

CORE HOLDING DERMATOOLS BIOTECH GMBH

DermaTools is BioXXmed's core holding, receiving its full attention and financial resources; its equity investment in this subsidiary totalled €18m by the end of 2021. DermaTools raised further net proceeds from BioXXmed of €1.5m in August 2022 and €500k in June 2023. DermaTools currently accounts for all of the value in BioXXmed. For this reason, we have focused this report on this subsidiary. DermaTools has a medical device candidate at the most advanced development stage, DermaPro, for treating chronic wounds, foremost in DFU patients. This product has shown a competitive efficacy profile in a comparative clinical study in the EU and in phase II and phase III studies in India. Commercialisation as a drug started in India in 2020, and preparations for registration as a medical device with a CE-mark in the EU and under the 510(k) pathway in the US are underway.

PROFILE OF THE LEAD DRUG CANDIDATE DERMAPRO

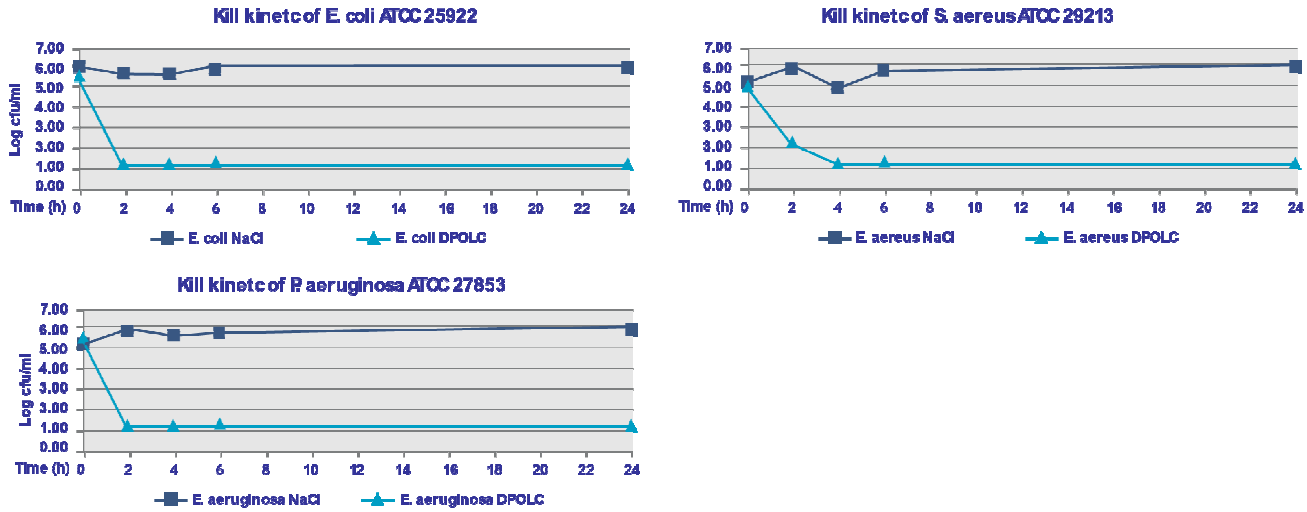
Lead drug DermaPro® offers a dual mode of action for chronic wound healing DermaTools' lead product is DermaPro, a patent-protected chemical substance intended for topical treatment of chronic wounds, particularly the hard-to-heal diabetic foot syndrome (DFU), but also others, such as venous or pressure ulcer. DermaPro's active ingredient is Diperoxochloric-acid (DPOCL), an inorganic, synthetic molecule. Before use, DPOCL is diluted with a salt solution (NaCl solution 1.2%) to a 1.2 mM final concentration and applied as a wet bandage dressing with a defined dosage of 0.2 ml/cm². According to BioXXmed/DermaTools, the drug appears to have a dual mechanism of action:

- it stimulates and enforces the proliferation of fibroblast cells, which serve to generate collagen (key proteins in the wound healing and tissue regeneration process);
- it aids the destruction of bacteria, killing germs and disinfecting the wound bed.

DERMAPRO'S PRE-CLINICAL DEVELOPMENT

Pre-clinical development demonstrated DPOCL's antibacterial activity… DermaTools conducted several pre-clinical trials to establish proof-of-concept and characterise the compound's safety profile. The company tested a 0.3% DPOCL solution which demonstrated strong antibacterial activity against the gram-positive and negative species *E. Coli* and *P. aeruginosa* within two hours and against *S. aureus* within four hours of incubation. The test lasted for more than 24 hours.

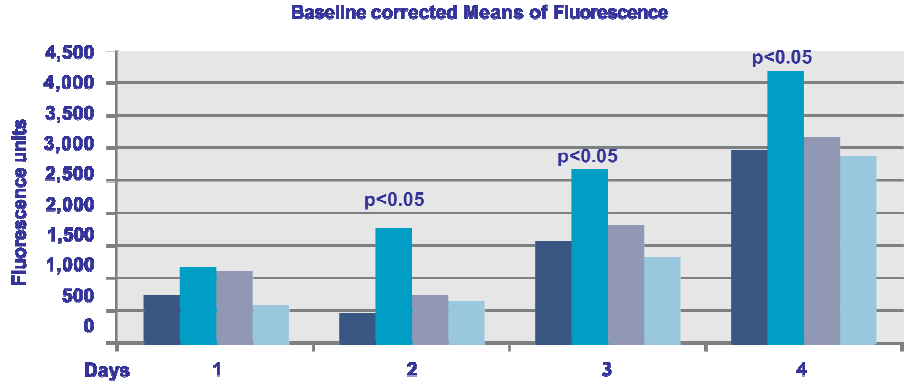
Figure 2: Overview of DPOCL's antibacterial effects



Source: First Berlin Equity Research, BioXXmed AG

…and proliferation of fibroblasts In a second study, DermaTools tested DPOCL against an NaCl solution 0.9% which served as control and other chlorine species to determine the ability of the drug to stimulate the proliferation of incubated MRC-5 fibroblasts. Fibroblasts are important cells that support the wound-healing process. The in vitro studies showed a statistically significant benefit for DPOCL after 24, 48, and 72 hours (see figure 3).

Figure 3: Overview of DPOCL's MRC 5 fibroblasts growth stimulation



Source: First Berlin Equity Research, BioXXmed AG

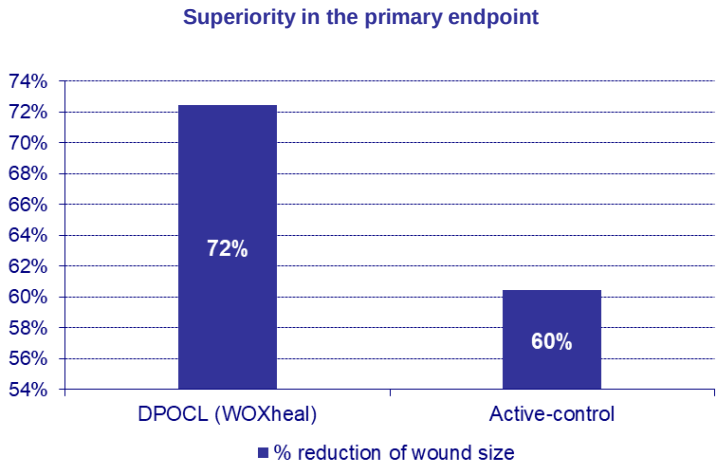
In vivo investigation demonstrated that DermaPro is safe The company also carried out safety and toxicological studies on assorted animal models (mice, rats, dogs). and found no safety issues. The compound showed no toxicity following acute and sub-chronic systemic administration in several animal species. The company established a no-effect-dose of 10 mg/kg and a toxicological threshold dose of 45 mg/kg body weight administered intravenously. We note that DermaPro has been conceived for topical administration, in which case the body does not absorb the compound. Also, none of the rabbits administered 0.5 mL DermaPro for 4 hours per patch showed any skin reactions or irritation.

DERMAPRO'S CLINICAL EFFICACY ESTABLISHED IN INDIA

Centaur Pharmaceuticals – development partner in India In April 2006, BioXXmed/DermaTools closed a licensing partnership for DermaPro (DPOCL) with the Indian company Centaur Pharmaceuticals (https://www.centaurpharma.com/). Centaur is primarily a producer of active pharmaceutical ingredients (API) and drug formulations, offering contract research and manufacturing (CRAM) services, drug registration, and sales for international pharmaceutical and biotech companies. In connection with the agreement, Centaur funded and conducted phase II and phase III clinical trials required for registering the compound as a drug in India, and it is also responsible for its commercialisation in India.

