Risk Factors Comparison 2024-03-15 to 2023-03-13 Form: 10-K

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Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Form 10- K, including our financial statements and the related notes and the section " Management' s Discussion and Analysis of Financial Condition and Results of Operations, " before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could materially and adversely affect our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations. Summary of Material Risk Factors Our business, results of operations and financial condition and the industry in which we operate are subject to various risks. We have listed below (in order of importance or probability of occurrence) the most significant risk factors applicable to us, but they do not constitute all of the risks that may be applicable to us. New risks may emerge from time to time, and it is not possible for us to predict all potential risks or to assess the likely impact of all risks. You should read this summary together with the more detailed description of each risk factor contained below. Some of these material risks include: Risks Related to the License and Supply Agreements and our Licensed Products ● Currently, our sole source of revenue is from sales of products we license from other companies, including a related party. If we fail to comply with our obligations in the agreements under which we license rights from such parties, or if the license agreements are terminated for other reasons, we could lose license rights that are important to our business. ● Certain important patents for our licensed product Ameluz ® expired in 2019. Although the process of developing generic topical dermatological products for the first time presents specific challenges that may deter potential generic competitors, generic versions of Ameluz ® may enter the market following the recent expiration of these patents. If this happens, we may need to reduce the price of Ameluz ® significantly and may lose significant market share. ● Our business depends substantially on the success of our principal licensed product Ameluz ®. If the Ameluz Licensor is unable to successfully obtain and maintain regulatory approvals or reimbursement for Ameluz ® for existing and additional indications, our business may be materially harmed. ● The Ameluz Licensor currently depends on a single unaffiliated contract manufacturer to manufacture Ameluz ® and has contracted with a second unaffiliated contract manufacturer to begin producing Ameluz ®. If the Ameluz Licensor fails to maintain its relationships with these manufacturers or if both of these manufacturers are unable to produce product for the Ameluz Licensor, our business could be materially harmed. ● If our Licensors or our Licensors' manufacturing partners, as applicable, fail to manufacture Ameluz ®, RhodoLED ® lamps, Xepi ® or other marketed products in sufficient quantities and at acceptable quality and cost levels, or to fully comply with current good manufacturing practice, or cGMP, or other applicable manufacturing regulations, we may face a bar to, or delays in, the commercialization of the products under license to us or we will be unable to meet market demand, and lose potential revenues. ● If our Licensors' efforts to protect the proprietary nature of their intellectual property related to our licensed products are not adequate, we may not be able to compete effectively in our market. ● Third party claims of intellectual property infringement may affect our ability to sell our licensed products and may also prevent or delay our Licensors' product discovery and development efforts ● The Biofrontera Group has been involved in lawsuits to defend or enforce patents related to our licensed products and they or another licensor may become involved in similar suits in the future, which could be expensive, time- consuming and unsuccessful. ● The trade secrets of our Licensors are difficult to protect. ● Our subsidiary and certain third- party employees and our licensed patents are subject to foreign laws. ● Our international dealings with our Licensors may pose currency risks, which may adversely affect our operating results and net income. Risks Related to Our Business and Strategy ● We are fully dependent on our collaboration with the Ameluz Licensor for our supply of Ameluz ® and RhodoLED ® lamps and future development of the Ameluz ® product line, on our collaboration with Ferrer for our supply of Xepi ® and future development of Xepi ® and may depend on the Ameluz Licensor, Ferrer or additional third parties for the supply, development and commercialization of future licensed products or product candidates. Although we have the authority under the Ameluz LSA with respect to the indications that the Ameluz Licensor is currently pursuing with the FDA (as well as certain other clinical studies identified in the Ameluz LSA) in certain circumstances to take over clinical development, regulatory work and manufacturing from the Ameluz Licensor if they are unable or unwilling to perform these functions appropriately, the sourcing and manufacture of our licensed products as well as the regulatory approvals and clinical trials related to our licensed products are currently controlled, and will likely continue to be controlled for the foreseeable future, by our existing and future collaborators. Our lack of control over some of these functions could adversely affect our ability to implement our strategy for the commercialization of our licensed products. ● Insurance coverage and medical expense reimbursement may be limited or unavailable in certain market segments for our licensed products, which could make it difficult for us to sell our licensed products. ● Healthcare legislative changes may have a material adverse effect on our business and results of operations. ● To date, we have a relatively short history of sales of our licensed products in the United States. ● Competing products and future emerging products may erode sales of our licensed products. ● We face significant competition from other pharmaceutical and medical device companies and our operating results will suffer if we fail to compete effectively. We also must compete with existing treatments, such as simple curettage and cryotherapy, which do

not involve the use of a drug but have gained significant market acceptance. ● If we are unable to maintain effective marketing and sales capabilities or enter into agreements with third parties to market and sell our licensed products, we may be unable to generate revenue growth. ● The U. S. market size for Ameluz ® for the treatment of actinic keratosis may be smaller than we have estimated. ● If our Licensors face allegations of noncompliance with the law and encounter sanctions, their reputation, revenues and liquidity may suffer, and our licensed products could be subject to restrictions or withdrawal from the market. ● Even if our Licensors obtain regulatory approvals for our licensed products and product candidates, or approvals extending their indications, they may not gain market acceptance among hospitals, physicians, health care payors, patients and others in the medical community. ● With respect to our licensed products, we may be subject to healthcare laws, regulation and enforcement. Our failure to comply with those laws could have a material adverse effect on our results of operations and financial condition. ● A recall of our licensed drug or medical device products, or the discovery of serious safety issues with our licensed drug or medical device products, could have a significant negative impact on us. ● Our licensed medical device product, the RhodoLED ® lamp, is subject to extensive governmental regulation, and failure to comply with applicable requirements could cause our business to suffer. ● As a result of our current IT infrastructure and German- based subsidiary, we are subject to governmental regulation and other legal obligations in the EU and European Economic Area, or EEA, related to privacy, data protection and data security and, as a result of our sales in California, the California Consumer Privacy Act (CCPA). Our actual or perceived failure to comply with such obligations could harm our business. ● We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may be unable to successfully implement our business strategy. ● Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. ● We will need to grow the size of our organization and we may experience difficulties in managing this growth. ● Our business and operations would suffer in the event of system failures or, cyber- attacks. ● If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our licensed products. ● Failure to comply with the U. S. Foreign Corrupt Practices Act or other applicable anti- corruption legislation could result in fines, criminal penalties and an adverse effect on our business. ● Our licensed products will be subject to ongoing regulatory requirements and we may face future development, manufacturing and regulatory difficulties. ● Generic manufacturers may launch products at risk of patent infringement. ● The results of our R & D efforts are uncertain and there can be no assurance they will enhance the commercial success of our products. Risks Related to Our Financial Position and Capital Requirements ● There is substantial doubt about our ability to continue as a " going concern. " ● Failure to achieve the conditions relating to the additional $ 7. 2 million of proceeds to be provided under the equity financing agreement entered into on February 19, 2024 could adversely affect our financial condition and liquidity over the next twelve months ● We have a history of operating losses and anticipate that we will continue to incur operating losses in the future and may never sustain profitability. ● If we fail to obtain additional financing, we may be unable to pursue our plans for strategic growth, including completing the commercialization of Xepi ® and other products we may license. ● Our existing and any future indebtedness could adversely affect our ability to operate our business. Risks Related to Corporate Governance, Including Being a Public Company ● We previously identified a material weakness in our internal control over financial reporting, resulting from control deficiencies related to management' s review of work performed by specialists. If we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business and stock price. ● We have incurred, and will continue to incur, increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance with our public company responsibilities and corporate governance practices. ● As a result of becoming a public company, we are obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common stock. ● We are an emerging growth company and smaller reporting company we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies or smaller reporting companies will make our common stock less attractive to investors. Risks Related to Our Securities and the Ownership of Our Common Stock ● Provisions of our outstanding warrants could discourage an acquisition of us by a third party. ● Our share price may be volatile, and you may be unable to sell your shares and / or warrants at or above the offering price. ● If we fail to regain compliance with applicable listing standards, our common stock and / or our publicly- traded warrants could be delisted from Nasdaq. ● Future sales of our common stock in the public market could cause our share price to fall. ● If the Preferred Warrants are not exercised, we will not receive up to $ 8 million in aggregate gross proceeds from the exercise of the Warrants which could have a material adverse effect on our financial condition. ● Warrants are exercisable for our common stock, which would increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders. ● If securities or industry analysts do not publish research or publish unfavorable research about our business, our stock price and trading volume could decline. ● Our quarterly operating results may fluctuate significantly. ● Future sales and issuances of our common stock or rights to purchase our common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause the stock price of our common stock to decline. ● We have never paid dividends on our common stock and we do not intend to pay dividends for the foreseeable future. Consequently, any gains from an investment in our common stock will likely depend on whether the price ● Our stockholder rights plan, or " poison pill, " includes terms and conditions which could discourage a takeover or other transaction that stockholders may consider favorable. ● Our charter documents and Delaware law could prevent a

takeover that stockholders consider favorable and could also reduce the market price of our stock. ● Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. ● Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third- party claims against us and may reduce the amount of money available to us for our common stock increases. ● Many of the warrants to purchase shares of our common stock are accounted for as a warrant liability and recorded at fair value with changes in fair value each period reported in earnings, which may have an adverse effect on the market price of our common stockRisks Related to the License and Supply Agreements and Our Licensed Products Currently, our sole source of revenue is from sales of products we license from other companies. If we fail to comply with our obligations in the agreements under which we license rights from such third parties, or if the license agreements are terminated for other reasons, we could lose license rights that are important to our business. We are a party to license agreements with Biofrontera Pharma, GmbH and Biofrontera Bioscience, GmbH (for Ameluz ® and the RhodoLED ® lamp series) and with Ferrer (for Xepi ®) and expect to enter into additional licenses in the future. Our existing license agreements impose, and we expect that future license agreements will impose, on us various development, regulatory diligence obligations, payment of milestones or royalties and other obligations. If we fail to comply with our obligations under our license agreements, the licensor may have the right to terminate the license. In the event that any of our existing or future important licenses were to be terminated by the licensor, we would likely need to cease further commercialization of the related licensed product or be required to spend significant time and resources to modify the licensed product to not use the rights under the terminated license. In the case of marketed products that depend upon a license agreement, we could be required to cease our commercialization activities, including sale of the affected product. For a summary of the terms of the license agreements, see " Business — Commercial Partners and Agreements ". Disputes may arise between us and any of our Licensors regarding intellectual property subject to such agreements, including: ● the scope of rights granted under the agreement and other interpretation- related issues; ● whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the agreement; ● our right to sublicense patent and other rights to third parties; ● our diligence obligations with respect to the use of the licensed intellectual property, and what activities satisfy those diligence obligations; ● the ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our Licensors and us, should any such joint creation occur; ● our right to transfer or assign the license; and ● the effects of termination. These, or other disputes over intellectual property that we have licensed may prevent or impair our ability to maintain our current arrangements on acceptable terms or may impair the value of the arrangement to us. Any such dispute, or termination of a necessary license, could have a material adverse effect on our business, financial condition and results of operations. Certain important patents for our licensed product Ameluz ® expired in 2019. Although the process of developing generic topical dermatological products for the first time presents specific challenges that may deter potential generic competitors, generic versions of Ameluz ® may enter the market following the recent expiration of these patents. If this happens, we may need to reduce the price of Ameluz ® significantly and may lose significant market share. The patent family that protected the technology relating to nanoemulsion of 5- aminolevulinic acid, the active ingredient in Ameluz ®, against copying by competitors expired on November 12, 2019. This patent family included U. S. Patent No. 6, 559, 183, which, prior to its expiration, served as a material, significant and possibly the only barrier to entry into the U. S. market by generic versions of Ameluz ®. Although the process of developing generic topical dermatological products presents specific challenges that may deter potential generic competitors, Patent No. 6, 559, 183 no longer prevents generic versions of Ameluz ® from entering the U. S. market and competing with Ameluz ®. If generic competitors do enter the market, this may cause a significant drop in the price of Ameluz ® and, therefore, a significant drop in our profits. We may also lose significant U. S. market share for Ameluz ®. The Ameluz Licensor holds another patent family protecting the technology relating to nanoemulsions for which they have been issued patents in various jurisdictions and which expire in December 2027. A corresponding U. S. patent application has been filed by the Ameluz Licensor but is still pending. We cannot guarantee that this U. S. patent will be issued or, if issued, will adequately protect us against copying by competitors. Our business depends substantially on the success of our principal licensed product Ameluz ®. If the Ameluz Licensor is unable to successfully obtain and maintain regulatory approvals or reimbursement for Ameluz ® for existing and additional indications, our business may be materially harmed. Although the Ameluz Licensor has received marketing approval in the United States for Ameluz ® for lesion- and field- directed treatment of actinic keratosis in combination with **PDT** ~~photodynamic therapy~~ using the BF- RhodoLED ® lamp series, there remains a significant risk that we will fail to generate sufficient revenue or otherwise successfully commercialize the product in the United States. The success of our product will depend on several factors, including: ● successful completion of further clinical trials by the Ameluz Licensor; ● receipt by the Ameluz Licensor of further regulatory approvals, including for the marketing of Ameluz ® for additional indications; ● the contract manufacturing facility maintaining regulatory compliance; ● compliance with applicable law for our sales force and marketing efforts; ● the contract manufacturing facility manufacturing sufficient quantities in acceptable quality; ● the Ameluz Licensor sourcing sufficient quantities of raw materials used to manufacture our licensed products; ● continued acceptable safety and effectiveness profiles for our licensed products; ● the Ameluz Licensor obtaining and maintaining patent and trade secret protection and regulatory exclusivity; and ● the Ameluz Licensor protecting its intellectual property rights. If the Ameluz Licensor does not achieve one or more of these factors in a timely manner, or at all, we could experience significant delays or an inability to successfully commercialize our licensed products, which would materially harm our business and we may not be able to earn sufficient revenue and cash flows to continue our operations. Because the Ameluz Licensor received approval from the FDA to market in the United States Ameluz ® in combination with **PDT** ~~photodynamic therapy~~ using the BF- RhodoLED ® lamp, any

