Biofrontera Inc.
Letter to Stockholders

To our valued stockholders,

We would like to extend warm wishes to all of you for a healthy and prosperous 2022. At Biofrontera Inc., we welcomed the New Year with optimism and continued business momentum. In this letter, we provide a summary of our successes in 2021 and highlight key elements of our strategic plan for 2022 and beyond.

The overarching strategy for Biofrontera's success continues to be gaining market share for our two FDA-approved licensed products, Ameluz® and Xepi®, while also broadening our commercial opportunities through label expansions of our flagship product, Ameluz®.

Looking back, 2021 was a foundational year for Biofrontera Inc. We completed a successful initial public offering (IPO) at the end of October, creating a publicly traded company focused on the U.S., the world's largest dermatology market. Our business rests upon license and supply agreements in the U.S. to market and sell Ameluz in combination with the red-light lamps BF-RhodoLED® and the new RhodoLED XL for the treatment of actinic keratosis (AK), as well as the topical antibiotic Xepi® for the treatment of impetigo.

In 2021, we created strong momentum that we expect will carry on into 2022, such as:

- A rebound from the pandemic-induced hesitation to perform in-office dermatology treatments, which resulted in sales now recovering to near pre-pandemic levels.
- Market share gains by both Ameluz® and Xepi® in their growing, multibillion-dollar categories.
- A Nasdaq listing that affords the flexibility to exploit market opportunities or cover short-term financing needs, supported by IPO proceeds of $18 million (gross), our recent $15 million (gross) private placement as well as well as proceeds from warrant exercises in excess of $13 million since the IPO.

Commercial Momentum

We are proud of the hard work by the talented members of our sales team across the country. Despite the challenges resulting from the COVID-19 pandemic, we returned to topline growth in 2021. Most dermatology offices have fully reopened and patients have shown increased willingness to undergo in-office treatments for AK. We exited 2021 with strengthened financial performance, including:

- Preliminary sales for the fourth quarter of 2021 in a range of $9.1 million to $9.2 million, representing an increase of approximately 7% compared with the fourth quarter of 2020.

- Preliminary revenue for the full year 2021 anticipated to be in the range of $24.1 million to $24.2million, an increase of approximately 27% over full year 2020.

Market Opportunity

According to the Skin Cancer Foundation, AK affects approximately 58 million people in the U.S. In 2020, an estimated 12.7 million AK treatments were performed in the U.S., which translates to a total addressable market of about $4 billion for Ameluz with its current FDA-approved indication. AK is a precursor to squamous cell carcinoma, a skin cancer with a potentially fatal outcome.
The most common treatment for AK is cryotherapy, with a 2020 market share of approximately 86%. Topical drugs for the treatment of AK had a market share of about 12%, followed by photodynamic therapy (PDT) treatments with about a 2% share. Despite its market dominance, we think cryotherapy lacks certain advantages as a treatment option compared with PDT. As such, the opportunity to gain share from cryotherapy is a key focus of our commercial efforts.

Expanding the Ameluz label allows us to consistently deliver innovative solutions for patients and serves as the key mechanism to unlock the drug's potential. Continued investment in clinical research by our license partner aiming at label expansion is thus an integral part of our business. According to our license agreement for Ameluz®, the licensor is obliged to conduct and finance the clinical studies required for defined label expansions. The FDA approval pathway takes significant investment and time but, if successful, the result can be very rewarding – not only for the patients, but also for the potential value creation for our shareholders.

The clinical successes for our licensed products in 2021 included regulatory approval for the new RhodoLED XL lamp, progress on the Phase 3 study for the treatment of basal cell carcinoma (BCC), the launch of a 3-tube safety study as well as a Phase 2b trial for acne – all of which keep the Ameluz® clinical program moving forward.

Our second licensed prescription drug is Xepi®. Xepi® is a topical antibiotic for the treatment of impetigo, a highly contagious bacterial skin infection with more than 3 million cases in the U.S. each year. Currently, no antibiotic resistance against Xepi® is known, and Xepi has also been specifically approved by the FDA for resistant strains of staphylococcus aureus or streptococcus pyogenes, including MRSA.