Indian phase II diabetic foot study – DPOCL delivered 72% wound closure vs 60% in the control group The superiority of the product against standard of care was first established in the previously conducted multi-centric, randomised, double-blind; active-controlled, comparative phase II study in 80 patients with DFU. According to the study design, the primary endpoint was the % reduction in wound area. DPOCL achieved a 72.45% wound reduction vs 60.40% in the active control group administering a basic moist wound dressing of isotonic sodium chloride solution 0.9% (ISCL). The study included diabetic mellitus patients with wound sizes ranging from 1cm to 15cm classified as per Wagner's scale as Grades 1 and 2 and present for at least 4 weeks (sources: https://www.centaurpharma.com/downloads/2022/diabetic-foot-ulcer/WOXheal.pdf; https://www.woxheal.com/efficacy-clinical-trials.html).

Figure 4: Overview of DermaPro's efficacy in the Indian phase II study



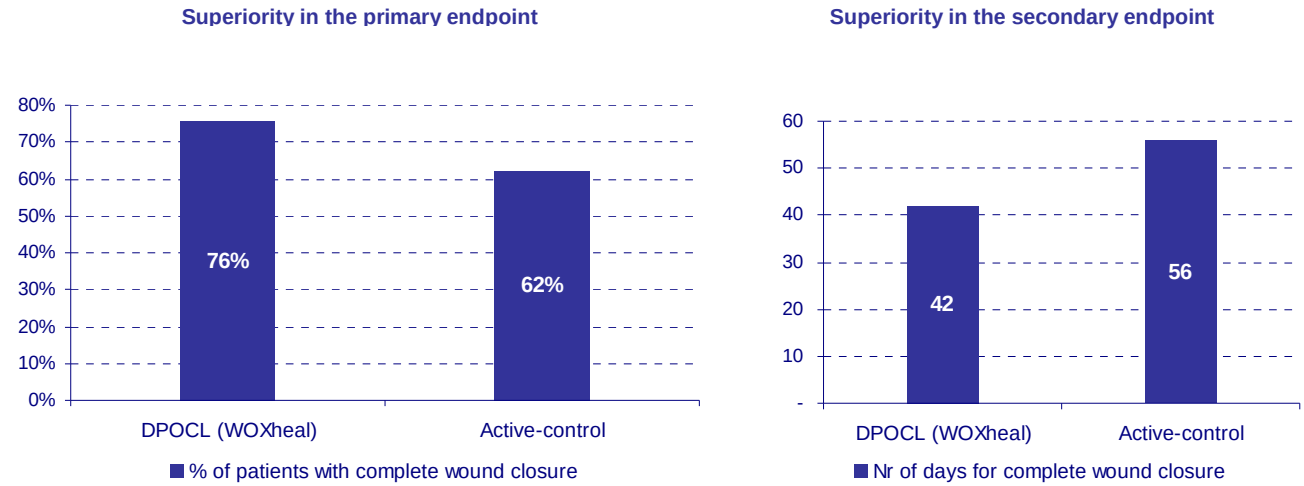
Source: First Berlin Equity Research, Centaur Pharmaceuticals

Indian phase III diabetic foot study – DPOCL achieved a statistically significant 76% complete healing rate against 62% in the control group Centaur also conducted a multicentre, randomised, double-blind, active-controlled study to evaluate the efficacy and safety of the topical DPOCL solution (European brand name DermaPro, Indian brand name WOXheal) compared with the standard of care for wound treatment, ISCL 0.9%, in patients suffering from DFU graded as stage Ia, IIa or Ib (Texas classification) in India. The company enrolled 311 patients, 289 of which were randomised to DPOCL (n=139) and ISCL (=150) to be treated over 10 weeks at 8 doctor visits.

The study's primary efficacy endpoint was the number of patients (%) achieving complete wound closure; the secondary efficacy endpoint was the reduction in wound surface area. According to Bal et al.'s 2022 scientific publication on the phase III study (https://pubmed.ncbi.nlm.nih.gov/35275009/), DPOCL achieved a superior statistically significant (p=0.0156) complete healing with 105 of the 139 patients, corresponding to a healing rate of 75.5%, compared to 93 of the 150 patients in the ISCL control arm, corresponding to a 62.0% healing rate by the end of the 10-week treatment period (delta superiority DPCOL vs ISCL = 13.5 percentage points).

The secondary endpoint was also met. DPOCL resulted in faster wound healing with a median time of 42 days versus 56 days in the active control group. The safety endpoint analysed the adverse events in both arms. DPOCL showed no side effects, and the safety profile was comparable to that of the control group. We give an overview of the efficacy results in figure 5 below.

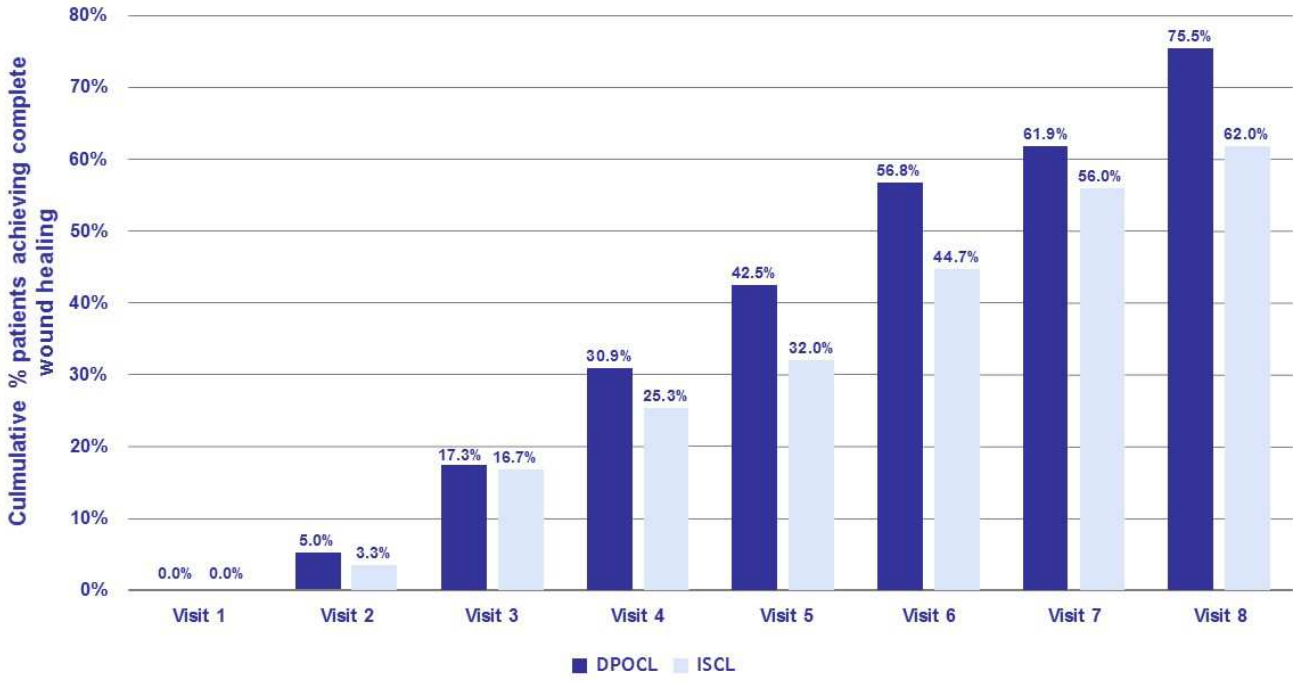
Figure 5: Overview of DermaPro/WOXheal's efficacy in the Indian phase III study at the visit 8 / week 10



Source: First Berlin Equity Research, Bal et al., 2022

Moreover, DPCOL showed better efficacy than ISCL at each doctor visit, and the percentage of patients achieving complete wound closure was always higher in the DPCOL group (see figure 6 overleaf).

Figure 6: Overview of DermaPro/WOXheal's efficacy in the Indian phase III study



Source: First Berlin Equity Research, Bal et al.; 2022

Indian WOXheal label & homepage reported different efficacy results for Centaur's phase III study, but the superiority difference of DPCOL against control remains the same In addition to Bal et al.'s paper publication in 2022, Centaur has posted the efficacy results of this study in the following two online documents:
(1) https://www.centaurpharma.com/downloads/2022/diabetic-foot-ulcer/WOXheal.pdf;
(2) https://www.woxheal.com/efficacy-clinical-trials.html.
Intriguingly, these two documents mentioned lower healing rates of 71.03% for DPCOL vs 57.53% for ISCL at the end of the treatment period of ten weeks. Notably, the efficacy superiority of DPCOL vs ISCL was the same 13.5 percentage points across all sources. We have requested clarification of this issue, but so far this has not been forthcoming. In the light of the high level of detail in the publication by Bal et al., we believe that this document has the correct data.