new lamp we may license would require new approval from the FDA. We cannot assure you that the Biofrontera Group will develop any new lamps (beyond the BF- RhodoLED ® XL lamp which was approved by the FDA on October 21, 2021) or obtain any such new approval. The Ameluz Licensor currently depends on a single unaffiliated contract manufacturer to manufacture Ameluz ® and has contracted with a second unaffiliated contract manufacturer to begin producing Ameluz ®. If the Ameluz Licensor fails to maintain its relationships with these manufacturers or if both of these manufacturers are unable to produce product for the Ameluz Licensor, our business could be materially harmed. Pursuant to the Ameluz LSA, the Ameluz Licensor supplies us with Ameluz ®. The Ameluz Licensor currently depends on a single unaffiliated contract manufacturer located in Switzerland to manufacture Ameluz ®, Glaropharm AG, and has signed an agreement with a second unaffiliated contract manufacturer located in Germany, Pharbil Waltrop GmbH, to begin to supply it with Ameluz ® to ensure stability of the supply chain. If the Ameluz Licensor fails to maintain its relationships with both of these manufacturers or if the Ameluz Licensor fails to maintain its relationship with its current manufacturer and the second manufacturer has not yet completed the necessary steps to begin manufacturing Ameluz ®, the Ameluz Licensor may be unable to obtain an alternative manufacturer of Ameluz ® that could deliver the quantity of the product at the quality and cost levels that we require. Even if an acceptable alternative manufacturer could be found, we would expect long delays in transitioning the manufacturing from the existing manufacturer to a new manufacturer. Problems of this kind could cause us to experience order cancellations and loss of market share. The failure of either manufacturer to supply the Ameluz Licensor with Ameluz ® that satisfies quality, quantity and cost requirements in a timely manner could impair our ability to deliver Ameluz ® to the U. S. market and could increase costs, particularly if the Ameluz Licensor is unable to obtain Ameluz ® from alternative sources on a timely basis or on commercially reasonable terms. In addition, each manufacturer is regulated by the country in which it is located and by the FDA and must comply with applicable laws and regulations. Finding a suitable replacement of these particular partners would therefore be extremely difficult for the Ameluz Licensor. If the Ameluz Licensor lost these manufacturers, this could have a material adverse effect on our business, prospects, financial condition and / or results of operations. If the suppliers fail to comply, this could harm our business. If our Licensor or our Licensors' manufacturing partners, as applicable, fail to manufacture Ameluz ®, RhodoLED ® lamps, Xepi ® or other marketed products in sufficient quantities and at acceptable quality and cost levels, or to fully comply with current good manufacturing practice, or cGMP, or other applicable manufacturing regulations, we may face a bar to, or delays in, the commercialization of the products under license to us or we will be unable to meet market demand, and lose potential revenues. Pursuant to the applicable LSA, our Licensors supply us with the licensed product that we sell in the U. S. market. The manufacture of the products we license requires significant expertise and capital investment. Currently, all commercial supply for each of our commercial licensed products are manufactured by single unaffiliated contract manufacturers. Our Licensors would each need to spend substantial time and expense to replace their respective contract manufacturer if such contract manufacturer failed to deliver products in the quality and quantities we demand or failed to meet any regulatory or cGMP requirements. Our Licensors take precautions to help safeguard their respective manufacturing facilities, including acquiring insurance and performing on site audits. However, vandalism, terrorism or a natural or other disaster, such as a fire or flood, could damage or destroy manufacturing equipment or the inventory of raw material or finished goods, cause substantial delays in operations, result in the loss of key information, and cause additional expenses. Our Licensors' insurance may not cover losses related to our licensed products in any particular case. In addition, regardless of the level of insurance coverage, damage to our Licensors' facilities may have a material adverse effect on our business, financial condition and operating results. Furthermore, while our Licensors take reasonable precautions to ensure the successful production of our commercially licensed products, their contract manufacturers may experience a myriad of business difficulties (i. e., workforce instability, supply chain issues, erosion of customer base, etc.) that could impact their financial solvency. Ferrer' s manufacturer of Xepi ® (Teligent, Inc.) filed for Chapter 11 bankruptcy on October 14, 2021, and on February 23, 2022 Teligent, Inc. filed a motion to convert their bankruptcy into a Chapter 7 liquidation. Ferrer is in the process of qualifying a new third- party manufacturer in North America. The process will require significant time and expense, including the time it will take the new contract manufacturer to reach a level of production to meet our commercial needs. Although we have inventory of Xepi ® on hand, we do not expect it will be enough to complete the commercialization of Xepi ® in accordance with the originally planned timeline. If there are any significant delays to, or changes in, our plans for the completion of the commercialization of Xepi ®, this could have a material adverse effect on our business, prospects, financial condition and / or results of operations. See " Management' s Discussion and Analysis of Financial Condition and Results of Operations — Key factors affecting our performance — Supply Chain " in this Form 10- K **. Our efforts to commercialize a new lamp (the " RhodoLED ® XL ") that was approved by the FDA on October 21, 2021 have been delayed due to supply chain matters. We have currently placed an order and issued a PO for 300 units and manufacturing has commenced on the units. While we anticipate that we will be able to commercialize the RhodoLED ® XL in or around the second quarter of 2024, slower than anticipated shipments or other delays are possible** . Our Licensors' manufacturing partners must comply with federal, state and foreign regulations, including FDA regulations governing cGMP enforced by the FDA through its facilities inspection program and by similar regulatory authorities in other jurisdictions where we do business. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. For the medical device products we license, our Licensors are required to comply with the FDA' s Quality System Regulation, or QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our medical device products. Our Licensors' facilities or our Licensors' contract facilities, as applicable, have been inspected by the FDA for cGMP compliance. If our Licensors' or our Licensors' contract manufacturers, as applicable, do not successfully maintain cGMP compliance for these facilities, commercialization of our licensed products could be prohibited or significantly delayed. Even after cGMP compliance has been achieved, the FDA or similar foreign regulatory authorities at any time may implement new standards or change their interpretation and enforcement of existing standards for manufacture, packaging, testing of or other

activities related to our licensed products. For our licensed commercialized medical device product, the FDA audits compliance with the through periodic announced and unannounced inspections of manufacturing and other facilities. The FDA may conduct inspections or audits at any time. Similar audit rights exist in Europe and other foreign jurisdictions. Any failure to comply with applicable cGMP, QSR and other regulations may result in fines and civil penalties, suspension of production, product seizure or recall, imposition of a consent decree, or withdrawal of product approval, and would limit the availability of our product. Any manufacturing defect or error discovered after products have been produced and distributed also could result in significant consequences, including adverse health consequences, injury or death to patients, costly recall procedures, re- stocking costs, warning letters, Form 483 reports, civil monetary penalties, product liability, damage to our reputation and potential for product liability claims. If our Licensors are required to find a new manufacturer or supplier, the process would likely require prior FDA and / or equivalent foreign regulatory authority approval and would be very time consuming. An inability to continue manufacturing adequate supplies of our licensed products at any contract facilities could result in a disruption in the supply of our licensed products. Delay or disruption in our ability to meet demand may result in the loss of potential revenue. In addition, we are subject to regulations in various jurisdictions, including the Federal Drug Quality and Security Act and the Drug Supply Chain Security Act in the United States, which require us to develop electronic systems to serialize, track, trace and authenticate units of our licensed products through the supply chain and distribution system. Compliance with these regulations may result in increased expenses for our company or impose greater administrative burdens on our organization, and failure to meet these requirements could result in fines or other penalties. Failure to comply with all applicable regulatory requirements may subject our company to operating restrictions and criminal prosecution, monetary penalties and other disciplinary actions, including, sanctions, warning letters, product seizures, recalls, fines, injunctions, suspension, shutdown of production, revocation of approvals or the inability to obtain future approvals, or exclusion from future participation in government healthcare programs. Any of these events could disrupt our company' s business and, consequently, have a material adverse effect on our revenue, profitability and financial condition. If our Licensors' efforts to protect the proprietary nature of their intellectual property related to our licensed products are not adequate, we may not be able to compete effectively in our market. Our Licensors rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to the products we license from them. Any disclosure to or misappropriation by third parties of their confidential proprietary information could enable competitors to quickly duplicate or surpass their technological achievements, thus eroding our competitive position in our market. In addition, the patent applications that they own may fail to result in issued patents in the United States. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, their patents and patent applications may not adequately protect their intellectual property or prevent others from designing around their claims. If the breadth or strength of protection provided by the issued patents and patent applications our Licensors hold with respect to our licensed products is threatened, it could threaten our ability to commercialize our licensed products. Further, if our Licensors encounter delays in their clinical trials, the period of time during which we could market our licensed products under patent protection would be reduced. Since patent applications in the United States are confidential for a period of time after filing, we cannot be certain that our Licensors were the first to file any patent application related to the products we license. Furthermore, for applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the U. S. Patent and Trademark Office, or USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For applications containing a claim not entitled to priority before March 16, 2013, there is greater level of uncertainty in the patent law with the passage of the America Invents Act (2012) which brings into effect significant changes to the U. S. patent laws that are yet untried and untested, and which introduces new procedures for challenging pending patent applications and issued patents. A primary change under this reform is creating a " first to file " system in the United States. This will require us to be cognizant going forward of the time from invention to filing of a patent application. In addition to the protection afforded by patents, our Licensors may rely on trade secret protection and confidentiality agreements to protect proprietary know- how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know- how, information or technology that is not covered by patents. Although our Licensors may require their employees to assign their inventions to us to the extent permitted by law, and may require our employees, consultants, advisors and any third parties who have access to our proprietary know- how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States or the EU. As a result, our Licensors may encounter significant problems in protecting and defending their intellectual property in the United States, in the EU and in other countries. If they are unable to prevent unauthorized material disclosure of their intellectual property to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition. Third party claims of intellectual property infringement may affect our ability to sell our licensed products and may also prevent or delay our Licensors' product discovery and development efforts. Our commercial success depends in part on our Licensors avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference and reexamination proceedings before the USPTO, or oppositions and other comparable proceedings in foreign jurisdictions. Recently, following U. S. patent reform, new procedures including inter partes review and post grant review have been implemented. This reform includes changes in law and procedures that are untried and untested and will bring uncertainty to the possibility of challenge to our

patents in the future. Numerous U. S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which our Licensors are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our licensed products may give rise to claims of infringement of the patent rights of others. Third parties may assert that we or our Licensors are employing their proprietary technology without authorization. There may be third party patents of which we or our Licensors are currently unaware with claims to materials, formulations, devices, methods of manufacture or methods for treatment related to the use or manufacture of the products we license. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our licensed products or product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our licensed technologies infringes upon such patents. If any third- party patents were held by a court of competent jurisdiction to cover the manufacturing process of our licensed products, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize the product unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third- party patent were held by a court of competent jurisdiction to cover aspects of the formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block our ability to commercialize the product unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we or our Licensors are unable to obtain a necessary license to a third- party patent on commercially reasonable terms, or at all, our ability to commercialize our licensed products may be impaired or delayed, which could in turn significantly harm our business. Parties making claims against us or our Licensors may seek and obtain injunctive or other equitable relief, which could effectively block our ability to sell our licensed products and to further commercialize our licensed products. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we or our Licensors may need to obtain licenses from third parties to advance their research or allow commercialization of the products we license. We or our licensors may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further commercialize our licensed products, which could harm our business significantly. ~~In March 2018, DUSA Pharmaceuticals, Inc., or DUSA, brought a lawsuit against Biofrontera AG and its subsidiaries, including us, before the District Court of Massachusetts (18- cv- 10568- RGS) alleging patent infringement and other claims related to sales practices.~~ On November 29, 2021, ~~before~~ the **Company** ~~trial began, we~~ entered into a ~~confidential~~ settlement and release agreement with ~~the~~ respect to **a lawsuit filed March 23, 2018** ~~the DUSA Litigation with DUSA. See " Commitments and Contingencies — Legal proceedings "~~ in ~~Note 24 to~~ the **United States District Court** ~~audited financial statements as of and~~ for the **District of Massachusetts** ~~years ended December 31, 2022 and 2021 as included~~ in ~~this Form 10- K While~~ **which we were alleged to have infringed on certain patents and misappropriated certain trade secrets. In the settlement, the Company and** Biofrontera AG ~~has~~ **together** agreed to **make** ~~pay a portion of the settlement, we remain jointly and~~ **an** ~~severally liable~~ **aggregate payment of $ 22. 5 million and engage a forensic expert** to ~~DUSA for~~ **destroy data at issue in** the ~~full~~ **litigation to** ~~settlement ----~~ **settle** ~~amount, meaning that in~~ the **claims in** ~~event Biofrontera AG does not pay all or a portion of~~ the **litigation** ~~amount it owes under the Agreement, DUSA could compel us to pay Biofrontera AG' s share~~. If either we or Biofrontera AG violates the terms of the settlement agreement, this could nullify certain aspects of the settlement and we may lose certain benefits of the settlement and be liable for a greater amount. If we become liable for more than our agreed share of the aggregate settlement amount, either of these events could have a material adverse effect on our business, prospects, financial condition and / or results of operations. As of December 31, ~~2022~~ **2023** , ~~the Company has~~ **we have recorded** a ~~receivable~~ **legal settlement liability in the amount** of $ ~~6~~ **0** . 4 million **for the remaining payments** due **under the settlement agreement for the cost of the forensic expert and a related receivable** from **related party of $ 2. 8 million for the remaining legal settlement costs to be reimbursed in accordance with the Settlement Allocation Agreement, which provided that the settlement payments, including the cost of the forensic expert, would first be made by the Company and then reimbursed by** Biofrontera AG for its share **. The $ 2. 8 million receivable is presented net** of **accounts payable, related party on the balance sheet. On September 13, 2023, Biofrontera was served with a complaint filed in United Stated District Court for the District of Massachusetts by DUSA, Sun Pharmaceutical Industries, Inc., and Sun Pharmaceutical Industries LTD in which DUSA alleges breach of contract, violation of the Lanham Act, and unfair trade practices. All claims stem from allegations that Biofrontera has promoted its Ameluz product in a manner that is inconsistent with its approved FDA labeling. Though this complaint was originally filed in the U. S. District Court for the District of Massachusetts, this matter has been transferred by agreement of the parties to the U. S. District Court for the District of New Jersey. The Company denies the Plaintiffs' claims and intends to defend** ~~the~~ **these** ~~settlement amount~~ **matters vigorously. Based on the Company' s assessment of the facts underlying the above claims, the uncertainty of litigation and the preliminary stage of the case, the Company cannot estimate the possibility of a material loss, nor the potential range of loss that may result from this action. If the final resolution of the matter is adverse to the Company, it could have a material impact on the Company' s financial position, results of operations, or cash flows** . The Biofrontera Group has been involved in lawsuits to defend or enforce patents related to our licensed products and they or another licensor may become involved in similar suits in the future, which could be expensive, time- consuming and unsuccessful. Competitors may infringe upon the patents for our licensed products. To