In 2020, more than 13 million prescriptions were written for drugs in indications where Xepi® could be effective. Xepi® is distributed through specialty pharmacies and is generally covered by most commercial payers without pre-authorization. We believe there is considerable market potential for Xepi® in the coming years.

Strategies for Sustained Growth

Our longer-term financial objectives include achieving consistent revenue growth and expanding operating margins. Accordingly, we are focused on balancing market expansion with operating efficiency, including effective resource utilization, information technology leverage and overhead cost management.

Our market-expansion strategy is based on bolstering awareness of our licensed products through industry recognition, data-driven sales strategies, and a robust and dynamic commercial infrastructure. We intend to optimize our sales force by adding sales territories, and to strengthen medical affairs to become a trusted partner through scientific data publication, interaction with key opinion leaders (KOLs) and industry support. Overall, our marketing and development goals align to form a commercial strategy that has uniquely positioned Biofrontera for leadership in the treatment of dermatological conditions.

As we move into 2022, the energy across our organization is palpable. We are poised to increase sales and gain further market share in the U.S. We intend to expand our corporate footprint and to invest in our long-term growth strategies. As we continue to build upon our position in the dermatology market in the U.S., we invite you along on our exciting journey and affirm our commitment to transparency on the progress and milestones we strive to achieve.

On behalf of all Biofrontera Inc. employees and our Board of Directors, we thank you for your continued support of Biofrontera Inc.

Sincerely,

Erica Monaco
Chief Executive Officer

Hermann Lübbert
Executive Chairman of the Board

January 18, 2022

Forward-looking statements: Certain statements in this letter may constitute "forward-looking statements" within the meaning of the United States Private Securities Litigation Reform Act of 1995, as amended to date. These statements include, but are not limited to, the Company's estimated revenue for the fourth quarter and year ended December 31, 2021 and statements regarding the future performance of the Company, opportunities for market growth, objectives of management, strategic plans and future operations. The words "believe", "anticipate", "intend", "expect", "target", "goal", "estimate", "plan", "assume", "may", "will", "predict", "project", "would", "could" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We have based these forward-looking statements on our current expectations and projections about future events, nevertheless, actual results or events could differ materially from the plans, intentions and expectations disclosed in, or implied by, the forward-looking statements we make. These risks and uncertainties, many of which are beyond our control, including, but not limited to, the impact of extraordinary external events, such as the current COVID-19 pandemic and its evolving nature; any changes in the Company's relationship with its licensors; the outcome of the Company's litigation with DUSA Pharmaceuticals, Inc.,; the Company's ability to achieve and sustain profitability; whether the current disruptions in the supply chain will impact the Company's ability to obtain and distribute its licensed products; changes in the practices of healthcare providers, including any changes to the coverage, reimbursement and pricing for procedures using the Company's licensed products; the uncertainties inherent in the initiation and conduct of clinical trials; availability and timing of data from clinical trials; whether results of early clinical trials or trials in different disease indications will be indicative of the results of ongoing or future trials; whether results of the studies described above will be indicative of results for any future clinical trials and studies of Ameluz® in combination with BF-RhodoLED®; uncertainties associated with regulatory review of clinical trials and applications for marketing approvals; whether the market opportunity for Ameluz® in combination with RhodoLED® lamps is consistent with the Company's expectations; whether the Company will be able to successfully transition to a public company operating independently of Biofrontera AG; the Company's ability to retain and hire key personnel; the sufficiency of cash resources and need for additional financing and other factors that may be disclosed in the Company's filings with the SEC, which can be obtained on the SEC website at www.sec.gov and are also available on our website at www.biofrontera-us.com. Readers are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date on which they are made and reflect management's current estimates, projections, expectations and beliefs. The Company does not plan to update any such forward-looking statements and expressly disclaims any duty to update the information contained in this press release except as required by law.