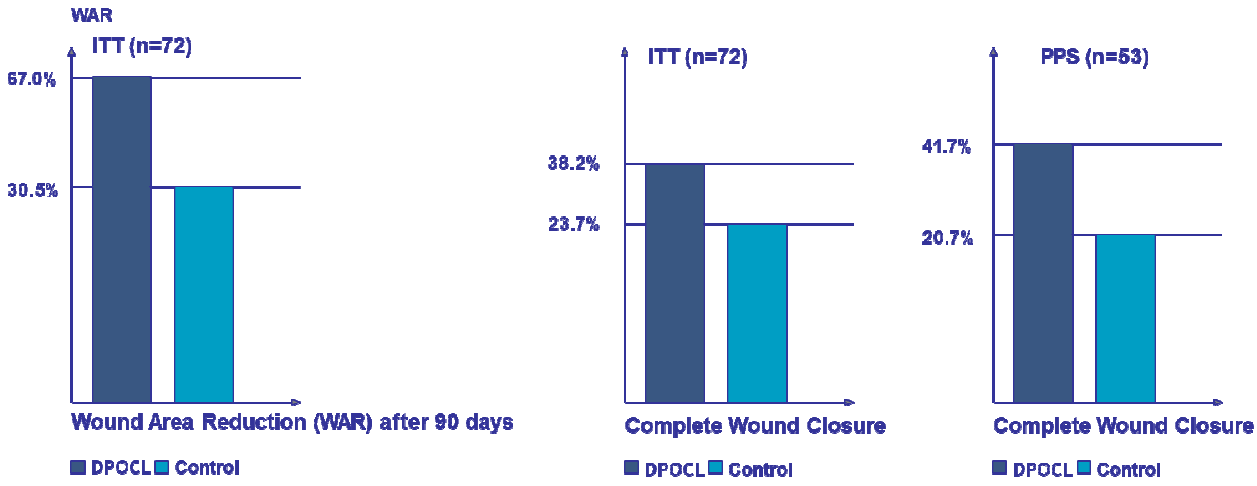
Indian partner Centaur is marketing the drug; sales so far have disappointed and we expect them to stay at a low level In 2020, Centaur launched the product using its own sales force and digital channels (https://www.woxheal.com/). The company employed a 50-strong sales force for the launch. However, the COVID-19 pandemic led to unexpected difficulties which constrained promotional activities and resulted in low revenue. BioXXmed recorded sales of merely €12k in FY 2022 (FY 2021: €9k), reflecting an agreement with DermaTools to share 50% of royalties. Considering that Centaur financed all clinical development and registration in India, we estimate that BioXXmed/DermaTools receives a low-to-mid single-digit royalty rate on sales. By February 2023, Centaur had treated about 1,000 patients and the company plans local revenue of only €600k in FY 2023/24 based on the pharmacies' net sales value. We note that India is largely a self-paying, price-sensitive market where most patients live in rural, difficult-to-reach areas. Centaur's sales force is mainly concentrated in metropolitan areas and the largest cities in India, which we believe limits its ability to reach the large rural population and the entire sales potential in the country.

EFFICACY PROFILE OF DERMAPRO IN EUROPE

European multicentre, double-blind, randomised, comparative phase IIb study of the efficacy of the wound healing solution DermaPro in patients with diabetic foot ulcer In 2012, the German subsidiary DermaTools completed a European multicentre, double-blind, randomised, clinical study investigating the efficacy of DermaPro (DPOCL) solution compared to a standard of care (saline wound dressing) as control in 85 DFU patients. The trial design included adult DBU patients of both genders who had wounds within a diameter of 1.5-3.5cm (corresponding to a wound size between 1.8 and 12.25 cm2) after debridement, which had been treated unsuccessfully for at least 6 weeks. The wound stage had to match Wagner grade I or II or Armstrong stadium A-C. The primary efficacy endpoints were: (1) change in wound size measure (area) from baseline after 30, 60 and 90 days of treatment; and (2) the time from onset of treatment until entire closure of the wound (i.e. wound area covered entirely with connective tissue). Secondary efficacy endpoints were: (1) the reduction of wound depth and wound volume during treatment; and (2) the percentage of patients showing improvement defined as 50% reduced wound area after 30, 60 and 90 days of treatment (source: https://www.clinicaltrialsregister.eu/ctr-search/trial/2010-020437-12/LV and BioXXmed AG).

DermaPro achieved overall wound closure of 67% (vs control: 30.5%) and complete wound closure in 38.2% of treated patients (vs control: 23.7%) In a randomised controlled trial (RCT), the set of all recruited patients that met the inclusion criteria and were randomised into a study group is known as the intention to treat (ITT) population. The ITT population usually represents the basis for inferences about the effectiveness of the treatment. After completion of a study, the records for all patients are reviewed and protocol deviations (violations) are listed. This is done while the patient data are still blinded to avoid bias. Then, a so-called "blind review committee" reviews the protocol deviations to decide if they are critical and define the Per-Protocol-Set (PPS), which represents the group of patients with no essential deviations of protocol during the study. In the European phase IIb study, DermaTools randomised 72 patients (ITT), establishing a PPS of 53 patients. DermaPro delivered superior efficacy results. In the ITT population, it achieved: (1) a 67% wound area reduction vs 30.5% in the control group; and (2) complete wound closure in 38.2% of ITT patients vs 23.7% in the control group. In the PPS population, the efficacy was even greater, with complete wound closure achieved in 41.7% of patients vs 20.7% in the control group. We give an overview of the results in figure 7 below.

Figure 7: Overview of the efficacy of DermaPro (DPOCL) compared to the standard of care in the European phase IIb clinical trials



Source: First Berlin Equity Research, BioXXmed AG

Secondary endpoints also showed superior efficacy of DermaPro The company reported that DermaPro showed an overall higher proportion of patients with wound reduction ⩾50% compared to the control. Moreover, the time to achieve ⩾50% wound closure was 20.7% faster in the DermaPro group (26.8 days, n=26) compared to the control group (33.8 days, n=10); these results were statistically significant with p-values < 0.05. There were no safety differences between DermaPro and the control group, including factors such as itching and well-being.

The European phase III study for diabetic foot failed due to an alleged production failure The DermaPro's European phase III trial in 295 patients for the treatment of diabetic foot took ~3 years (Jan 2013 – Nov 2015) to be completed and failed to show the expected efficacy. The reason was an alleged failure of the contract manufacturer, which apparently did not adhere to the specifications. The drug used in the trial included a 50-90% less of the active ingredient and most of the data was useless. If the company still wanted drug approval, it would have to repeat the trial. The company sued the contract manufacturer for damages in August 2016. Management is currently negotiating an extrajudicial settlement of these lengthy and expensive proceedings.

A European clinical study for open leg ulcer was also affected by the production failure The DermaPro's European double-blind, randomised, active-controlled study for the treatment of open leg ulcer was terminated in May 2016 due to the above-mentioned production error, which also affected this trial, after treating 110 of the planned 260 patients. The drug used had only 50% of the specified active ingredient concentration.

Second phase III study in 150 patients initiated at the end of 2020 was stopped in 2022 by new management In October 2020, BioXXmed, still led by the old management team, raised funds amounting to €3.7m from the strategic investor Klocke Holding. This amount plus the company's €2.6m cash resources were expected to cover the estimated €6m cost of a new European phase III study in 150-400 patients, which started preparation at the end of 2020. In early 2022, after the start of the clinical study, BioXXmed asked Dr Gahlmann to confirm the total costs of the trial. The recalculation showed costs significantly above the initially assumed value. The proposal to terminate the study was approved by about 95% of DermaTools' shareholders. The company had recruited and partially treated about 42 patients, but unfortunately the sample was not representative enough to provide new useful supporting data.

REGISTRATION PATHWAY OF DERMAPRO IN EUROPE AND THE US

Did a switch of development and registration strategy make sense? In connection with Dr Rosen's transition as CEO at the end of 2021, the company engaged a team of experts in regulatory, clinical development, chemistry/manufacturing & controls (CMC) and statistics to conduct due diligence on DermaPro's development status. The main findings were:

- The development strategy and current status of DermaPro would not meet the requirements to warrant registration as a drug with the EMA. Drug approval in the EU before patent expiry was ruled out. The clinical studies conducted thus far had substantial deficiencies, requiring further pre-clinical and clinical studies, which would cost an additional €7-9m. The ongoing phase III study - even if successful - would not have been sufficient to file for a drug approval.
- In contrast, a medical device CE-mark registration in the EU would allow a fast market access with comparable financial benefits for BioXXmed's shareholders. The registration could be achieved based on the data generated to date, while the costs are largely covered by BioXXmed's €2.0m investment in DermaTools into Q1 2024. Practically all topical wound healing products are approved as CE or 510(k) medical devices.