counter infringement or unauthorized use, we or our Licensors may be required to file infringement claims, which can be expensive and time- consuming. In addition, in an infringement proceeding, a court may decide that one or more of our Licensors' patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings, could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim or counterclaim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Interference or derivation proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome in any patent related litigation could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States or the EU. Furthermore, because of the substantial amount of discovery that could be required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our securities. The trade secrets of our Licensors are difficult to protect. Confidentiality agreements with employees and others may not adequately prevent disclosure of our Licensors' trade secrets and other proprietary information and may not adequately protect their intellectual property. Our success depends upon the skills, knowledge and experience of our Licensors' scientific and technical personnel, consultants and advisors as well as our partners, Licensors and contractors. Because drug development is a highly competitive technical field, our Licensors may rely in part on trade secrets to protect their proprietary technology and processes. However, trade secrets are difficult to protect. We enter into confidentiality agreements with our Licensors, corporate partners, employees, consultants and other advisors. These agreements typically require that the receiving party keep confidential and not disclose to third parties all confidential information developed by the receiving party or made known to the receiving party during the course of the receiving party' s relationship. Our Licensors' trade secrets also could be independently discovered by their competitors, in which case, they would not be able to prevent use of such trade secrets by their competitors. The enforcement of a claim alleging that a party illegally obtained and was using our trade secrets could be difficult, expensive and time consuming and the outcome would be unpredictable. There exists a risk that we or our Licensors may not be able to detect when misappropriation of trade secrets has occurred or where a third party is using such trade secrets without our or their knowledge. The failure to obtain or maintain meaningful trade secret protection could adversely affect the competitive position of our licensed products. Our subsidiary and certain third- party employees and our licensed patents are subject to foreign laws. All employees of our wholly owned subsidiary, Bio- FRI GmbH, and a majority of the employees of Biofrontera AG, the parent company of the Ameluz Licensor, work in Germany and are subject to German employment law. Ideas, developments, discoveries and inventions made by such employees and consultants are subject to the provisions of the German Act on Employees' Inventions, which regulates the ownership of, and compensation for, inventions made by employees. We face the risk that disputes can occur between Biofrontera AG and its employees or former employees pertaining to alleged non- adherence to the provisions of this act that may impact our license depending on whether Biofrontera AG prevails or fails in any such dispute. There is a risk that the compensation Biofrontera AG provided to employees who assign patents to them may be deemed to be insufficient and Biofrontera AG may be required under German law to increase the compensation due to such employees for the use of the patents. In those cases where employees have not assigned their interests to Biofrontera AG, Biofrontera AG may need to pay compensation for the use of those patents. If Biofrontera AG is required to pay additional compensation or face other disputes under the German Act on Employees' Inventions, the impact on our license could adversely affect our results of operations. Our international dealings with our Licensors may pose currency risks, which may adversely affect our operating results and net income. Our operating results may be affected by volatility in currency exchange rates and our ability to effectively manage our currency transaction risks. In general, we conduct our business with our Licensors and any third- party vendors in the local currency of the country in which such licensor or vendor operates. We do not manage our foreign currency exposure in a manner that would eliminate the effects of changes in foreign exchange rates. Therefore, changes in exchange rates between these foreign currencies, the dollar and the euro will affect our selling, general and administrative, related party, and the recorded levels of assets and liabilities held in a foreign currency and could result in exchange losses in any given reporting period. Given the volatility of exchange rates, we can give no assurance that we will be able to effectively manage our currency transaction risks or that any volatility in currency exchange rates will not have an adverse effect on our results of operations. ~~Risks Related to Our Business and Strategy The COVID- 19 global pandemic still affects our business and presents new challenges. Since the beginning of 2020, COVID- 19 has become a global pandemic. As a result of the measures implemented by governments around the world, our business operations have been directly affected. In particular, we experienced a significant decline in demand for our licensed products as a result of different priorities for medical treatments emerging, thereby causing a delay of actinic keratosis treatment for most patients. Our revenue was directly affected by the global COVID- 19 pandemic starting in mid- March of 2020. From that point on, rising infection rates and the resulting American Academy of Dermatology' s official recommendation to care for patients through remote diagnosis and treatment (telehealth) led to significantly declining patient~~

~~numbers and widespread, albeit temporary, physician practice closures. As COVID- 19 vaccines started to roll- out to the general public in March 2021, we experienced an increase in patients willing to undergo treatment for actinic keratosis. In the fourth quarter of 2021 continuing through 2022, we again saw a seasonally strong increase in sales, indicating a revenue recovery from the global COVID- 19 pandemic. We are optimistic that our business will continue to thrive throughout 2023 as a result of the COVID- 19 PHE sunsetting on May 11, 2023. However, the ultimate extent of the impact of any epidemic, pandemic, outbreak, or other public health crisis on our business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of such epidemic, pandemic, outbreak, or other public health crisis and actions taken to contain or prevent the further spread, including the effectiveness of vaccination and booster vaccination campaigns, among others. Accordingly, we cannot predict the extent to which our business, financial condition and results of operations will continue to be affected. We remain focused on maintaining a strong balance sheet, liquidity and financial flexibility and continue to monitor developments as we deal with the disruptions and uncertainties from a business and financial perspective relating to COVID- 19 and variants thereof.~~ We are fully dependent on our collaboration with the Ameluz Licensor for our supply of Ameluz ® and RhodoLED ® lamps and future development of the Ameluz ® product line, on our collaboration with Ferrer for our supply of Xepi ® and future development of Xepi ® and may depend on the Ameluz Licensor, Ferrer or additional third parties for the supply, development and commercialization of future licensed products or product candidates. Although we have the authority under the Ameluz LSA with respect to the indications that the Ameluz Licensor is currently pursuing with the FDA (as well as certain other clinical studies identified in the Ameluz LSA) in certain circumstances to take over clinical development, regulatory work and manufacturing from the Ameluz Licensor if they are unable or unwilling to perform these functions appropriately, the sourcing and manufacture of our licensed products as well as the regulatory approvals and clinical trials related to our licensed products are currently controlled, and will likely continue to be controlled for the foreseeable future, by our existing and future collaborators. Our lack of control over some of these functions could adversely affect our ability to implement our strategy for the commercialization of our licensed products. We do not own or operate manufacturing facilities for clinical or commercial manufacture of any of our licensed products. We outsource all manufacturing and packaging of our licensed products to our Licensors, who may in turn contract with third parties to provide these services. We have no direct control over the manufacturing process of our licensed products. This lack of control may increase quality or reliability risks and could limit our ability to quickly increase or decrease production rates. See " — If our Licensors' manufacturing partners fail to manufacture Ameluz ®, RhodoLED ® lamps, Xepi ® or other marketed products in sufficient quantities and at acceptable quality and cost levels, or to fully comply with current good manufacturing practice, or cGMP, or other applicable manufacturing regulations, we may face a bar to, or delays in, the commercialization of the products under license to us or we will be unable to meet market demand, and lose potential revenues " for more information on the risks related to the manufacture of our licensed products. Although under the Ameluz LSA we are entitled to enter into a direct agreement with the Ameluz Licensor' s supplier under certain circumstances, this is only with respect to the indications that the Ameluz Licensor is currently seeking from the FDA (as well as certain other clinical studies identified in the Ameluz LSA) and there is no guarantee that we will be able to do so under terms similar to the Ameluz Licensor' s existing agreement or without delays or difficulties, each of which could have an adverse impact on our business or results of operations. We currently do not have the ability to conduct any clinical trials. Under the Ameluz LSA and the Xepi LSA, our Licensors' control clinical development as well as the regulatory approval process for our licensed products. Our lack of control over the clinical development and regulatory approval process for our licensed products could result in delays or difficulties in the commercialization of our licensed products and / or affect the development of future indications for our licensed products. Although under the Ameluz LSA we are entitled to take over clinical trial and regulatory work under certain circumstances with respect to the indications that the Ameluz Licensor is currently seeking from the FDA (as well as certain other clinical studies identified in the Ameluz LSA) and subtract the cost of the trials from the transfer price of Ameluz ®, there is no guarantee that we will be able to do so without delays or difficulties that could have an adverse impact on our business or results of operations and we do not have that right with respect to indications for Ameluz ® that we may desire the Ameluz Licensor to pursue in the future. In addition, under the Ameluz LSA and the Xepi LSA, we are not obligated or tasked with the duty to defend the intellectual property related to our licensed products and rely on our Licensors to defend the relevant intellectual property. This lack of control may increase the litigation risks and could limit our ability to utilize the relevant intellectual property. See " — If our Licensors' efforts to protect the proprietary nature of their intellectual property related to our licensed products are not adequate, we may not be able to compete effectively in our market " for more information on the risks related to the defense of the intellectual property related to our licensed products. Biofrontera AG is a significant stockholder of the Company and, as a result of its control of the manufacture, clinical development and regulatory approval of Ameluz ® may exert greater influence on the Company relative to the percentage of its ownership of the Company' s outstanding common stock. See " — Risks Related to Our Securities and Ownership of Our Common Stock — As of December 31, ~~2022~~ **2023** , Biofrontera AG beneficially owns ~~30~~ **26** . ~~0~~ **4** % of our stock after the completion of the initial public offering and will be able to exert significant control over matters subject to stockholder approval, and its interests may conflict with ours or other stockholders' in the future " for more information on the risks related to Biofrontera AG' s beneficial ownership of the Company' s common stock. Insurance coverage and medical expense reimbursement may be limited or unavailable in certain market segments for our licensed products, which could make it difficult for us to sell our licensed products. Government authorities and third- party payors, such as private health insurers and health maintenance organizations, decide which products they will cover and the amount of reimbursement. Reimbursement by a third- party payor may depend upon a number of factors, including the government or third- party payor' s determination that use of a product is: ● a covered benefit under its health plan; ● safe, effective and medically necessary; ● reasonable and appropriate for the specific patient; ● cost- effective; and ● neither experimental nor

investigational. Obtaining coverage and reimbursement approval for a product from a government or other third- party payor is a time consuming and costly process that could require our Licensors to provide to the payor supporting scientific, clinical and cost- effectiveness data for the use of our licensed products. Our Licensors may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement or a particular reimbursement amount. If reimbursement of future products or extended indications for existing licensed products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability. Healthcare legislative changes may have a material adverse effect on our business and results of operations. In the United States and certain other countries, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our licensed products profitably. In particular, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 revised the payment methodology for many products under Medicare in the United States, which has resulted in lower rates of reimbursement. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 the (" PPACA " or collectively, the " ACA "), was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States. Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. On January 20, 2017, President Donald Trump signed an executive order stating that the administration intended to seek prompt repeal of the Affordable Care Act, and, pending repeal, directed by the U. S. Department of Health and Human Services and other executive departments and agencies to take all steps necessary to limit any fiscal or regulatory burdens of the Affordable Care Act. On January 28, 2021, President Joseph R. Biden, Jr. signed the Executive Order on Strengthening Medicaid and stated his administration' s intentions to reverse the actions of his predecessor and strengthen the Affordable Care Act. As part of this Executive Order, the Department of Health and Human Services, United States Treasury, and the Department of Labor are to review all existing regulations, orders, guidance documents, policies, and agency actions to consider if they are consistent with ensuring both coverage under the Affordable Care Act and if they make high- quality healthcare affordable and accessible to Americans. On March 11, 2021, President Joseph R. Biden Jr. signed into law the American Rescue Plan Act of 2021 to further strengthen Medicaid and the ACA and on April 5, 2022, President Joseph R. Biden Jr. signed the Executive Order on Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage in which he celebrated the significant progress across the U. S. in making healthcare more affordable and accessible. In this Executive Order, President Joseph R. Biden Jr. directed agencies " with responsibilities related to Americans' access to health coverage " to " review agency actions to identify ways to continue to expand the availability of affordable health coverage. " The continued expansion of the government' s role in the U. S. healthcare industry may further lower rates of reimbursement for pharmaceutical products. While we are unable to predict the likelihood of changes to the Affordable Care Act or other healthcare laws which may negatively impact our profitability, we continue to closely monitor all changes. President Biden intends, as his predecessor did, to take action against drug prices which are considered " high. " The most likely time to address this would be in the reauthorization of the Prescription Drug User Fee Act (" PDUFA ") in 2022 as part of a package bill. Drug pricing continues to be a subject of debate at the executive and legislative levels of U. S. government. The American Rescue Plan Act of 2021 signed into law by President Biden on March 14, 2021 includes a provision that will eliminate the statutory cap on rebates drug manufacturers pay to Medicaid beginning in January 2024. With the elimination of the cap, manufacturers may be required to compensate states in an amount greater than what the state Medicaid programs pay for the drug. Additionally, the Inflation Reduction Act of 2022 contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U. S. Department of Health and Human Services that would require manufacturers to charge a negotiated " maximum fair price " for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the Inflation Reduction Act of 2022. The Inflation Reduction Act of 2022 could have the effect of reducing the prices we can charge and reimbursement we receive for our products, if approved, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations and growth prospects. The effect of **the** Inflation Reduction Act of 2022 on our business and the pharmaceutical industry in general is not yet known. Following the passage of the Inflation Reduction Act of 2022, President Biden signed The Executive Order on Lowering Prescription Drug Costs for Americans, effective October 14, 2022. This Executive Order is intended to drive down prescription drug costs and attempts to make use of HHS' s Center for Medicare and Medicaid Innovation (" Innovation Center "). The Innovation Center tests health care payment and delivery models with the goal of improving health care quality and ensuring the efficiency of health care delivery. This Executive Order further requires that HHS consider utilizing the Innovation Center' s testing to identify payment and delivery models that would " lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled in Medicare and Medicaid programs, including models that may lead to lower cost- sharing for commonly used drugs and support value- based payment that promotes high- quality care. " At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. We expect that additional federal, state and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures. Additionally, third- party payors, including governmental payors, managed care organizations and private health insurers, are increasingly challenging the prices charged for medical products and services and examining their cost effectiveness. The continuing efforts of governments, insurance companies, managed care organizations and other payors of healthcare services to