Medical device registration in the EU In the EU, the approval of medical devices is regulated by the European medicine agency (EMA) under the new European Medical Device Regulation 2017/745 (EU MDR), which was approved in April 2017 and introduced in May 2021. Under the new MDR, tests are classified according to their risk from class I, which is the lowest risk, to class III, the highest risk (e.g. pacemakers, heart valves, or implantable defibrillators). Devices in the highest-risk class are subject to more stringent registration requirements. Class IIa, IIb and III products require the certification of compliance with MDR requirements from a notified body (e.g. TÜV agency). The new regulation is more rigorous and also requires clinical evidence of clinical benefits (device performance) and safety, including ongoing post-market follow-up. The new regulation also provides more transparency through a comprehensive EU medical device database EUDAMED (source: Maresova et al., 2021; Prince at al., 2022; EUDAMED database: https://ec.europa.eu/tools/eudamed/#/screen/home). At the end of the process, the company can affix the CE mark to its products.

We anticipate DermaPro to be classified as a class IIb medical device in Europe Wound solutions with active substances or medications that are specifically formulated to treat or manage complex wounds are in our view classified under class IIb. For example, the wound solution Microdacyn, which is based on comparable active ingredients such as sodium hypochlorite and hypochlorous acid, is approved as a class IIb medical device in Europe for use in debridement and moisturisation of acute and chronic wounds.

Approval of medical devices in the US Medical devices are regulated by the FDA in the US, and there are three registration pathways:

a. **FDA approved/cleared according to 510(k)** The 510(k) is the regulatory path for a new test approval which can prove to be substantially equivalent to an existing predicate device on the market.

b. **De Novo approval for class I or II medical devices (low to moderate risk)** This pathway applies to products for which there are no predicate devices. These products should provide reasonable assurance of safety and effectiveness for their intended use in humans and represent a low or moderate risk to users. The risk reflects the consequences depending on their use and depending on how serious it is, if the device works incorrectly, or gives an incorrect result.

c. **Premarket approval (PMA) for class III medical devices (highest risk)** This registration path applies to products whose underlying technology cannot be considered substantially equivalent to an existing technology and will be used to make a critical medical decision concerning treatment, or medical management. This represents the most stringent type of device marketing application required by the FDA and applies to high-risk devices used to support or sustain human life.

BioXXmed will pursue the 510(k) registration approach in the US DermaPro's active ingredient, Diperoxochloric-acid (DPOCL), is a compound chemically similar to hypochlorous acid (HOCL) as both are chlorine-based compounds. HOCL is a weak acid that forms when chlorine dissolves in water. Neutrophils produce HOCL in the body as part of its defence mechanism. Therefore, this compound is often used in wound care due to its antimicrobial properties and ability to help promote wound healing. HOCL-based products have been approved and used for over a decade to treat chronic wounds. Novel forms of HOCL are used in approved medical device products to treat chronic wounds largely at a concentration of 0.01%, which is within a range effective for wound care while still being safe for the surrounding healthy tissue. We have identified several HOCL-based wound care products approved in the US, such as Convatec's ChloraSolv, URGO Medical's Vashe, Innovacyn's Puracyn Plus Wound Solution, or NovaBay Pharmaceuticals' NovaBay NeutroPhase. Any of these products could potentially be used as a substantially equivalent predicate device in connection with a 510(k) registration pathway.

BioXXmed claims DPOCL's superiority over commercialised HOCL in chronic wound therapy According to BioXXmed, despite its similarity, DPOCL is a distinct chlorine-based compound with more powerful capabilities compared to HOCL. DPOCL can act via two pathways depending on pH and concentration. On the wound surface, where the concentration is higher, its oxidising property kills pathogens (similar to HOCL), whereas in the deeper tissue layers, where the concentration is lower, it stimulates growth and tissue regeneration. These properties were shown in pre-clinical studies.

CE registration in Europe is projected for YE 2024, potential partnership deal(s) and market launch could take place by H1 2024 DermaTools initiated preparations for the CE registration in Q4 2022 (later than originally agreed), which includes setting up the quality management (QM) ISO 13485 certification and preparing the dossiers under advice of an experienced German regulatory consultant, the Hamburg-based NSF Prosystem GmbH. BioXXmed/DermaTools expects to obtain the CE mark by YE 2024. DermaTools is carrying out optimisation of the product in cooperation with external contract manufacturers regarding sterilisation, vials filling and final packaging in commercial quantities. These steps should be completed during Q4 2023. In parallel, DermaTools is currently preparing the documentation required for partnering discussions on DermaPro for Europe and the US. BioXXmed/DermaTools has conducted initial contacts with first potential marketing candidates since November 2022. However, BioXXmed's lack of a network in the wound healing community with key opinion leaders made it necessary for management to focus first on presenting its study results in some major wound healing congresses in the USA and Europe during 2023 to increase awareness. We anticipate management to approach further potential candidates and conduct active negotiations with potential partners starting in late 2023. We believe that attracting a strong, committed partner is currently BioXXmed's biggest challenge. Management is guiding that a deal or multiple deals are likely to be closed during H1 2024. If management finds either one or multiple partners (e.g. either one big partner for all regions or several partners on a country-by-country base), we anticipate that the partner(s) will launch the product in H1 2025.

We have concerns that the FDA could request US efficacy and safety data and conservatively assume a US registration and market launch in H2 2025 Whereas BioXXmed's advisors believe they can obtain a 510(k) approval with the existing data, we have concerns that the FDA will request clinical data generated in the US. While European studies can provide valuable information, they may not be sufficient on their own for FDA clearance. In our experience, the FDA tends to require clinical data also involving subjects from the US patient population, as there may be variations in patient demographics, healthcare practices, or other factors that could impact the device's performance. We are therefore cautious in our assumptions regarding US registration and have estimated a 35% probability of success with current data, registration in H1 2025 (BioXXmed guidance: mid-2024), and market launch in H2 2025 (BioXXmed guidance: H2 2024), about 6 months later than in the EU.

Based on a lack of cost-benefit studies, a potential near-term reimbursement is unlikely and it will initially be a self-payer product From a marketing point of view, a critical issue after achieving CE and 510(k) approvals will be to qualify for reimbursement from healthcare insurance bodies in Europe as well as the US. In our view, the key challenge to obtaining reimbursement is to demonstrate positive cost-benefit based on improvement compared to standard of care. The reimbursement is – depending on the Ministry of Health involved – awarded by a commission and is based on the evidence level of the product's efficacy, its economic profit (e.g. savings of healthcare costs due to faster healing) and its cost. As the company has not conducted cost-benefit studies, we believe it is unlikely that reimbursement will be obtained soon and will initially be a self-payer product. We expect DermaTools to perform the required small studies for Europe and the US in 2024 and 2025 to achieve reimbursement.

ADVANCED CHRONIC WOUND THERAPY

THE WOUND CARE MARKET

Biology of wound healing Wound healing is a natural process following tissue injury involving a complex interplay between numerous cell types, cytokines, mediators, and the vascular system. The healing process includes four main stages: (1) Haemostasis through vasoconstriction of blood vessels and platelet aggregation to stop bleeding and trigger coagulation; (2) Inflammation, wherein white blood cells called neutrophils, T-cells, and macrophages enter the wound to kill bacteria and remove damaged tissues & debris; (3) In the proliferation stage fibroblasts secrete collagen, which together with growth factors & other proteins support tissue repair and help to strengthen the wound. Contraction of the wound takes place in order to reduce the surface area of the wound, while the formation of new vessels also takes place & epithelial cells form granulation tissue filling and shielding the wound from the environment; and (4) In the maturation stage the new tissue gains strength and flexibility, collagen is replaced with higher strength collagen in order to increase the tensile strength of the wound (source: Wallace et al., 2023; Zhao et al., 2016).

Introduction to chronic wounds Chronic wounds are wounds that do not heal in a timely or orderly manner. Traditionally, wounds that do not heal within 3 months are considered chronic wounds, though some wounds can go several years without healing. Chronic wounds usually do not progress through the normal stages of healing as expected due to a breakdown in one of the four stages. Rather, degradation of the wound is often as fast as the production of healing factors. Chronic wounds are most commonly seen in elderly patients (due to slowed healing factors) or in wounds with large surface areas (significant trauma injury). Other reasons skin wounds do not heal include poor diet (lack of nutrients needed for the healing process), infections or underlying medical conditions such as diabetes, some vascular diseases or skin cancers (sources: Heather et al., 2023). Approximately 70-90% of chronic wounds are the result of venous ulcers. These are believed to form as the result of poor regulation of blood pressure in the body, usually in the legs. Diabetic foot ulcers also represent a sizable and growing portion of this condition, scaling with the growth in diabetes prevalence. Pressure ulcers and ischemia resulting from surgery largely round out the other causes of chronic wounds (sources: Cwajda-Białasik et al., 2021; Frykberg et al., 2015).