contain or reduce costs of healthcare and / or impose price controls may adversely affect: ● the demand for our licensed products, ● if our Licensors obtain regulatory approvals; ● our ability to set a price or obtain reimbursement that we believe is fair for our licensed products; ● our ability to generate revenues and achieve or maintain profitability; and ● the level of taxes that we are required to pay. Any denial or reduction in reimbursement from Medicare or other programs or governments may result in a similar denial or reduction in payments from private payors, which may adversely affect our future profitability. To date, we have a relatively short history of sales of our licensed products in the United States. We have limited relatively short history of sales of our licensed products to date. The Biofrontera Group, including Biofrontera as a wholly owned subsidiary of Biofrontera AG at the time, launched the commercialization of Ameluz ® and the RhodoLED ® lamp for actinic keratosis in the United States in October 2016 and we have a limited history of marketing our licensed products in the United States. In addition, we began marketing the drug Xepi ® in the United States following our acquisition of Cutanea in March 2019 and have a limited history of marketing Xepi ® in the United States. While our licensed products have gained acceptance in the markets we serve, our licensed products may never generate substantial revenue or profits for us. We must establish a larger market for our licensed products and build that market through marketing campaigns to increase awareness of, and confidence by doctors in, our licensed products. ~~We expect this to continue to be even more challenging in the near-term as a result of current measures and regulations implemented by governments worldwide in an attempt to control the COVID- 19 pandemic, which may lead to declining demand in some of our markets in the foreseeable future for our licensed products as different priorities for medical treatments emerge, thereby causing a delay of actinic keratosis treatment for most patients.~~ If we are unable to expand our current customer base and obtain market acceptance of our licensed products, our operations could be disrupted and our business may be materially adversely affected. Even if we achieve profitability, we may not be able to sustain or increase profitability. Competing products and future emerging products may erode sales of our licensed products. Reimbursement issues affect the economic competitiveness of our licensed products as compared to other therapies. See " — Insurance coverage and medical expense reimbursement may be limited or unavailable in certain market segments for our licensed products, which could make it difficult for us to sell our licensed products. " Our industry is subject to rapid, unpredictable and significant technological change and intense competition. Our competitors may succeed in developing, acquiring, or licensing on an exclusive basis, products that are safer, more effective or more desirable than our licensed products. Many of our competitors have substantially greater financial, technical and marketing resources than we have. In addition, several of these companies have significantly greater experience than we or our Licensors do in developing products, conducting preclinical and clinical testing, obtaining regulatory approvals to market products for health care, and marketing healthcare products. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. We cannot guarantee that new drugs or future developments in drug technologies will not have a material adverse effect on our business. Increased competition could result in price reductions, lower levels of government or other third- party reimbursements, failure to achieve market acceptance and loss of market share, any of which could adversely affect our business, results of operations and financial condition. Further, we cannot give any assurance that developments by our competitors or future competitors will not render our technologies obsolete or less advantageous. We face significant competition from other pharmaceutical and medical device companies and our operating results will suffer if we fail to compete effectively. We also must compete with existing treatments, such as simple curettage and cryotherapy, which do not involve the use of a drug but have gained significant market acceptance. The pharmaceutical and medical device industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other products that are able to achieve similar or better results for the treatment of actinic keratosis. We expect that our future competitors will include mostly established pharmaceutical companies, such as Sun Pharma (DUSA) and Galderma. Most of our competitors have substantially greater financial, technical and other resources, such as larger ~~research and development~~ **R & D** staffs and experienced marketing and manufacturing organizations and well- established sales forces. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing products that are more effective or less costly than our licensed products and product candidates. In addition, our licensed products compete with other therapies, such as simple curettage and, particularly in the United States, cryotherapy, which do not involve the use of a drug but have gained significant market acceptance. If we are not able to compete effectively with the competitors and competing therapies, we may lose significant market share in the relevant markets, which could have a material adverse effect on our revenue, results of operations and financial condition. If we are unable to maintain effective marketing and sales capabilities or enter into agreements with third parties to market and sell our licensed products, we may be unable to generate revenue growth. In order to grow the market for our licensed products, especially a newer licensed product like Xepi ®, we must continue to build our marketing, sales and distribution capabilities in the United States. The development and training of our sales force and related compliance plans to market our licensed products are expensive and time consuming and can potentially delay the growth of sales of our licensed products. In the event we are not successful in ~~expanding~~ **maintaining** our marketing and sales infrastructure, we may not be able to successfully grow the market **of** our licensed products, which would limit our revenue growth. The U. S. market size for Ameluz ® for the treatment of actinic keratosis may be smaller than we have estimated. The public data regarding the market for actinic keratosis treatments in the United States may be incomplete. Therefore, some of our estimates and judgments are based on various sources which we have not independently verified and which potentially include outdated information, or information that may not be precise or correct, potentially rendering the U. S. market size for treatment of actinic keratosis with Ameluz ® smaller than we have estimated, which may reduce our potential and ability to increase sales of Ameluz ® and revenue in the United States. Although we have not independently verified the data obtained from these sources, we believe that such data provide the best available information relating to the present market

for actinic keratosis treatments in the United States, and we often use such data for our business and planning purposes. If our Licensors face allegations of noncompliance with the law and encounter sanctions, their reputation, revenues and liquidity may suffer, and our licensed products could be subject to restrictions or withdrawal from the market. Any government investigation of alleged violations of the law could require our Licensors to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenues from our licensed products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. Additionally, if we are unable to generate revenues from our product sales, our potential for achieving profitability will be diminished and the capital necessary to fund our operations will be increased. Even if our Licensors obtain regulatory approvals for our licensed products, or approvals extending their indications, they may not gain market acceptance or become widely accepted among hospitals, physicians, health care payors, patients and others in the medical community. In May 2016, Biofrontera Bioscience received approval from the FDA to market in the United States. Ameluz ® in combination with **PDT** ~~photodynamic therapy~~ using the BF- RhodoLED ® lamp for lesion- directed and field- directed treatment of actinic keratoses of mild- to- moderate severity on the face and scalp. We launched the commercialization of Ameluz ® and the BF- RhodoLED ® lamp for actinic keratosis in the United States in October 2016. Even with regulatory approval, Ameluz ® may not receive wide acceptance among hospitals, physicians, health care payors, patients and others in the medical community. In addition, Xepi ® received approval from the FDA in 2017 and may not gain market acceptance over time. Market acceptance of any of our licensed products depends on a number of factors, including: ● the clinical indications for which they are approved, including any restrictions placed upon the product in connection with its approval, such as patient registry or labeling restriction; ● the product labeling, including warnings, precautions, side effects, and contraindications that the FDA or other regulatory authorities approve; ● the potential and perceived advantages of our product candidates over alternative products or therapies; ● relative convenience and ease of administration; ● the effectiveness and compliance of our sales and marketing efforts; ● acceptance by major operators of hospitals, physicians and patients of our licensed products or candidates as a safe and effective treatment; ● the prevalence and severity of any side effects; ● product labeling or product insert requirements of the FDA or other regulatory authorities; ● any Risk Evaluation and Mitigation Strategy that the FDA might require for our drug product candidates; ● the timing of market introduction of our licensed product or product candidates as well as competitive products; ● the perceived advantages of our licensed products over alternative treatments; ● the cost of treatment in relation to alternative products; and ● the availability of adequate reimbursement and pricing by third party payors and government authorities, including any conditions for reimbursement required by such third- party payors and government authorities. If our licensed products and product candidates are approved, and / or receive label extensions, but fail to achieve market acceptance among physicians, patients, payors, or others in the medical community in the United States, we will not be able to generate significant revenues, which would have a material adverse effect on our business, prospects, financial condition and results of operations. With respect to our licensed products, we may be subject to healthcare laws, regulation and enforcement. Our failure to comply with those laws could have a material adverse effect on our results of operations and financial condition. We may be subject to additional healthcare regulation and enforcement by the U. S. federal government and by authorities in the United States. Such U. S. laws include, without limitation, state and federal anti- kickback, federal false claims, privacy, security, financial disclosure laws, anti- trust, Physician Payment Sunshine Act reporting, fair trade regulation and advertising laws and regulations. Many states and other jurisdictions have similar laws and regulations, some of which are broader in scope. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, but not limited to, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal, state or other healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results. Increased Health and Human Services, Office of Inspector General (OIG), scrutiny on the sale of products through specialty pharmacies or through physician practices by means of direct investigation or by issuance of unfavorable Opinion Letters which may curtail or hinder the sales of our licensed products based on risk of enforcement upon ourselves or our buyers. The OIG continues to make modifications to existing Anti-Kickback Statute, or AKS, safe harbors which may increase liability and risk for our company as well as adversely impact sales relationships. On November 20, 2020, OIG issued the final rule for Safe Harbors under the Federal AKS. This new final rule creates additional safe harbors including ones pertaining to patient incentives. OIG is able to modify safe harbors as well as regulatory compliance requirements which could impact out business adversely. The majority of states also have statutes or regulations similar to these federal laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. In addition, some states have laws that require pharmaceutical companies to adopt comprehensive compliance programs. Certain states also mandate the tracking and require reporting of gifts, compensation, and other remuneration paid by us to physicians and other health care providers. In September 2010, OIG issued a Special Advisory Bulletin to notify drug manufacturers that OIG intended to pursue enforcement actions against drug manufacturers that failed to submit timely average manufacturer price, or AMP, and average sales price, or ASP, information. The Medicaid Drug Rebate Program requires manufacturers to enter into and have in effect a national rebate agreement with the Secretary of Health and Human Services in order for Medicaid payments to be available for the manufacturer' s covered outpatient drugs. Companies with such rebate agreements are required to submit certain drug pricing information to CMS, including quarterly and monthly pricing data. There has been an increased level of federal enforcement against drug manufacturers that have failed to provide timely and accurate pricing information to the government. Since September 2010, OIG has settled 13 cases against drug manufacturers relating to drug price reporting issues, totaling approximately $ 18. 5 million. We expect continued enforcement directed at companies that fail to make accurate and timely price reports. If we were found to make the required pricing disclosures, we could incur significant expense and delay. A recall of our licensed drug or

medical device products, or the discovery of serious safety issues with our licensed drug or medical device products, could have a significant negative impact on us. The FDA and other relevant regulatory agencies have the authority to require or request the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Manufacturers may, under their own initiative, recall a product. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of our licensed products would divert managerial and financial resources and have an adverse effect on our and our Licensors' reputation, financial condition and operating results, which could impair our or our Licensors' ability to market, sell or produce our licensed products in a cost-effective and timely manner **. In February 2024, our Ameluz Licensor initiated a voluntary recall of a limited number of lots of Ameluz ® due to a manufacturing defect in the impacted product' s packaging, which is provided by an unaffiliated supplier. The Ameluz Licensor confirmed that the recalled product is not likely to cause adverse health consequences. We promptly notified all impacted physician customers of this recall and arranged for the prompt replacement of the recalled products. Refer to Note 25. Subsequent Events- Voluntary Product Recall of Limited Lots of Ameluz ® for more information** . Further, under the FDA' s medical device reporting, or MDR, regulations, our Licensors are required to report to the FDA any event which reasonably suggests that our licensed product may have caused or contributed to a death or serious injury or in which our licensed product malfunctioned and, if the malfunction of the same or similar device marketed by us were to recur, would likely cause or contribute to death or serious injury. The FDA also requires reporting of serious, life- threatening, unexpected and other adverse drug experiences and the submission of periodic safety reports and other information. Product malfunctions or other adverse event reports may result in a voluntary or involuntary product recall and other adverse actions, which could divert managerial and financial resources, impair our and our Licensors' ability to market, sell or manufacture our licensed products in a cost- effective and timely manner and have an adverse effect on our reputation, financial condition and operating results. Any adverse event involving our licensed products could result in future voluntary corrective actions, such as recalls or customer notifications, or regulatory agency action, which could include inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, will require the dedication of our Licensors' time and capital, distract our Licensors' management from operating their business and may harm our and our Licensors' reputation and financial results as well as threaten our marketing authority for such products. Our licensed medical device product, the RhodoLED ® lamp, is subject to extensive governmental regulation, and failure to comply with applicable requirements could cause our business to suffer. The medical device industry in the United States is regulated extensively by governmental authorities, principally the FDA and corresponding state agencies. The regulations are very complex and are subject to rapid change and varying interpretations. Regulatory restrictions or changes could limit our ability to carry on or expand our operations or result in higher than anticipated costs or lower than anticipated sales. The FDA and other U. S. governmental agencies regulate numerous elements of our and our Licensors' business, including: ● product design and development; ● pre- clinical and clinical testing and trials; ● product safety; ● establishment registration and product listing; ● distribution; ● labeling, manufacturing and storage; ● pre- market clearance or approval; ● advertising and promotion; ● marketing, manufacturing, sales and distribution; ● relationships and communications with health care providers; ● adverse event reporting; ● market exclusivity; ● servicing and post- market surveillance; and ● recalls and field safety corrective actions. We are working to commercialize a new lamp, the " RhodoLED ® XL, " which was approved by the FDA on October 21, 2021 and allows use of Ameluz ® on more distant Actinic Keratosis lesions. Management believes that this new lamp, could provide new business growth opportunities for our company. In the United States, according to FDA guidance, products for PDT, such as Ameluz ® gel and its corresponding lamp (s), must be approved as combination products that cover both the drug and the lamp. In May 2016, the Biofrontera Group (which included Biofrontera prior to our initial public offering) received approval from the FDA to market in the United States Ameluz ® in combination with **PDT** ~~photodynamic therapy~~ using the BF-RhodoLED ® lamp for lesion- directed and field- directed treatment of actinic keratoses of mild- to- moderate severity on the face and scalp. The applicable office of the FDA has determined that if the Ameluz Licensor develops a new lamp to be used with Ameluz ®, beyond the existing approved RhodoLED ® lamp series, the Ameluz Licensor must seek a new approval utilizing the " New Drug Application " procedure. As part of a drug / device combination, the lamp is by definition classified as a class III medical device and as such requires a premarket approval, or PMA, by the FDA. A new lamp will also require changes in the " Prescribing Information " of the drug. If the Ameluz Licensor develops this new lamp, once the Ameluz Licensor' s PMA application is submitted to the FDA as part of this approval process, it may take more than six months, plus, if needed, time required to answer questions or provide additional data. Prior to submission, the Ameluz Licensor will need to perform final tests on the lamp prototype, including technical tests by a certified laboratory and a usability study. During the process, there is a risk that the FDA might ask for additional tests or even clinical trials, and there is no assurance that the Ameluz Licensor will be able to satisfy the FDA' s requests for additional tests or trials in a timely manner, or at all, and there is no assurance that the Ameluz Licensor will be able to develop this new lamp, or obtain approval to use it in the United States for PDT treatment of actinic keratosis in combination with Ameluz ®. The FDA can delay, limit or deny clearance or approval of a device for many reasons, including: ● the Biofrontera Group' s inability to demonstrate that its products are safe and effective for their intended uses or substantially equivalent to a predicate device; ● the data from the Biofrontera Group' s clinical trials may not be sufficient to support clearance or approval; and ● the manufacturing process or facilities we use may not meet applicable requirements. In addition, the FDA and other regulatory authorities may change their respective clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our licensed products under development or impact our ability to modify our currently cleared or approved products on a timely basis. Any delay in, or failure to receive or maintain, clearance or approval for such products under development that we expect to license could prevent us from generating revenue from these products or achieving

profitability. Additionally, the FDA and comparable foreign regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny of us, could dissuade some customers from using our licensed products and adversely affect our reputation and the perceived safety and efficacy of our licensed products. Failure to comply with applicable regulations could jeopardize our ability to sell our licensed products and result in enforcement actions against our Licensors such as fines, civil penalties, injunctions, warning letters, Form 483 reports, recalls of products, delays in the introduction of products into the market, refusal of the FDA or other regulators to grant future clearances or approvals, and the suspension or withdrawal of existing approvals by the FDA or other regulators. Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and operating results. As a result of our current IT infrastructure and German- based subsidiary, we are subject to governmental regulation and other legal obligations in the EU and European Economic Area, or EEA, related to privacy, data protection and data security and, as a result of our sales in California, the California Consumer Privacy Act (CCPA). Our actual or perceived failure to comply with such obligations could harm our business. We are subject to diverse laws and regulations relating to data privacy and security in the EU and eventually in the EEA, including Regulation 2016 / 679, known as the GDPR. The GDPR applies extraterritorially and implements stringent operational requirements for controllers and processors of personal data. New global privacy rules are being enacted and existing ones are being updated and strengthened. We are likely to be required to expend capital and other resources to ensure ongoing compliance with these laws and regulations. Complying with these numerous, complex and often changing regulations is expensive and difficult. Failure by us, any partners, our service providers, or our employees or contractors to comply with the GDPR could result in regulatory investigations, enforcement notices and / or fines of up to the higher of € 20 million or up to 4 % of our total worldwide annual revenue. In addition to the foregoing, a breach of privacy laws or data security laws, particularly those resulting in a significant security incident or breach involving the misappropriation, loss or other unauthorized use or disclosure of sensitive or confidential patient or consumer information, could have a material adverse effect on our business, reputation and financial condition. As a data controller, we are accountable for any third- party service providers we engage to process personal data on our behalf. We attempt to mitigate the associated risks by performing security assessments and due diligence of our vendors and requiring all such third- party providers with data access to sign agreements and obligating them to only process data according to our instructions and to take sufficient security measures to protect such data. There is no assurance that these contractual measures and our own privacy and security- related safeguards will protect us from the risks associated with the third- party processing, storage and transmission of such information. Any violation of data or security laws by our third- party processors could have a material adverse effect on our business and result in the fines and penalties outlined above. Where we transfer personal data of EU citizens or anyone residing in the EU out of the EU and EEA, we do so in compliance with the relevant data export requirements from time to time. There is currently ongoing litigation challenging the commonly used transfer mechanism, the EU Commission approved model clauses. On July 16, 2020, the Court of Justice of the European Union, or CJEU, issued a judgment which annulled, without granting a grace or transition period, the European Commission' s Decision (EU) 2016 / 1250 of July 12, 2016 on the adequacy of the protection provided by the U. S. Privacy Shield (a mechanism for complying with data protection requirements when transferring personal data from the EU to the United States). Accordingly, such framework is not a valid mechanism to comply with EU data protection requirements when transferring personal data from the European Union to the United States. To the extent that we were to rely on the EU- U. S. Privacy Shield Framework, we will not be able to do so in the future, which could increase our costs and limit our ability to process personal data from the EU. The same decision also cast doubt on the viability of one of the primary alternatives to the U. S. Privacy Shield, namely, the European Commission' s Standard Contractual Clauses, as a vehicle for such transfers in all circumstances. Use of the standard contractual clauses must now be assessed on a case- by- case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and / or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. The CJEU went on to state that if a competent supervisory authority believes that the Standard Contractual Clauses cannot be complied with in the destination country and the required level of protection cannot be secured by other means, such supervisory authority is under an obligation to suspend or prohibit that transfer. At present, there are few, if any, viable alternatives to the Standard Contractual Clauses, and the law in this area remains dynamic. These changes may require us to find alternative bases for the compliant transfer of personal data outside the EEA and we are monitoring developments in this area. The GDPR is directly applicable in each EU Member State, however, it provides that EU Member States may introduce further conditions, including limitations which could limit our ability to collect, use and share personal data (including health and medical information), or could cause our compliance costs to increase, ultimately having an adverse impact on our business. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and implement policies as part of its mandated privacy governance framework. It also requires data controllers to be transparent and disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used, imposes limitations on retention of personal data; defines for the first time pseudonymized (i. e., key- coded) data; introduces mandatory data breach notification requirements; and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. In addition to the foregoing, a breach of the GDPR could result in regulatory investigations, reputational damage, orders to cease / change our use of data, enforcement notices, as well potential civil claims including class action type litigation where individuals suffer harm. On January 1, 2020, California enacted the California Consumer Privacy Act, or CCPA, which, among other things, requires new disclosures to California consumers and affords such consumers new abilities to opt out of certain sales of personal information. This Act also applies to any information of certain patients that a drug company may possess. It remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted in the years to come. The effects of the CCPA potentially are significant, however, and may require us to modify our

data processing practices and policies and to incur substantial costs and expenses in an effort to comply. As a general matter, compliance with laws, regulations, and any applicable rules or guidance from self- regulatory organizations relating to privacy, data protection, information security and consumer protection, may result in substantial costs and may necessitate changes to our business practices, which may compromise our growth strategy, adversely affect our ability to acquire customers, and otherwise adversely affect our business, financial condition and operating results. Noncompliance with CCPA could result in regulatory investigations, reputational damage, orders to cease / change our use of data, enforcement notices, as well potential civil claims including class action type litigation where individuals suffer harm. Since its enactment, four (4) additional states – Colorado, Connecticut, Utah, and Virginia – have enacted comprehensive consumer data privacy laws similar to the CCPA, indicating a potential trend that may continue to spread across the U. S. We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may be unable to successfully implement our business strategy. Our ability to compete in the highly competitive pharmaceutical industry depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel with specialized scientific and technical skills. We are highly dependent on our management, scientific, medical and operations personnel, including ~~Erica Monaco~~ **Prof. Dr. Hermann Lübbert** , our Chief Executive Officer **and** ~~, Prof. Dr. Hermann Lübbert, our Executive~~ Chairman and Fred Leffler, our Chief Financial Officer. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements could potentially harm our business, prospects, financial condition or results of operations. Despite our efforts to retain valuable employees, members of our management team may terminate their employment with us on short notice. Although we have, or are in the process of negotiating, employment agreements with our key employees, these employees could leave our employment at any time, with certain notice periods. We do not maintain " key man " insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid- level and senior managers as well as junior, mid- level and senior scientific and medical personnel and sales representatives. Many of the other biotechnology and pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They may also provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we can offer. If we are unable to continue to attract and retain high quality personnel, our ability to commercialize our licensed products will be limited. Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self- dealing and other abusive practices in the United States as well as in any other jurisdictions where we conduct our business. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions, inability to obtain product approval and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and any precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. We will need to grow the size of our organization and we may experience difficulties in managing this growth. As of December 31, ~~2022~~ **2023** , we had ~~81~~ **85** employees. In the longer term, as our development and commercialization plans and strategies develop, and as we continue operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including: ● identifying, recruiting, integrating, maintaining and motivating existing or additional employees; and ● improving our operational, financial and management controls, reporting systems and procedures. Our future financial performance and our ability to commercialize and market our licensed products will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day- to- day activities in order to devote a substantial amount of time to managing these growth activities. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to commercialize our licensed products and, accordingly, may not achieve our commercialization goals. Due to our ongoing assessment of the size of the required sales force, we may be required to hire substantially more sales representatives to adequately support the commercialization and marketing of our licensed products or we may incur excess costs as a result of hiring more sales representatives than necessary. We may be competing with companies that currently have extensive and well- funded marketing and sales operations. Our business and operations would suffer in the event of system failures ~~,~~ **or** cyber- attacks ~~or a deficiency in our cyber- security~~ . Despite the implementation of security measures, our internal computer systems and those of our current and future contract and research organizations, or CROs, **licensors,** and other contractors and consultants are vulnerable to damage from **breaches of information systems, attempts to access information, including customer and company information, malicious code, theft, misuse, loss, release, or destruction of data (including confidential customer information), account takeovers, unavailability of service,** computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. The risk of a security breach or disruption, particularly through cyber- attacks or cyber- intrusion, including

by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. While we have not experienced any such material system failure ~~, or cyber- related accident~~ **incident** ~~or security breach to date~~, if such an event were to occur and cause interruptions in our operations, it could ~~result in a~~ **(i)** ~~material~~ **materially** ~~disruption~~ --- **disrupt** ~~of~~ our development programs **. The proper functioning of our networks** and **systems and therefore** our business **operations and those of our customers; (ii) result in the unauthorized access to, and destruction, loss, theft, misappropriation, or release of confidential, sensitive, or otherwise valuable information of ours or our customers; (iii) result in a violation of applicable privacy, data protection, and other laws, subjecting us to additional regulatory scrutiny and exposing us to civil litigation, enforcement actions, governmental fines, and possible financial liability; (iv) require significant management attention and resources to remedy the damages that result; or (v) harm our reputation or cause a decrease in the number of customers that choose to do business with us. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, and results of operations. Furthermore, in the event of a cyber- related incident, we may be delayed in identifying or responding to the incident, which could increase the negative impact of the incident on our business, financial condition, and results of** operations. To the extent that any disruption or ~~security breach~~ **cyberrelated incident** were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our licensed products and product candidates could be delayed. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our licensed products. We face an inherent risk of product liability as a result of the clinical testing of our licensed products and face an even greater risk if we commercialize our licensed products on a larger scale. For example, we may be sued if our licensed products allegedly cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing; defects in design; a failure to warn of dangers inherent in the product, negligence, strict liability; and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our licensed products and product candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: ● costs to defend litigation and other proceedings; ● a diversion of management' s time and our resources; ● decreased demand for our licensed products; ● injury to our reputation; ● withdrawal of clinical trial participants; ● initiation of investigations by regulators; ● product recalls, withdrawals or labeling, marketing or promotional restrictions; ● loss of revenue; ● substantial monetary awards to trial participants or patients; ● exhaustion of any available insurance and our capital resources; ● the inability to commercialize our licensed products; and ● a decline in our share price. We currently maintain product liability insurance. If such insurance is not sufficient, or if we are not able to obtain such insurance at an acceptable cost in the future, potential product liability claims could prevent or inhibit the commercialization of our licensed products and the products we license in the future. A successful claim could materially harm our business, financial condition or results of operations. Additionally, we cannot guarantee that continued product liability insurance coverage will be available in the future at acceptable costs. Failure to comply with the U. S. Foreign Corrupt Practices Act or other applicable anti- corruption legislation could result in fines, criminal penalties and an adverse effect on our business. We do business with Licensors in a number of countries throughout the world. We are committed to doing business in accordance with applicable anti- corruption laws. We are subject, however, to the risk that our officers, directors, employees, agents and collaborators may take action determined to be in violation of such anti- corruption laws, including the U. S. Foreign Corrupt Practices Act of 1977, the U. K. Bribery Act 2010 and the European Union Anti- Corruption Act, as well as trade sanctions administered by the U. S. Office of Foreign Assets Control and the U. S. Department of Commerce. Any such violation could result in substantial fines, sanctions, civil and / or criminal penalties or curtailment of operations in certain jurisdictions and might adversely affect our results of operations. In addition, actual or alleged violations could damage our reputation and ability to do business. Our licensed products will be subject to ongoing regulatory requirements and we may face future development, manufacturing and regulatory difficulties. Our licensed drug products Ameluz ® and Xepi ® and any other drug products we license or acquire will be subject to ongoing regulatory requirements for labeling, packaging, storage, advertising, promotion, sampling, record- keeping, submission of safety and other post- market approval information, importation and exportation. In addition, approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA requirements and the requirements of other similar regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMP requirements. Accordingly, we rely on our Licensors to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. Our Licensors will also be required to report certain adverse reactions and production problems, if any, to the FDA and other similar regulatory authorities and to comply with certain requirements concerning advertising and promotion for our licensed products and potential products. If a regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated or unacceptable severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, it may impose restrictions on that product, including requiring withdrawal of the product from the market. If our licensed products or potential products fail to comply with applicable regulatory requirements, a regulatory authority may, among other actions against our Licensors or applicable third parties: ● issue warning letters or Form 483 (or similar) notices requiring our Licensors or applicable third parties to modify certain activities or correct certain deficiencies; ● require product recalls or impose civil monetary fines; ● mandate modifications to promotional materials or require our Licensors to provide corrective information to healthcare practitioners; ● require our Licensors or applicable third parties to enter into a consent decree or permanent injunction; ● impose other administrative or judicial civil or criminal actions, including monetary or other