Diabetes, a driving force of diabetic foot ulcers (DFUs) Diabetes mellitus (DM) is a chronic metabolic disease characterised by elevated blood glucose or blood sugar levels. In people suffering from DM, the pancreas does not produce enough insulin or the body cannot effectively use the insulin it produces. DM can cause several other conditions such as cardiac failure, stroke, diabetic neuropathy (nerve damage), diabetic foot ulcers (DFUs) & amputations, kidney failure, liver failure and blindness, leading to reduced life expectancy and enormous health costs. DM is a serious public health problem that is reaching epidemic dimensions worldwide (sources: Spampinato et al., 2020; Zimmer et al., 2017). According to the WHO and statistics from the International Diabetes Federation, there are 60m people with diabetes in Europe. As a common complication of DM, DFUs result from arterial problems and diabetic neuropathy (damage of the peripheral nerves) that can produce numbness, pain, and tingling in the foot. The neuropathy can cause patients to hurt their feet without feeling much or any pain, which can lead to greater damage. This damage, coupled with slow wound healing and circulation problems, can allow infection or gangrene to set in, leading to amputation. Part of the reason these wounds can become chronic is that diabetes slows wound healing, which can cause the ratio of healing factors to decomposition factors to be too low. The prevalence of DFUs among diabetes patients in Europe has been estimated at 5.1%, equating to about 3m DFU patients in the region. In the US, the DFU prevalence is even higher at 13%, which based on existing 37.3m diabetic patients, translates to 4.8m potential DFU patients (sources: Zhang et al., 2016; CDC's National

Diabetes Statistics Report for 2022). Also, experts believe that the COVID-19 pandemic led to an increase in the prevalence of DM and its fatal complications. The main factors leading to an increase in the diabetic population are an ageing population, increasing physical inactivity, unhealthy diet, overweight and obesity.

Traditional treatment of chronic wounds is increasingly being replaced with advanced/active wound care products There are several categories of non-healing wounds and ulcers, each of which has its own specialised treatment. These treatments include debridement of necrotic tissue, infection control and local wound care. However, non-healing wounds and ulcers are both typically caused by a deficient local blood supply, which fails to provide the nutritional means of keeping the cells involved in healing fully active. Traditional wound care techniques consisting of low-technology wound dressings such as synthetic bandages, gauzes plasters, lint or wadding are mostly used to treat minor wounds by stopping bleeding, absorbing blood or other fluid, drying the wound, preventing irritation and reducing the risk of infection. For the medical treatment of chronic wounds, advanced wound care products are increasingly gaining momentum. This has led to exponential growth in the development of new wound dressings. Overall, there is a consensus among wound care experts on the necessity to apply new treatment concepts such as "advanced wound care ", which treat wounds, control infection and promote healing. Since the discovery of the first growth factor in 1962, the techniques available for chronic wound management have advanced significantly (sources: Grand View Research, 2022; Market Data Forecast, 2023).

In our view there is high unmet medical need for chronic wound management Despite significant wound care advances, we see a substantial unmet medical need. Many wounds cannot be treated optimally, even with the most modern products. We therefore believe that innovative products with superior efficacy and cost/benefit performance have a good chance to penetrate the market and create market expansion opportunities. According to Frost & Sullivan and Polaris Market Research, the most relevant advanced care active therapy options are: (1) moist wound dressings; (2) other therapies to promote wound healing; and (3) medical devices.

Moist wound dressings We estimate that moist wound dressings represent the largest segment of the worldwide advanced wound care market. Their purpose of is to keep a wound moist. This has been shown to improve healing rates. The human body usually develops a scab as a natural mechanism to keep a wound moist so that it can heal, however some wounds are too large to scab effectively, hence the need for moist dressings. The seven most common types of moist dressings are: alginates, hydrocolloids, hydrogels, foams, transparent film, silicones and collagen/antimicrobial dressings. Often, manufacturers sell all of these dressing types, and sometimes they combine aspects of two types. Following surgical debridement, moist wound dressings are the standard of care for DFU in the US and Europe (source: Everett et al., 2018).

- Alginate dressings' active compound is alginic acid, which has the property of being able to absorb over 20+ times its own weight in water, turning into a gel. When applied to a wound, the alginate absorbs the wound's exudate (circulatory system fluid) to form a gel that keeps the wound moist. These are primarily used for wounds that have large amounts of exudate or bleeding wounds.
- Hydrogels and hydrocolloids are similar in consistency. Hydrocolloids are usually made of gelatine or pectin, and as the name suggests, they are colloids (molecules dispersed evenly in a substance but not dissolved) in water. Hydrogels are gels with very high water content (they can be greater than 99% water in composition). Both can be used in a dressing to help deliver moisture to a dry wound (low exudate) and show considerable flexibility.

- Foam dressings are usually made with polyurethane and are quite simple in structure. Low-density dressings can absorb considerable amounts of water as they are hydrophilic, though usually less absorptive than alginates. These dressings can keep a wound moist with the exudate while sealing the wound site to protect it from harmful bacteria.
- Transparent film dressings are usually adhesive, waterproof dressings intended to provide a bacteria/virus barrier, allow oxygen and water vapours to transfer, and continuously observe and monitor the wound by the physician.
- Silicone dressings are coated with a tacky hydrophobic soft silicone layer that does not stick to the moist wound bed and does not dry out. Silicones are synthetic compounds made up of long-chain polymers. The dressings include several chains of silicon with other substances such as oxygen, carbon, and hydrogen.
- Collagen and other antimicrobial wound dressings which usually include an antimicrobial agent to inhibit the development of infection. These products are largely used for the treatment of DFU, venous leg ulcers and post-operative infections. Doctors may also prescribe antibiotics (topical, oral, or intravenously, depending on the patient/infection risk). A better method is to use collagen/antimicrobial wound dressings to protect against or treat a broad range of infectants, from bacterial to fungal. There are two major types of dressings within this class, those that contain silver and those that do not, and depend instead on other antimicrobials. Silver has been shown to be effective in inhibiting bacterial growth and is usually combined to allow for an ionised silver molecule to be free to bind bacterial enzymes.

Other therapies promoting active wound healing The idea behind other new therapies is to combine a dressing with a component that actively stimulates regrowth within the wound establishing an optimum environment for healing. Collagen and hyaluronic acid have both been used with varying degrees of success. Many other therapy mechanisms exist that physicians use or are investigating to accelerate healing. These include stem cells, gene therapy, maggot therapy (for debridement), new debridement agents such as hypochlorous acid (HOCL) to clean infected wounds, VEG-F (vascular endothelial growth factor), nitric oxide, oestrogen and plant compounds. New approaches are tissue engineering & 3D bioprinting (source: Deng et al., 2022; Antezana et al., 2022).

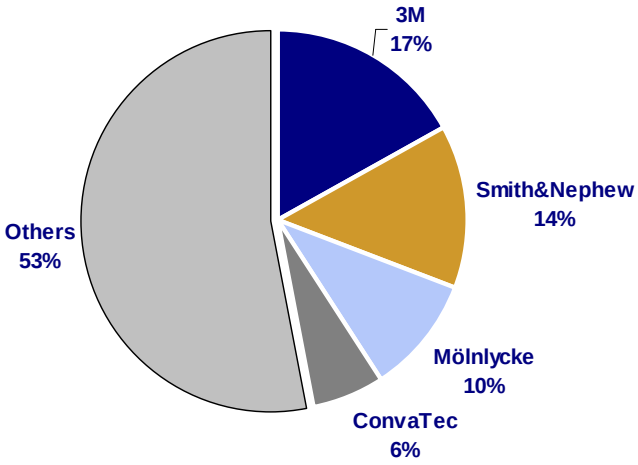
Medical devices to accelerate wound healing Several advanced medical devices, such as negative pressure wound therapy (NPWT), oxygen & hyperbaric oxygen equipment, electric stimulation, pressure relief, or wearable wound monitors, have been developed to correct the chronic wound environment and achieve skin tissue regeneration. NPWT, also known as vacuum-assisted closure, is the most widely used medical device in this class, particularly in the US. In this approach, a vacuum pump is connected to a dressing, which applies suction to the wound, creating negative pressure in and around the wound to increase the blood flow and draw out excess fluid. This technology is intended to encourage healing by three pathways: (1) it promotes cell migration and proliferation; (2) draws wound edges closer together and eliminates exudate and infectious material via vacuum, a process that normally takes the body considerable time in the natural healing process; and (3) promote granulation tissue formation.

European DFU market is projected to grow at CAGR of 5.4% until 2030 The European DFU treatment market was estimated at USD 1.45bn in 2021 and is projected to expand at CAGR of 5.4% until 2030, whereas the global DFU market was valued at USD 4.7bn in 2021 and is forecast to grow at CAGR of 5.9% until 2030. The increasing base of patients suffering from diabetes and DFU, an ageing population, as well as rising demand for novel therapies, are the main growth drivers (source: Grand View Research).

KEY PEERS / COMPETITORS

As is often the case with small-cap niche healthcare companies, there are almost no listed firms truly comparable with BioXXmed/DermaTools in terms of strategy, technology, programme depth (including development stage), indications and risk profile. The global wound care market is highly fragmented and most peers are privately owned and not listed. Most listed players are large, diversified healthcare or medtech companies dominating the wound care market. 3M Company (US), Smith&Nephew (US), Mölnlycke Health Care AB (Sweden), Convatec Group (UK), Medtronic PLC (Ireland), Cardinal Health (US), Baxter International, Inc. (US), B. Braun Melsungen AG (Germany), Johnson &Johnson/Ethicon (US), Paul Hartmann AG (Germany), Coloplast A/S (Denmark), URGO Group/URGO Medical Care (France) are among the leading players operating in the market. According to Smith&Nephew, the advanced care market grew by 6% to USD 10.7bn in 2022 and 3M was the market leader (see figure 8 below). Considering that DermaTools does not have its own distribution network, we also view all these companies as potential out-licensing partners.

Figure 8: Overview of the top 4 players among the advanced wound management market



Source: First Berlin Equity Research, Smith & Nephew Investor Presentation April 2023

Looking at DermaTools' lead product DermaPro which has Diperoxochloric-acid (DPOCL) as active ingredient, we also see the following companies commercialising chlorine-based chronic wound care solutions, particularly the chemically comparable compound hypochlorous acid (HOCL), as peers.

Table 4: Overview of peers commercialising an advanced chronic wound product based on HOCL

Company	Headquarter	Country approved	Product	Active substance	Status
Convatec plc	UK	US, Europe	ChloraSolv solution	HOCL	prescription device, is reimbursed
URGO Medical	France	US, Europe	Vashe wound solution	HOCL	prescription & OTC, is reimbursed
Innovacyn Inc	US	US	Puracyn Plus wound solution	HOCL	OTC
NovaBay Pharma Inc	US	US	NeutroPhase wound cleanser	HOCL	prescription & OTC
Sonoma Pharma Inc	US	US, Europe	Microcyn / Microdacyn solution	HOCL	prescription & OTC

Source: First Berlin Equity Research, companies

HOCL – competitive environment According to NovaBay Pharmaceuticals, the US wound cleanser market, where HOCL products are positioned, is crowded and highly competitive. There are many older and lower-priced products with similar uses, such as URGO Medical's Vashe and Purdue Pharma's Betadine Surgical Scrub, putting pressure on the market. We provide an overview of the more relevant peers active in the advanced wound care market:

3M Inc (US) 3M is a US-based listed conglomerate operating in the fields of safety & industrials, transportation & electronics, healthcare and consumer goods. Skin, wound care, and infection prevention products and solutions is only one of the focus areas among the healthcare business unit. Still, the company has become the leading player in the advanced wound care therapy market. 3M offers a range of innovative wound care products such as 3M™ Tegaderm™ silicone foam dressings, 3M™ Cavilon™ advanced skin protectant (creates environment that supports healing and lowers pain), 3M™ Coban™ 2 two-layer compression systems, negative pressure wound therapy (NPWT) equipment and devices, non-invasive wound healing support provided by 3M™ Steri-Strip™ adhesive skin closures. The company reported 2022 revenue of USD 34.2bn with the healthcare segment contributing USD 8.4bn, or 25% of the group topline. The current market cap is ~USD 53.0bn.

Smith & Nephew plc (UK) The listed healthcare/medtec specialist, Smith & Nephew (SNN), is the second largest player in advanced care wound therapy. The company has three main business units: sports medicine, orthopaedics and advanced wound management which represents close to 30% of group revenue. SNN offers a broad range of advanced wound care products, including films, gels, wound dressings (e.g. Allevyn foam dressing, Intrasite hydrogel dressing, Algisite alignite dressing, Acticoat antimicrobial dressings with nanocrystalline silver technology, etc) and its PICO NPWT products using Airlock technology; SNN is the primary challenger to NPWT incumbent 3M. The company reported group sales of USD 5.2bn in 2022 and has a current market cap of ~USD 13.2bn.

Mölnlycke Health Care (Sweden) Mölnlycke is a private medical solutions company with a broad number of products for clinical use and wound care. Its product portfolio for wound care includes many dressings (e.g. Mepitel film dressings, antimicrobial dressings such as Melgisollb alinate dressing, Mepilex foam dressing, etc) and proprietary gels to support the healing process (e.g. Granudacyn for wound moistening and rinsing) and avoid infections (e.g. silver-based Normigel). The company is 99% owned by the industrial holding Patricia Industries – a subsidiary of Investor AB. Mölnlycke sells its products in 100+ countries and has its own operations in 40% of them. In 2022, the company generated revenue of €1.8m, delivering organic y/y revenue growth of 8.4% and EBITDA of €476m.

Convatec Group plc (UK) Convatec is a listed medical products and technologies company active in the areas of advanced wound care, ostomy care, continence and infusion devices. For advanced wound care, the company has leading positions with antimicrobial dressings (e.g. silver-based Aquacell), foam dressings (e.g. Aquacell foam) hydrocolloid dressings (e.g. Duoderm dressing), wound biologics (e.g. Innova Matrix AC from Triad Life Sciences Inc, a company focusing on biologically-derived products acquired by Convatec for USD 450m in 2022), NPWT products such as Avelle and chemical wound debridement products such as the HOCL-based ChloraSolv solution. The company generated group revenue of USD 2.1bn in 2022with advanced wound care products accounting for USD 621m of this amount. Convetec has a ~GBP 4.2bn market cap.

URGO Medical Group (France) Founded in 1958, URGO is a family-owned, global healthcare and medical products company specialised in advanced wound care solutions. The firm's product portfolio includes wound dressings such as foam dressings (e.g. UrgoClean), Hydrocolloid dressings (e.g. UrgoStart combining Technology Lipido-Colloid-

TLC with Nano-Oligo Saccharide Factor – NOSF that helps stimulate the healing process and manage wound exudate), alginate dressings (e.g. UrgoSorb), foam dressings (e.g. UrgoCell), other wound care solutions such as the HOCL-based Vashe Wound Solution, as well as bandages and compression systems. The company has a staff of ~3,500 employees and is active in 20 countries. According to Zoominfo, the company last reported revenue of ~USD 500m.

Innovacyn Inc (US) Founded in 2009, Innovacyn is a privately held, family-owned company focusing on wound care and animal-health applications. The firm's portfolio is based on its patent-pending electrochemical treatment process of diluting saltwater to generate a pH-balanced solution of HOCL. Innovacyn's flagship product brand is Vetericyn, a range of HOCL-based topical solutions and sprays formulated to clean, irrigate, and help promote healing in animal wounds, skin irritations, and infections. The company has also developed the OTC topical HOCL-based wound care product for human use. Puracyn Plus Wound Solution is designed to help cleanse, irrigate, and promote healing in acute and chronic wounds. According to Zoominfo, the company last reported sales of ~USD 15.5m.

NovaBay Pharmaceuticals Inc (US) Founded in 2000, NovoBay is a biopharmaceutical company developing and commercialising innovative eye care, skin care and wound care products. The company's portfolio has been developed based on its proprietary HOCL and Aganocide (synthetic analogues of molecules naturally produced by white blood cells to combat pathogens, e.g. Neutrox) compounds to address select eye and skin conditions related to infections. NovaBay's flagship product is Avenova, an eyelid and eyelash hygiene solution. For wound care, the company commercialises its 510(k) HOCL-based product NovaBay NeutroPhase/PhaseOne (prescription only) for wound cleaning. In 2022, NovaBay achieved revenue of USD 14.4m with y/y growth of 41.2% and a net loss of USD 16.3m (including non-cash impairment of USD 6.7m). The company has a market cap of ~USD 3m.

Sonoma Pharmaceuticals Inc (US) Sonoma is a listed healthcare company developing and commercialising HOCL-based products for various applications, including wound care, eye care, oral care, dermatological conditions and animal health care. The company uses its proprietary Microcyn® Technology to stabilise its HOCL solutions. Sonoma's product portfolio includes advanced wound care solutions, such as wound cleansers, wound dressings, and wound gels, designed to promote healing and prevent infections in acute and chronic wounds. One of its lead products is a HOCL-based Microcyn / Microdacyn solution. Sonoma has access to pharmaceutical-grade manufacturing capabilities in Mexico allowing for low COGS. The company's products are sold either directly or via partners in 55 countries worldwide. In the FY 2021/22, Sonoma generated revenue of USD 12.6m. The company has a market cap of ~USD 6m.