penalties, or pursue criminal prosecution; ● withdraw regulatory approval; ● refuse to approve pending applications or supplements to approved applications filed by our Licensors; ● impose restrictions on operations, including costly new manufacturing requirements; or ● seize or detain products. To the extent that such adverse actions impact our rights under our license and supply agreements or otherwise restrict our ability to market our licensed products, they could adversely impact our business and results of operation. Generic manufacturers may launch products at risk of patent infringement. If other manufacturers launch products to compete with our licensed products or product candidates in spite of our Licensors' patent position, these manufacturers would likely erode our market and negatively impact our sales revenues, liquidity and results of operations. ~~Risks Related~~ **We believe that we will need** to ~~Our~~ **incur additional R & D expenditures to improve the capabilities of our BF- RhodoLED ® lamps to better fulfill the needs of dermatologists and may also incur R & D expenditures to develop new products. The products we are developing and may develop in the future may not be technologically successful. At this time, we have limited internal R & D personnel, which makes us dependent on consulting relationships. In addition, the length of our product development cycle may be greater than we originally expected, and we may experience delays in product development. If our resulting products are not technologically successful, they may not achieve market acceptance or compete effectively with our competitors' products and services. There is substantial doubt about our ability to continue as a " going concern ", which has been alleviated through managements plans to mitigate these conditions and obtain additional liquidity. In connection with our assessment of going concern considerations under applicable accounting standards, the Company' s management has determined that substantial doubt exists about our ability to continue as a going concern for at least one year from the date the unaudited condensed consolidated** ~~Financial~~ **financial** ~~Position~~ **statements were issued, which management believes has been alleviated through its plans to mitigate these conditions** and **obtain additional liquidity. The future viability of the Company is dependent on its ability to continue to execute its growth plan and raise additional** ~~Capital~~ **capital** ~~Requirements~~ **or find alternative methods of financing to fund its operations during the first half of 2024, and until cash flow from operations is sufficient, if ever. As of March 11, 2024 our unaudited cash was approximately $ 4. 1 million. There can be no guarantee that the Company will be successful in raising additional capital or finding alternative methods of financing. If the Company is not successful in these endeavors, it would likely have a material adverse effect on the Company' s business, results of operations and financial condition. See Note 1. Organization and Business Overview- Liquidity and Going Concern for additional information.** We have a history of operating losses and anticipate that we will continue to incur operating losses in the future and may never sustain profitability. We have incurred losses in each year since inception. Our net loss for the fiscal years ended December 31, ~~2022~~ **2023** and December 31, ~~2021~~ **2022** was $ **20. 1 million and $** 0. 6 million ~~and $ 37. 7 million~~ , respectively. As of December 31, ~~2022~~ **2023** , we had an accumulated deficit of $ ~~79~~ **99** . ~~5~~ **7** million. Our ability to become profitable depends on our ability to further commercialize our principal licensed product Ameluz ® **and to further commercialize and obtain a larger market share for Xepi** . Even if we are successful in increasing our licensed product sales, we may never achieve or sustain profitability. In the long term, we anticipate increasing our sales and marketing expense as we attempt to exploit the regulatory approvals to market Ameluz ® in the United States for the **PDT** ~~photodynamic therapy~~ treatment of actinic keratoses of mild- to- moderate severity on the face and scalp. There can be no assurance that our sales and marketing efforts will generate sufficient sales to allow us to become profitable. Moreover, because of the numerous risks and uncertainties associated with commercializing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if ever. We **will likely** ~~cannot rule out the possibility that we may~~ engage in additional equity or debt financing in the future, which could dilute the voting rights of stockholders and the value of their shares. If we are unable to achieve profitability over time or to obtain additional equity or debt financing in such a scenario, this would have a material adverse effect on our financial condition. If we fail to obtain additional financing, we may be unable to pursue our plans for strategic growth, including completing the commercialization of Xepi ® and other products we may license. Our operations have consumed substantial amounts of cash since inception. Going forward, we expect that we will require significant funds in order to pursue our plans for strategic growth, including completing the commercialization of the drug Xepi ®, the rights to which we acquired in March 2019 through our purchase of Cutanea, and the subsequent merger of Biofrontera and Cutanea. During the year ended December 31, ~~2022~~ **2023** , we received an aggregate of $ ~~14~~ **4. 1** million ~~, including $ 9. 4 million from a private placement~~ , net of issuance costs, **from a registered public offering. On February 19, 2024, we entered into** ~~and~~ **an equity financing agreement which provided net proceeds of** $ ~~4~~ **7** . ~~6~~ **2** million ~~from warrants exercised~~ **with an additional $ 7. 2 million to be provided upon the satisfaction of certain conditions. For additional details, see Note 25. Subsequent Events- Securities Purchase Agreement** for ~~common stock~~ **Series B Convertible Preferred** . We believe ~~with~~ **that** the funds available from these transactions and ~~availability~~ under ~~a~~ **our** working capital line of credit, ~~that~~ we will have sufficient funds to support the operating, investing, and financing activities of the Company through at least twelve months from the date of ~~the issuance of~~ this Form 10- K. However, changing circumstances may cause us to consume capital significantly faster than currently anticipated, and we may need to spend more money than currently expected because of circumstances beyond our control. In addition, if we choose to take significant steps towards the realization during the current fiscal year of longer- term goals for our strategic growth, we may need to raise additional capital through debt or equity financing in order to complete those steps during the current fiscal year. Our future funding requirements, both near- and long- term, will depend on many factors, including, but not limited to: ● the effects of competing technological and market developments; ● the cost and timing of completion of commercial- scale manufacturing activities; ● the cost of establishing or maintaining sales, marketing and distribution capabilities for Ameluz ® **PDT** ~~photodynamic therapy~~ or other licensed products or potential products in the United States; and ● the impact of COVID- 19 on our licensor' s clinical trials, the timing of regulatory approvals obtained by our Licensors, demand for our licensed products, our ability to market and sell our licensed products and other matters. We cannot be certain that additional funding for any purpose will be available to us on

acceptable terms, or at all. If we are unable to raise additional capital in sufficient amounts and on terms acceptable to us, we may have to significantly delay, scale back or discontinue the commercialization of our licensed products or other plans for strategic growth. We also could be required to license our rights to our licensed products and product candidates to third parties on unfavorable terms. In addition, any equity financing would likely result in dilution to holders of our securities, and any debt financing would likely involve significant cash payment obligations and include restrictive covenants that may restrict our ability to operate our business. Any of the above events could prevent us from realizing business opportunities or prevent us from growing our business or responding to competitive pressures, which could have a material adverse effect on our business, prospects, financial condition and / or results of operations and could cause the price of our shares to decline. Our existing and any future indebtedness could adversely affect our ability to operate our business. ~~Under the Share Purchase~~ **On December 21, 2023, we entered into credit facilities with two different lenders, each pursuant to a Business Loan** and ~~Transfer~~ **Security** Agreement ~~dated March 25~~ **for a term loan in the principal amount of $ 2** , ~~2019~~ **000, 000 evidenced by a Secured Promissory Note, effective as of December 21, 2023** (**collectively** ~~as amended~~ , the " **Loan** ~~Share Purchase Agreement~~ **Agreements** ") ~~, by and among Biofrontera Newderm LLC, Biofrontera AG, Maruho Co~~ . **Each loan under the Loan Agreements** ~~, Ltd. and Cutanea, pursuant to which Biofrontera Newderm Inc. LLC, a wholly owned subsidiary of Biofrontera Inc., acquired Cutanea from Maruho Co., Ltd., we are required to repay to Maruho Co., Ltd., $ 3. 6 million on December 31, 2022 and $ 3. 7 million on December 31, 2023 in start- up costs that Maruho Co., Ltd. paid to us, in connection with such acquisition~~ (~~not to exceed $ 7. 3 million in~~ the ~~aggregate). We have filed for arbitration against Maruho with the International Chamber of Commerce (~~ " ~~ICC~~ **Loans** ") ~~regarding issues with Maruho~~ **requires the Company to make weekly payments of principal and interest in the amount of approximately $ 102, 857 through July 5, 2024, the maturity date. Each Loan is secured by a security interest in substantially all of the Company** ' s **assets** ~~contract manufacturer that were not disclosed at the time of the Agreement and therefore are evaluating the repayment of the $ 7. 3 million of start- up costs. The arbitration notes that Maruho breached the agreement with Cutanea due to the undisclosed manufacturing issues and seeks damages as well as a declaration that we are not obligated to repay Maruho In addition, on March 9, 2023, we entered into a commitment letter~~ (the " **Collateral** ~~Commitment Letter~~ ") **. The default interest rate for each** ~~with MidCap Business Credit LLC (" MidCap "), in respect~~ of ~~MidCap~~ **the Loans is 5. 0 %. Each Loan Agreement includes limitations on the Company** ' s ~~commitment~~ **ability** to ~~provide us with a senior secured~~ **sell, lease, transfer, or otherwise dispose of its** ~~asset~~ **assets outside** ~~based revolving line of credit, subject to the borrowing base formula, minimum excess availability and other~~ -- **the ordinary course** ~~terms and conditions thereof, in the aggregate principal amount~~ of ~~up~~ **its business; or** to **create, incur, allow or suffer to exist any** ~~$ 6. 5 million (the " Revolving Facility "). The Revolving Facility shall be secured by a~~ lien on **any** ~~substantially all~~ of ~~the~~ **its** assets ~~of the Company, subject to customary exceptions. For additional details regarding the Revolving Facility see Item 9. B. Other~~ **other** ~~Information~~ **than liens** in **favor of the applicable lender and certain** ~~this Form 10- K. Entry into the~~ **other permitted liens. Each Loan Agreement also contains** ~~Revolving Facility will be subject to customary closing conditions, including the execution and delivery of appropriate definitive documentation related to the Revolving Facility, to include~~ customary representations ~~,~~ **and** warranties **and customary** ~~, covenants,~~ events of default ~~and~~ **, upon** ~~other~~ -- **the** ~~terms and conditions~~ **occurrence of which** , ~~and~~ **after any applicable grace period,** ~~there~~ -- **the applicable lender would have** ~~can be no assurance that such closing conditions will be satisfied or that~~ the ~~Revolving Facility~~ - **ability** ~~will be entered into prior~~ to **accelerate its loan and exercise remedies with respect to** the **Collateral** ~~expiration of MidCap' s commitment or at all~~ . Our indebtedness could have significant adverse consequences, including: ● requiring us to dedicate a portion of our cash to the payment of interest and principal, reducing money available for working capital, capital expenditure, product development and other general corporate purposes; ● increasing our vulnerability to adverse changes in general economic, industry and market conditions; ● increasing the risk of dilution to the holders of our shares in the event any of these bonds are exercised for or converted into our ordinary shares; ● limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete, including changes arising as a result of the COVID- 19 pandemic; and ● placing us at a competitive disadvantage to competitors that are better capitalized than we are ~~. We may not have sufficient funds and may be unable to arrange for additional financing to pay the amounts due under our existing debt obligation to Maruho Co. Ltd. under the terms of such Share Purchase Agreement, and which must be repaid if certain profits from the sale of Cutanea products the Biofrontera Group agreed to share with Maruho are less than the amount of such start- up costs~~ . We may also engage in debt financing in the future. Failure to make payments or comply with covenants under such debt could result in an event of default and acceleration of amounts due. If an event of default occurs and the lender or lenders accelerate the amounts due, we may not be able to make accelerated payments, and such lenders could file suit against us to collect the amounts due under such obligations or pursue other remedies. In addition, the covenants under such debt obligations could limit our ability to obtain additional debt financing. If we are unable to satisfy such debt obligations it could have material adverse effect on our business, prospects, financial condition and / or results of operations. ~~The valuation of our equity investments is subject to volatility. The market valuation of our equity investments, especially as it relates to our investment in Biofrontera AG which is publicly traded, may experience substantial price volatility which, when accounted for under GAAP, could have a material adverse effect on our financial condition and results of operations. Refer to Note 6, Investments in Equity Securities, to our consolidated financial statements for information on our equity investments. As of December 31, 2022, our investment in Biofrontera AG, a foreign publicly held company and significant shareholder, had a balance of $ 10. 5 million. Our shares of Biofrontera AG are carried in our consolidated balance sheets at fair value based on the closing price of the shares owned on the last trading day of the reporting period. Those investments can be negatively affected by market and economic factors including liquidity, credit deterioration, financial results, interest rate fluctuations, or other factors. Although we intend to liquidate our investment in Biofrontera AG within the next twelve months, we cannot guarantee that we will able to do so within that timeframe. As a result, as long as we hold these equity investments, future fluctuations in their value could result in significant losses and could~~