FINANCIAL HISTORY AND OUTLOOK

Financial statement in accordance with German HGB – key considerations BioXXmed AG published its audited 2022 annual report in accordance with German accounting principles and the German Commercial Code (Handelsgesetzbuch - HGB). The company is classified as a small corporation pursuant to Sec. 267 (1) HGB and is therefore not obliged to publish a cash flow statement. The company has one core operating holding of 67.6%, the subsidiary DermaTools Biotech GmbH. The second holding, CytoPharma GmbH, has underperformed and is not focus of the company's investment strategy going forward. Importantly, BioXXmed AG records its holdings as financial investments and the associated companies are not consolidated. The holdings are booked in the balance sheet under financial assets.

FY/22 RESULTS

Income Statement FY/22 BioXXmed's revenues are insignificant and the company is loss-making. FY/22 group revenues chiefly stemming from consulting to its holdings amounted to merely €12k (FY/21: €45k).

As a result of the group's strategic realignment measures which included the departure as of 30 September 2021 of the old management and founder team consisting of Dr Freyberg and Dr Kaiser, both replaced by the new CEO Dr Rosen, personnel expenses dropped sharply to only €4k (FY/21: €549k). Dr Rosen has signed a special-order contract and his professional fees are booked under other operating expenses. The implemented cost-cutting measures led to lower other operating expenses of €826k (FY/21: €973k).

The company's EBIT came in at €-823k in FY/22, substantially below the previous year figure of €-1.5m. BioXXmed reported a net loss of €-830k (FY/21: €-4.1m). In FY/21 the company took a non-cash write-down on financial assets of €2.5m due to a reduction in the fair value of the holding CytoPharma GmbH; this measure contributed to the substantial net loss expansion.

Table 4: Income Statement FY/22 vs FY/21 (selected items)

in EUR'000	2022	2021	Delta
Revenue	12	45	*-66%*
Other operating income	0	8	-
Personnel expenses	4	549	*-99%*
Other operating expenses	826	973	*-15%*
Depreciation & amortisation	5	59	*-91%*
EBIT	-823	-1,529	-
Net income	-830	-4,059	-

Source: BioXXmed AG

FY/22 Balance Sheet highlights BioXXmed's equity position has strengthened from €17.9m at the end of FY/21 to €21.4m at the end of FY/22. In May 2022, the company completed a capital increase of €4.4m; thereof €2.0m (€1.5m in August 2022 and €500k in June 2023) was invested in DermaTools increasing the stake to 67.6%. BioXXmed reported a stronger cash position of €1.8m at the end of FY/22 (FY/21: €1k). Based on the reduced OpEx, these funds provide sufficient financial latitude until approximately Q4 2024. As a result of the €1.5m investment in DermaTools, financial assets increased to €19.7m at YE/22 (FY/21: 18.2m). We give an overview of the main balance sheet positions in table 5 overleaf.

Table 5: Balance Sheet FY/22 vs FY/21 (selected items)

in EUR'000	2022	2021	Delta
Cash and cash equivalents	1,840	1	-
Accounts receivables	45	43	*5%*
Other current assets	54	60	*-10%*
Current Assets, Total	**1,953**	**110**	*1671%*
Property plant and equipment	1	2	*-69%*
Intangible assets	0	0	-
Goodwill	0	0	-
Financial assets	19,654	18,154	*8%*
Non-Current Assets, Total	**19,655**	**18,156**	*8%*
Accounts payable	33	101	*-68%*
Other current liabilities	156	177	*-12%*
Provisions	0	0	-
Financial debt ST+LT	0	122	-
Total Liabilities	**189**	**400**	*-53%*
Equity	21,419	17,866	*20%*
Equity ratio	99%	98%	-

Source: BioXXmed AG

Cash Flow FY/22 Since BioXXmed does not report cash flows, we have calculated the key cash flow line items for a rough overview. On our numbers, FY/22 operating cash flow amounted to €-855k (FY/21: €-1.6m). Cash flow from investing activities increased to €-1.6m (FY/21: €-130k) chiefly due to investment in the core holding DermaTools. Cash flow from financing activities rose to €4.3m, due to the capital increase (FY/21: €120k). Net cash flow thus came in at €1.8m (FY/21: €-1.6m) last year.

Table 6: Cash flow statement FY/22 and FY/21 (selected items)

in EUR'000	2022	2021	Delta
Operating cash flow	-855	-1,561	-
Cash flow from investing	-1,560	-130	-
Cash flow from financing	4,254	120	-
Net cash flow	1,839	-1,570	-

Source: Calculated by First Berlin Equity Research (BioXXmed does not report a cash flow statement)

FINANCIAL OUTLOOK

Considering that BioXXmed reports its only valuable holding DermaTools as a financial investment and does not consolidate its financials, the company's financial statements will not reflect the revenue, costs or cash flows arising from DermaTools and its commercialisation of DermaPro. Under the non-controlling financial investment method of accounting, BioXXmed, as the holding company, will earn a profit on its investment at some later point in time either through a potential dividend distribution or through the sale of its stake at a higher value recording a transaction gain (gain on disposal). We assume that BioXXmed/DermaTools will successfully achieve CE-mark and 510(k) clearance for DermaPro. Based on the product's positive data, we also anticipate the company will win partners for the commercialisation of the product. For modelling purposes we also assume that DermaTools will take about two years to reach a revenue level required to stabilise its small business so that from 2025 it will begin paying out 60% of net income as dividends to its investors, including BioXXmed. Considering management's disciplined spending, we project OpEx to rise only moderately from €835k in 2022 to €846k in 2023 and €912k in 2025. We project that the company will slightly expand its negative EBIT in the period 2023 – 2025 (see table 6 overleaf). Thanks to the dividends from DermaTools, we expect BioXXmed to achieve a sustainable break-even in 2026.

Table 6: Revenue, EBIT, net income forecasts (selected items)

in EUR'000	2020	2021	2022	2023E	2024E	2025E
Revenue	36	45	12	15	0	0
Other operating income	4	8	0	0	0	0
Personnel expenses	778	549	4	10	16	22
Other operating expenses	1,079	973	826	830	855	881
Depreciation & amortisation	21	59	5	6	8	10
OPEX	1,882	1,590	835	846	879	912
EBIT	-1,838	-1,529	-823	-831	-879	-912
Net income	-1,839	-4,059	-830	-821	-873	-910

Source: First Berlin Equity Research

Balance Sheet We believe BioXXmed will operate debt-free going forward. We have also considered that BioXXmed invested €500k in DermaTools in June 2023. Through this measure, BioXXmed has expanded its stake to 67.6%. BioXXmed's cash resources are projected to fund operations until approximately Q4 2024. Therefore, we assumed that BioXXmed will raise funds of €3.0m in 2024-2026.

Table 7: Balance sheet forecasts (selected items)

in EUR'000	2020	2021	2022	2023E	2024E	2025E
Cash and cash equivalents	1,571	1	1,840	490	1,009	1,079
Accounts receivables	0	43	45	47	50	50
Other current assets	153	67	69	95	99	115
Current Assets, Total	**1,724**	**110**	**1,953**	**632**	**1,158**	**1,244**
Property plant and equipment	15	2	1	6	12	20
Intangible assets	53	0	0	0	0	0
Financial assets	20,503	18,154	19,654	20,154	20,154	20,154
Non-Current Assets, Total	**20,571**	**18,156**	**19,655**	**20,160**	**20,166**	**20,174**
Accounts payable	97	101	33	36	39	43
Provisions	259	167	145	145	145	145
Other current liabilities	14	10	11	12	13	13
Financial debt ST+LT	0	122	0	0	0	0
Total Liabilities	**370**	**400**	**189**	**193**	**197**	**201**
Equity	21,925	17,866	21,419	20,599	21,127	21,216

Source: First Berlin Equity Research

Cash flow We expect group's net loss to result in negative operating cash flows in 2023 - 2025. Cash flow from investing chiefly reflects the company's investments in its holding DermaTools. For 2023, we have factored a €500k investment in DermaTools into our model. We forecast that cash flow from financing will amount to €1.4m in 2024 and €1.0m in 2025 from capital increases. In 2026, we anticipate that the company will book the DermaTools' dividends for 2025.

Table 8: Cash flow forecasts (selected items)

in EUR'000	2020	2021	2022	2023E	2024E	2025E
Operating cash flow	-1,658	-1,561	-910	-850	-874	-914
Cash flow from investing	-4,799	-130	-1,505	-510	-14	-18
Cash flow from financing	1,221	120	4,254	10	1,406	1,002
Net cash flow	-5,236	-1,570	1,839	-1,350	519	70

Source: Calculated by First Berlin Equity Research (BioXXmed does not report a cash flow statement)

NEWSFLOW

In our view, BioXXmed's stock price will be driven by news about its business in the holding DermaTools as well as achievement of financial milestones. We expect the company to make a number of announcements during the coming 12-18 months which will act as catalysts for the stock. These include:

Business

- Completion of the CE-mark registration in Europe of its lead product DermaPro,
- Progress on the 510(k) registration in the US of its lead product DermaPro, feedback from a first FDA meeting if US data is required, and given the case, conduction of a small trial in the US,
- Completion of outlicensing deals for DermaPro for commercialisation in Europe and the US,
- Completion of a capital increase in H1 2024 to fund operations

Financial Schedule

- H1/23 financial results due approx. in September 2023,
- FY/23 audited financial report due approx. in June 2024.

MANAGEMENT

Dr Bruno Rosen, CEO
Dr Rosen studied medicine in Cologne. After doctoral and post-doctoral work, he joined Bayer AG. He held functions in research & development, research management and business development. After 13 years, he moved to medium-sized companies. Initially he was co-founder of a VC-financed medical imaging company, then he served as managing director in generic and research-based pharmaceutical and diagnostic companies; overall he worked for 10 years in executive management positions in the UK, Switzerland and the Netherlands. Dr Rosen is medical specialist in pharmacology and toxicology (German Medical Council) and Fellow of the Faculty of Pharmaceutical Medicine in London, England.

SUPERVISORY BOARD

Arne Björn Segler, Chairman of the Board
He is a lawyer.

Ralph Bieneck, Board Member
He is on the Board of Directors at Heidelberger Beteiligungsholding AG.

Sören Rose, Board Member
He is an entrepreneur.

Ronald Beckerbauer, Board Member
He is a Certified Public Accountant and Auditor.

SHAREHOLDERS & STOCK INFORMATION

Stock Information	
ISIN	DE000A0KFRJ1
WKN	A0KFRJ
Bloomberg ticker	T5O GR
No. of issued shares	5,137,498
Transparency Standard	Open Market /Entry Standard
Country	Germany
Sector	Biotechnology
Subsector	Biotechnology

Source: Börse Frankfurt, First Berlin Equity Research

Shareholder Structure	
Heidelberger Beteiligungsholding AG	19.7%
Delphi Unternehmensberatung AG	22.2%
Klocke Holding GmbH	7.1%
Freefloat and other	51.0%

Source: bioXXmed AG

INCOME STATEMENT

All figures in € '000	2020	2021	2022	2023E	2024E	2025E
Total revenue	**36**	**45**	**12**	**15**	**0**	**0**
Cost of goods sold	0	0	0	0	0	0
Gross profit	36	45	12	15	0	0
Other operating income	4	8	0	0	0	0
Personnel expenses	778	549	4	10	16	22
Other operating expenses	1,079	973	826	830	855	881
EBITDA	**-1,817**	**-1,470**	**-818**	**-825**	**-871**	**-902**
Depreciation & amortisation	21	59	5	6	8	10
Operating income (EBIT)	**-1,838**	**-1,529**	**-823**	**-831**	**-879**	**-912**
Net financial result	-1	-2,490	-7	10	6	2
Pre-tax income (EBT)	**-1,839**	**-4,019**	**-830**	**-821**	**-873**	**-910**
Income taxes	0	-40	0	0	0	0
Net income / loss	**-1,839**	**-4,059**	**-830**	**-821**	**-873**	**-910**
Diluted EPS (€)	**-0.46**	**-1.01**	**-0.18**	**-0.16**	**-0.16**	**-0.15**
Ratios						
EBITDA margin on total revenue	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
EBIT-Margin on total revenue	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Net Margin on total revenue	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Expenses as % of revenue						
Personnel expenses	-42.8%	-37.4%	-0.4%	-1.2%	-1.8%	-2.4%
Other operating expenses	-59.4%	-66.2%	-101.1%	-100.6%	-98.2%	-97.6%
Y-Y Growth						
Total revenue	n.a.	24.0%	-72.6%	22.6%	n.a.	n.a.
Operating income	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Net income/ loss	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

BALANCE SHEET

All figures in € '000	2020	2021	2022	2023E	2024E	2025E
Assets						
Current Assets, Total	**1,724**	**110**	**1,953**	**632**	**1,158**	**1,244**
Cash and cash equivalents	1,571	1	1,840	490	1,009	1,079
Accounts receivables	0	43	45	47	50	50
Inventories	0	0	0	0	0	12
Prepaid expenses	45	7	15	15	15	15
Other current assets	108	60	54	80	84	88
Non-Current Assets, Total	**20,571**	**18,156**	**19,655**	**20,160**	**20,166**	**20,174**
Property plant and equipment	15	2	1	6	12	20
Intangible assets	53	0	0	0	0	0
Financial assets	20,503	18,154	19,654	20,154	20,154	20,154
Total Assets	**22,295**	**18,266**	**21,608**	**20,792**	**21,324**	**21,418**
Shareholders' Equity & Debt						
Current Liabilities, Total	**370**	**400**	**189**	**193**	**197**	**201**
Short-term debt	0	122	0	0	0	0
Accounts payable	97	101	33	36	39	43
Provisions	259	167	145	145	145	145
Other current liabilities	14	10	11	12	13	13
Longterm Liabilities, Total	**0**	**0**	**0**	**0**	**0**	**0**
Minority interests	**0**	**0**	**0**	**0**	**0**	**0**
Shareholders Equity	**21,925**	**17,866**	**21,419**	**20,599**	**21,127**	**21,216**
Total Consolidated Equity and Debt	**22,295**	**18,266**	**21,608**	**20,792**	**21,324**	**21,418**
Ratios						
Current ratio (x)	4.66	0.28	10.34	3.28	5.88	6.18
Quick ratio (x)	4.66	0.28	10.34	3.28	5.88	6.12
Net gearing	-7.2%	0.7%	-8.6%	-2.4%	-4.8%	-5.1%
Book value per share (€)	5.44	4.44	4.56	4.01	3.84	3.48
Net debt	-1,571	121	-1,840	-490	-1,009	-1,079
Equity ratio	98.3%	97.8%	99.1%	99.1%	99.1%	99.1%

CASH FLOW

All figures in € '000	2020	2021	2022	2023E	2024E	2025E
Net income	**-1,839**	**-4,059**	**-830**	**-821**	**-873**	**-910**
Interest, net	1	2,490	7	-10	-6	-2
Tax provision	0	40	0	0	0	0
EBIT	**-1,838**	**-1,529**	**-823**	**-831**	**-879**	**-912**
Depreciation and amortisation	21	59	6	6	8	10
EBITDA	**-1,817**	**-1,470**	**-817**	**-825**	**-871**	**-902**
Changes in w orking capital	-57	-48	-93	-25	-3	-12
Other adjustments	217	-43	1	0	0	0
Operating cash flow	**-1,658**	**-1,561**	**-910**	**-850**	**-874**	**-914**
CapEx	-3	-130	-1,505	-510	-14	-18
Free cash flow	**-1,661**	**-1,691**	**-2,415**	**-1,360**	**-887**	**-932**
Other investments	-4,796	0	-1,500	-500	0	0
Cash flow from investing	**-4,799**	**-130**	**-1,505**	**-510**	**-14**	**-18**
Debt Financing, net	0	120	-122	0	0	0
Equity Financing, net	6,017	0	4,383	0	1,400	1,000
Net financial result	-4,796	0	-7	10	6	2
Cash flow from financing	**1,221**	**120**	**4,254**	**10**	**1,406**	**1,002**
Net cash flows	**-440**	**-1,570**	**1,839**	**-1,350**	**519**	**70**
Cash, start of the year	2,011	1,571	1	1,840	490	1,009
Cash, end of the year	**1,571**	**1**	**1,840**	**490**	**1,009**	**1,079**

Y-Y Growth						
Operating Cashflow	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Free cashflow	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
EBITDA/share	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.

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Category		1	2
Current market capitalisation (in €)		0 - 2 billion	> 2 billion
Strong Buy[1]	An expected favourable price trend of:	> 50%	> 30%
Buy	An expected favourable price trend of:	> 25%	> 15%
Add	An expected favourable price trend of:	0% to 25%	0% to 15%
Reduce	An expected negative price trend of:	0% to -15%	0% to -10%
Sell	An expected negative price trend of:	< -15%	< -10%

[1] The expected price trend is in combination with sizable confidence in the quality and forecast security of management.

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Report No.:	Date of publication	Previous day closing price	Recommendation	Price target
Initial Report	Today	€1.70	Buy	€3.10

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