~~have a material adverse impact on the Company' s financial condition and results of operations. Risks Related to Corporate Governance, Including Being a Public Company~~ We previously identified a material weakness in our internal control over financial reporting, resulting from control deficiencies related to management' s review of work performed by specialists. If we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business and stock price. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis. In connection with the audit of our financial statements as of and for the year ended December 31, 2021, we identified a material weakness in our internal control over financial reporting. The material weakness we identified pertains to management' s review of work performed by specialists; as the Company' s management review control over information provided to and produced by a third- party specialist was not sufficiently precise to identify errors in the valuation of an intangible asset. Specifically, as part of the initial valuation of an intangible asset in connection with the Cutanea acquisition we failed to identify a computational error within the valuation model for the Xepi ® intangible asset. In addition, in 2021 an error in the valuation of the same intangible asset was identified relating to insufficient information being provided to the third- party specialist in connection with an impairment assessment. We have taken steps to enhance our internal control environment and continue to address the underlying cause of the material weakness with the implementation of additional controls including those designed to strengthen our review and validation of the work product from third- party service providers. As of December 31, 2022, the steps we have taken to date were determined to be sufficient to remediate this material weakness. As a result, management has concluded that the material weakness was fully remediated as of December 31, 2022. If we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, our stock price. We have incurred, and will continue to incur, increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance with our public company responsibilities and corporate governance practices. As a public company, and particularly after we are no longer an " emerging growth company, " we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes- Oxley Act of 2002, or the Sarbanes Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations impose various requirements on public companies. Our management and other personnel will need to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time- consuming and costly. If, notwithstanding our efforts to comply with new or changing laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. Further, failure to comply with these laws, regulations and standards may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance, which could make it more difficult for us to attract and retain qualified members to serve on our board of directors or committees or as members of senior management. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs. As a result of becoming a public company, we are obligated to develop and maintain proper and effective internal control over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common stock. We will be required, pursuant to Section 404 of the Sarbanes Oxley Act, or Section 404, to furnish a report by management on, among other things, the effectiveness of our internal controls over financial reporting for the fiscal year ended December 31, ~~2022~~ **2023** . This assessment will need to include disclosure of any material weaknesses identified by our management in our internal controls over financial reporting. Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting until our first annual report required to be filed with the SEC following the date we are no longer an emerging growth company, as defined in the JOBS Act. At such time as we are required to obtain auditor attestation, if we then have a material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered public accounting firm. We will be required to disclose significant changes made in our internal control procedures on a quarterly basis. We have already begun the process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404 and anticipate we will be able to complete our evaluation, testing and any required remediation in a timely fashion. Our compliance with Section 404 will require that we incur additional legal, accounting and other compliance expense and expend significant management efforts. We currently do not have an internal audit group, and although we have accounting and finance staff with appropriate public company experience and technical accounting knowledge, we may need to hire additional consultants or staff to perform the evaluation needed to comply with Section 404. During the evaluation and testing process of our internal controls, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting ~~are~~ **is** effective. For example, in connection with the audits of our financial statements as of and for the years ended December 31, 2021 and 2020, we identified a material weakness in our internal control over financial reporting. See " — We previously identified a material weakness in our internal control over financial reporting, resulting from control deficiencies related to management' s review of work performed by specialists. If we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business and stock price. " We cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to avoid additional material weaknesses or significant deficiencies in our internal controls over financial reporting in the future. Any failure to maintain effective internal controls over financial reporting could severely inhibit our ability to accurately report our

financial condition or results of operations. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of shares of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also negatively impact our ability to access to the capital markets. In addition, effective disclosure controls and procedures enable us to make timely and accurate disclosure of financial and non- financial information that we are required to disclose. As a public company, if our disclosure controls and procedures are ineffective, we may be unable to report our financial results or make other disclosures accurately on a timely basis, which could cause our reported financial results or other disclosures to be materially misstated and result in the loss of investor confidence and cause the market price of our securities. We are an emerging growth company and a smaller reporting company and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies or smaller reporting companies will make our common stock less attractive to investors. We are an " emerging growth company " as defined in the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use this exemption from new or revised accounting standards and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that have not made this election. For as long as we continue to be an emerging growth company, we also intend to take advantage of certain other exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non- binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of $ 1. 235 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the closing of our initial public offering; (iii) the date on which we have issued more than $ 1. 0 billion in nonconvertible debt during the previous three fiscal years; or (iv) the date on which we are deemed to be a " large accelerated filer " under the rules of the SEC. Additionally, we are a " smaller reporting company " as defined in Item 10 (f) (1) of Regulation S- K. Even after we no longer qualify as an emerging growth company, we may still qualify as a " smaller reporting company, " which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including presenting only the two most recent fiscal years of audited financial statements and reduced disclosure obligations regarding executive compensation in this Form 10- K and our periodic reports and proxy statements. We will remain a smaller reporting company until the last day of the fiscal year in which (1) the market value of our shares of common stock held by non- affiliates exceeds $ 250 million as of the prior the end of our second fiscal quarter ending December 31st of each year, or (2) our annual revenues exceeded $ 100 million during such completed fiscal year and the market value of our ordinary shares held by non- affiliates exceeds $ 700 million as of the prior to the end of our second fiscal quarter ending December 31st of each year. To the extent we take advantage of such reduced disclosure obligations, it may also make **the** comparison of our financial statements with other public companies difficult or impossible. Risks Related to Our Securities and Ownership of Our Common Stock ~~As of December 31, 2022, Biofrontera AG beneficially owns 30. 0 % of our outstanding shares of common stock and will be able to exert significant control over matters subject to stockholder approval, and its interests may conflict with ours or other stockholders in the future. As of December 31, 2022, Biofrontera AG beneficially owns in the aggregate approximately 30. 0 % of our outstanding voting stock and will continue to exert significant influence on the company. In addition, Biofrontera AG' s beneficial ownership would be further reduced by the exercise of any of the 9, 197, 109 outstanding warrants issued in connection with our initial public offering and private placements. However, it would likely continue to have a significant portion (and perhaps even a majority) of the voting power in a shareholder meeting. As a result, Biofrontera AG will have the ability to significantly influence us through this ownership position. Biofrontera AG may be able to determine all matters requiring stockholder approval. For example, Biofrontera AG may be able to control elections of directors, amendments of our organizational documents, our financing and dividend policy and approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. Moreover, because of the significant ownership position held by Biofrontera AG and our classified board structure, new investors may not be able to effect a change in the Company' s business or management, and therefore, stockholders would be subject to decisions made by management and Biofrontera AG. Biofrontera AG' s interests may differ from our interests and the interests of our other stockholders, and therefore actions Biofrontera AG takes with respect to us, as a significant shareholder, including under the Ameluz LSA, may not be favorable to us or our public stockholders. For a discussion of the risks related to our license agreement with Biofrontera AG, see " Risks Related to the License and Supply Agreements and Our Licensed Products. " Furthermore, Biofrontera AG is a public company with a comparatively low amount of shares that are regularly traded and several shareholders who each hold a significant stake in Biofrontera AG. Any of these shareholders may exert their influence on Biofrontera AG by voting in favor of proposals that are in their individual interest or electing members to Biofrontera AG' s supervisory board who could act to align Biofrontera AG' s actions with the interests of such shareholders. Under German law, company management must obtain the consent of the supervisory board for certain actions. Since 2017, several legal actions have been filed by one of Biofrontera AG' s significant shareholders opposing resolutions passed at the shareholders' meetings, including actions for annulment and rescission of resolutions related to financing transactions undertaken by Biofrontera AG and~~

~~they could seek to cause Biofrontera AG to take actions as our significant shareholder that no longer support our strategy as set forth in this Form 10- K and may be contrary to the interests of our other stockholders. If Biofrontera AG sells a controlling interest in our company to a third party in a private transaction, you may not realize any change- of- control premium on shares of our common stock and we may become subject to the control of a presently unknown third party. Although Biofrontera AG holds less than the majority of the voting power of our common stock, it may still exert a controlling influence over us, since many shares of our common stock are held by retail investors who may not vote at shareholder meetings. The ability of Biofrontera AG to privately sell its shares of our common stock, with no requirement for a concurrent offer to be made to acquire all of the shares of our common stock held by our other stockholders, could prevent you from realizing any change- of- control premium on your shares of our common stock that may otherwise accrue to Biofrontera AG on its private sale of our common stock. Additionally, if Biofrontera AG privately sells its controlling equity interest in our company, we may become subject to the control of a presently unknown third party. Such third party may have conflicts of interest with those of other stockholders. In addition, if Biofrontera AG sells a controlling interest in our company to a third party, our indebtedness may be subject to acceleration, and our other commercial agreements and relationships, including any remaining agreements with Biofrontera AG, could be impacted, all of which may adversely affect our ability to run our business as described herein and may have a material adverse effect on our business, financial condition and results of operations.~~ Provisions of our outstanding warrants could discourage an acquisition of us by a third party. In addition to the discussion of the provisions of our certificate of incorporation and our bylaws, certain provisions of our outstanding warrants could make it more difficult or expensive for a third party to acquire us. The warrants prohibit us from engaging in certain transactions constituting " fundamental transactions " unless, among other things, the surviving entity assumes our obligations under the warrants. These and other provisions of our outstanding warrants could prevent or deter a third party from acquiring us even where the acquisition could be beneficial to you. Our share price may be volatile, and you may be unable to sell your shares and / or warrants at or above the offering price. The market price of our common stock is likely to be volatile and could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including: ● the success of existing or new competitive products or technologies; ● regulatory actions with respect to Ameluz ®, the BF- RhodoLED ® lamp (and its successors) or Xepi ® or our competitors' products; ● actual or anticipated fluctuations in our financial condition and operating results, including fluctuations in our quarterly and annual results; ● announcements of innovations by us, our Licensors or our competitors; ● overall conditions in our industry and the markets in which we operate; ● market conditions or trends in the biotechnology industry or in the economy as a whole; ● addition or loss of significant healthcare providers or other developments with respect to significant healthcare providers; ● changes in laws or regulations applicable to Ameluz ®, the BF- RhodoLED ® lamp (and its successors) or Xepi ®; ● actual or anticipated changes in our growth rate relative to our competitors; ● announcements by us, our Licensors or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments; ● additions or departures of key personnel; ● issuance of new or updated research or reports by securities analysts; ● fluctuations in the valuation of companies perceived by investors to be comparable to us; ● disputes or other developments related to the patents covering our licensed products, and our Licensors' ability to obtain intellectual property protection for our licensed products; ● security breaches; ● litigation matters; ● announcement or expectation of additional financing efforts; ● sales of our common stock by us or our stockholders; ● share price and volume fluctuations attributable to inconsistent trading volume levels of our shares; ● the expiration of contractual lock- up agreements with our executive officers, directors and stockholders; and ● general economic and market conditions. Furthermore, the stock markets have experienced price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations, may negatively affect the market price of our common stock. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities litigation. This risk is especially relevant for biopharmaceutical companies, which have experienced significant stock price volatility in recent years. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management' s attention from other business concerns, which could seriously harm our business. If we fail to regain compliance with applicable listing standards, our common stock and publicly- traded warrants could be delisted from Nasdaq. Nasdaq requires listing issuers to comply with certain standards in order to remain listed on its exchange. If, for any reason, Nasdaq should delist our common stock from trading on its exchange and we are unable to obtain listing on another reputable national securities exchange, a reduction in some or all of the following may occur, each of which could materially adversely affect our stockholders: ● the liquidity and marketability of our common stock and / or publicly- traded warrants; ● the market price of our common stock; ● our ability to obtain financing for the continuation of our operations; ● the number of institutional and general investors that will consider investing in our common stock; ● the number of market makers in our common stock; ● the availability of information concerning the trading prices and volume of our common stock; and ● the number of broker- dealers willing to execute trades in shares of our common stock. On ~~February 24~~ **November 22** , 2023, we received a letter (the " Notice ") from the Listing Qualifications ~~Staff~~ **staff** of ~~the~~ Nasdaq **notifying the Company** ~~Stock Market, LLC (" Nasdaq ") indicating~~ that, **because** ~~based upon~~ the ~~closing bid price of our common stock~~ **Company' s stockholders' equity as reported in its Quarterly Report on Form 10- Q** for the ~~last~~ **period ended September** 30 ~~consecutive business days~~ , ~~we are~~ **2023 was $ 1, 038, 000, the Company is** no longer in compliance with the ~~requirement to maintain a minimum bid price of $ 1. 00 per share for~~ continued listing **requirement under** ~~on the Nasdaq Capital Market, as set forth in~~ Nasdaq Listing Rule 5550 (~~a~~ **b**) (**1), which requires that a listed company' s stockholders' equity be at least $** 2 **, 500, 000. Additionally, as of the date of the Notice, the Company did not meet either of the alternative requirements of maintaining a market value of listed securities of $ 35 million or achieving a net income from continuing operations of $ 500, 000 in the most recently**

completed fiscal year or in two of the last three most recently completed fiscal years. As a result, as of the date of this Report, the Company does not satisfy Nasdaq Marketplace Rule 5550 (b). We **submitted a compliance plan to Nasdaq on January 8, 2024. The compliance plan was accepted and we** were **granted** ~~provided a compliance period of~~ 180 calendar days from **November 22** ~~the date of the Notice, or until August 23~~ , 2023 ~~,~~ to ~~regain~~ **evidence** compliance ~~with the minimum closing bid requirement, pursuant to Nasdaq Listing Rule 5810 (c) (3) (A). If we fail to regain compliance within the allotted compliance periods, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that our common stock and publicly- traded warrants will be subject to delisting. We would then be entitled to appeal Nasdaq' s determination, but there can be no assurance that Nasdaq would grant our request for continued listing. We will continue to monitor the closing bid price of our common stock and seek to regain compliance with all applicable Nasdaq requirements within the allotted compliance periods and may, if appropriate, consider available options, including implementation of a reverse stock split of our common stock, to regain compliance with the minimum closing bid requirement. If we seek to implement a reverse stock split in order to remain listed on Nasdaq, the announcement or implementation of such a reverse stock split could negatively affect the price of our common stock and / or publicly- traded warrants~~ . In addition, if we fail to regain compliance to be eligible to trade on Nasdaq or obtain listing on another reputable national securities exchange, we may have to pursue trading on a less recognized or accepted market, such as the over the counter markets, our stock may be traded as a " penny stock " which would make transactions in our stock more difficult and cumbersome, and we may be unable to access capital on favorable terms or at all, as companies trading on alternative markets may be viewed as less attractive investments with higher associated risks, such that existing or prospective institutional investors may be less interested in, or prohibited from, investing in our common stock. This may also cause the market price of our common stock to further decline. Future sales of our common stock in the public market could cause our share price to fall. Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We had ~~26~~ **5** , ~~699~~ **089** , ~~002~~ **413** shares of common stock outstanding as of ~~December 31~~ **March 11** , ~~2022~~ **2024** , of which ~~18~~ **2** , ~~699~~ **172** , ~~002~~ **628** shares are freely tradable without restrictions or further registration required under the Securities Act. **2, 516, 785 shares were issued in a private placement that closed on February 22, 2024 (the " Offering ") and are currently unregistered, but are subject to registration rights. We have filed a registration statement to register the resale of the shares issued in the Offering and once it is declared effective by the SEC (which we expect to occur soon after the date of this Annual Report on Form 10- K) those 2, 516, 785 shares will be freely tradable without restriction.** The remaining ~~8~~ **400** , 000 ~~, 000 million~~ shares are currently unregistered and held by Biofrontera AG. **In addition, we have issued** ~~Warrants~~ **warrants to purchase our common stock that, if such warrants are exercised, could be sold in the public market. See " We have issued several warrants that** are exercisable for our common stock **and issued Series B Convertible Preferred Stock** , which **, if exercised or converted,** ~~would~~ **could substantially** increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders **" for more information regarding the potential impact of such warrants. If the Preferred Warrants are not exercised, we will not receive up to $ 8 million in aggregate gross proceeds from the exercise of the Warrants which could have a material adverse effect on our financial condition. We issued warrants (the " Preferred Warrants ") to purchase up to 8, 000 shares of Series B- 3 Convertible Preferred Stock (the " Series B- 3 Preferred Stock ") at an exercise price of $ 1, 000 per share of Series B- 3 Preferred Stock. If the Preferred Warrants are exercised, we will receive up to $ 8. 0 million in gross proceeds as a result of such exercise. The Preferred Warrants will expire within 5 days of meeting certain milestones, which we expect to occur in the second quarter of 2024. Although we anticipate that the holders of the Preferred Warrants will exercise the Preferred Warrants prior to their expiration, the holders of the Preferred Warrants are not required to do so. In addition, if those milestones are not met the Preferred Warrants will not expire until February 22, 2027 and the Preferred Warrants, if they are exercised at all, will not be exercised within the currently anticipated timeframe. In addition, while the Company has reserved sufficient shares of Common Stock to cover the number of shares issuable upon conversion of the remaining shares of Series B- 1 Convertible Preferred Stock, the Company does not currently have enough authorized shares of Common Stock to cover the shares of Common Stock that would be issuable upon conversion of the Series B- 3 Preferred Stock if the investors exercised all of their Warrants. Based on the current conversion price of $ 0. 7074 per share, an additional 11, 309, 019 shares of Common Stock would need to be reserved and, unless the stockholders approve an amendment to our Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock, we only have 7, 354, 059 shares of common stock available to reserve for the issuance of common stock upon conversion of the Series B- 3 Preferred Stock. If we are unable to obtain the stockholder approval necessary to reserve sufficient shares to cover the conversion of the Series B- 3 Preferred Stock, then the investors will not be able to exercise any of their Warrants. If the Preferred Warrants are not exercised or are not exercised within the currently anticipated timeline for any of the reasons described above or if the Preferred Warrants are not exercised in full, we would not receive the anticipated proceeds from the exercise of the Preferred Warrants which could have a material adverse effect on our financial condition since our current plans for ensuring sufficient liquidity to continue as a going concern depend on receiving the anticipated proceeds. Even if there were alternate sources of financing available to us, there is no guarantee that they would be sufficient to offset the loss of such proceeds. We have issued several warrants, which are exercisable for our common stock, and issued Series B Convertible Preferred Stock, which, if exercised or converted, as applicable, could substantially increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders** . As of March 10, ~~2023~~ **2024** , we have a total of ~~9~~ **2** , ~~197~~ **269** , ~~109~~ **356** outstanding warrants which may each be exercised for one share of our common stock. All of the shares issuable upon exercise of ~~the~~ **these** warrants have been registered on effective registration statements and therefore, when issued, will be freely tradable without restriction or further registration required under the

Securities Act. Any shares of our common stock issued upon exercise of outstanding warrants will result in dilution to the then existing holders of our common stock and increase the number of shares eligible for resale in the public market. **In addition, in the Offering we issued shares of Series B- 1 Convertible Preferred Stock (“ Series B- 1 Preferred Stock ”). Each share of Series B- 1 Preferred Stock may be converted into approximately 1, 413 shares of our common stock (based on the conversion price of $ 0. 7074 per share and a liquidation preference of $ 1, 000 per share of Series B- 1 Preferred Stock). At the time of issuance, the holders of the Series B- 1 Preferred Stock converted some of their shares resulting in the issuance of 2, 516, 785 shares of common stock. However, 4, 806 shares of Series B- 1 Preferred Stock remain outstanding, which could be converted into up to 6, 793, 893 shares of common stock. We also issued in the Offering, the Preferred Warrants, which if exercised, would result in the issuance of Series B- 3 Preferred Stock. Each share of Series B- 3 Preferred Stock may convert into approximately 1, 413 shares of our common stock (based on the conversion price of $ 0. 7074 per share and a liquidation preference of $ 1, 000 per share of Series B- 3 Stock). While it is not certain that any of the Preferred Warrants will be exercised, if they are exercised in full, the Series B- 3 Preferred Stock issued could be converted into up to 11, 309, 019 shares of common stock. Although the Series B- 1 Preferred Stock and Series B- 3 Preferred Stock each have a beneficial ownership limitation that prevents the holder from converting if it would result in the holder’ s beneficial ownership exceeding 9. 99 % of the then outstanding common stock and although the initial conversion into 2, 516, 785 shares is close to the beneficial ownership limitation for all current holders of the Series B- 1 Stock and the Preferred Warrants, the remaining Series B- 1 Preferred Stock and any Series B- 3 Preferred Stock issued upon exercise of the Preferred Warrants could be converted into common stock at a future date if the total number of outstanding shares of our common stock increases, if the beneficial ownership limitation is removed or if the holders of the Series B- 1 Preferred Stock and Series B- 3 Preferred Stock sell any of the common stock they currently hold. Under the terms of the Certificate of Designation for the Series B Convertible Preferred Stock, if our stockholders approve an amendment to our Amended and Restated Certificate of Incorporation to increase the number of authorized shares, the Series B- 1 Preferred Stock will automatically be converted into common stock (to the extent such conversion does not exceed the beneficial ownership limitation described above) or Series B- 2 Convertible Preferred Stock with the same terms as the Series B- 3 Preferred Stock.** Sales of substantial numbers of **any** such shares **described above** in the public market could adversely affect the market price of our common stock. If securities or industry analysts do not publish research or publish unfavorable research about our business, our stock price and trading volume could decline. The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Moreover, if our operating results do not meet the expectations of the investor community, one or more of the analysts who cover our company may change their recommendations regarding our company, and our stock price could decline. Our quarterly operating results may fluctuate significantly. We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including: ● variations in the level of expenses related to our marketing efforts; ● any litigation, including intellectual property infringement lawsuits related to our licensed products, in which we may become involved; ● regulatory developments affecting Ameluz ®, the BF- RhodoLED ® lamp (and its successors) or Xepi ®; ● our execution of any licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements; ● the timing of milestone payments under our existing license agreements; and ● the level of underlying demand for Ameluz ® and Xepi ® and customers’ buying patterns. If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially. Future sales and issuances of our common stock or rights to purchase our common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause the stock price of our common stock to decline. In the future, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. We also expect to issue common stock to employees, consultants and directors pursuant to our equity incentive plans. If we sell common stock, convertible securities or other equity securities in subsequent transactions, or common stock is issued pursuant to equity incentive plans or the Unit Purchase Option, investors may be materially diluted. New investors in such subsequent transactions could gain rights, preferences and privileges senior to those of holders of our common stock. We have never paid dividends on our common stock and we do not intend to pay dividends for the foreseeable future. Consequently, any gains from an investment in our common stock will likely depend on whether the price of our common stock increases. We have never declared or paid any dividends on our common stock and do not intend to pay any dividends in the foreseeable future. We anticipate that we will retain all of our future earnings for use in the operation of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our board of directors. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments. For more information, see the section of this Form 10- K captioned “ Management’ s Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources. ” Our stockholder rights plan, or “ poison pill, ” includes terms and conditions which could discourage a takeover or other transaction that stockholders may consider favorable. On October 24, 2022, stockholders of record at the close of business on that date received a dividend of one right (a “ Right ”) for each outstanding share of common stock. Each Right entitles the registered holder to purchase one one- thousandth of a share of Series A Junior Participating Cumulative Preferred Stock of the Company (the “ Preferred Stock ”), at a price of $ 5. 00 per one thousandth of a share of Preferred Stock, subject to adjustment (the “ Exercise Price ”). The Rights are not exercisable until the Distribution Date (as defined below). The description and terms of the Rights are set forth in the Stockholder Rights Agreement between the

Company and Computershare Trust Company, N. A., as rights agent, dated as of October 13, 2022 **, as amended by Amendment No. 1 to the Stockholder Rights Agreement, dated as of April 26, 2023** . The Rights Agreement imposes a significant penalty upon any person or group that acquires 20 % or more (but less than 50 %) of our then- outstanding common stock without the prior approval of our board of directors. A person or group that acquires shares of our common stock in excess of the applicable threshold, subject to certain limited exceptions, is called an " Acquiring Person. " Any rights held by an Acquiring Person are void and may not be exercised. A person or group who beneficially owned 20 % or more of our outstanding Common Stock prior to the first public announcement of the adoption of the Rights Agreement will not trigger the Rights Agreement so long as they do not acquire beneficial ownership of any additional shares of Common Stock at a time when they still beneficially own 20 % or more of such Common Stock. The Rights will not be exercisable until the earlier of ten days after a public announcement by us that a person or group has become an Acquiring Person and ten business days (or a later date determined by our board of directors) after a person or group begins a tender or an exchange offer that, if completed, would result in that person or group becoming an Acquiring Person (the earlier of such dates being herein referred to as the " Distribution Date "). At any time after a person becomes an Acquiring Person, the Board of Directors may, at its option, exchange all or any part of the then outstanding and exercisable Rights for shares of Common Stock at an exchange ratio of one share of Common Stock for each Right, subject to adjustment as specified in the Rights Agreement. Notwithstanding the foregoing, the Board of Directors generally will not be empowered to effect such exchange at any time after any person becomes the beneficial owner of 50 % or more of the Common Stock of the Company. The Rights will expire at the ~~close~~ **earlier** of ~~business on October 13~~ **(a) June 30** , ~~2023~~ **2026** ~~; provided that if~~ **or (b) the first day after** the Company' s ~~stockholders have not ratified the Stockholder Rights Agreement by the close of business on the first day after the Company' s 2023~~ **2025** annual meeting ~~of~~ **, if** ~~stockholders~~ **stockholder** ~~(including any adjournments or postponement thereof)~~ **approval has not been obtained prior to such date** , the Rights will expire at such time, in each case, unless previously redeemed or exchanged by the Company. The Rights have certain anti- takeover effects, including potentially discouraging a takeover that stockholders may consider favorable. The Rights will cause substantial dilution to a person or group that attempts to acquire us on terms not approved by the board of directors. Our charter documents and Delaware law could prevent a takeover that stockholders consider favorable and could also reduce the market price of our stock. Our amended and restated certificate of incorporation and our amended and restated bylaws ~~contains~~ **contain** provisions that could delay or prevent a change in control of our company. These provisions could also make it more difficult for stockholders to elect directors and take other corporate actions. These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, we are subject to the anti- takeover provisions contained in Section 203 of the Delaware General Corporation Law, or the DGCL. Under Section 203 of the DGCL, a corporation may not, in general, engage in a business combination with any holder of 15 % or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction. These and other provisions in our amended and restated certificate of incorporation and our amended and restated bylaws and under Delaware law could discourage potential takeover attempts, reduce the price investors might be willing to pay in the future for shares of our common stock and result in the market price of our common stock being lower than it would be without these provisions. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is, to the fullest extent permitted by applicable law, the exclusive forum for: ● any derivative action or proceeding brought on our behalf; ● any action asserting a claim of breach of a fiduciary duty owed by, or other wrongdoing by, any of our current or former directors, officers, employees or our stockholders; ● any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws (as either may be amended from time to time) or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; and ● any action asserting a claim against us that is governed by the internal-affairs doctrine. However, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Consequently, the exclusive forum provisions will not apply to suits brought to enforce any liability or duty created by the Exchange Act or to any claim for which the federal courts have exclusive jurisdiction. Moreover, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Our amended and restated certificate of incorporation will further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts are the sole and exclusive forum for the resolution of any complaint asserting a right under the Securities Act. The Supreme Court of the State of Delaware has held that such provisions are facially valid under Delaware law. While there can be no assurance that federal or state courts will follow the holding of the Delaware Supreme Court or determine that the provision should be enforced in a particular case, application of the provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court. By becoming a stockholder in our Company, you will be deemed to have notice of and have consented to the provisions of our amended and restated certificate of incorporation related to choice of forum. This exclusive forum provision may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees and result in increased costs for investors to bring a claim. If a court were to find the exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an

action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business. Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us. Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law. In addition, as permitted by Section 145 of the DGCL, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that: ● we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person' s conduct was unlawful; ● we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law; ● we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification; ● we will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification; ● the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and ● we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents. Many of the warrants to purchase shares of our common stock are accounted for as a warrant liability and recorded at fair value with changes in fair value each period reported in earnings, which may have an adverse effect on the market price of our common stock. Under U. S. GAAP, we are required to evaluate the outstanding warrants to purchase our common stock to determine whether they should be accounted for as a warrant liability or as equity. At each reporting period (1) the accounting treatment of the warrants will be reevaluated for proper accounting treatment as a liability or equity and (2) the fair value of the liability of the warrants will be re- measured and the change in the fair value of the liability will be recorded as other income (expense) in our consolidated statement of operations. Such accounting treatment may adversely affect the market price of our securities. In addition, changes in the inputs and assumptions for the valuation model we use to determine the fair value of such liability may have a material impact on the estimated fair value of the warrant liability. As a result, our financial statements and results of operations will fluctuate quarterly, based on various factors, such as the share price of our common stock, many of which are outside of our control. If our share price is volatile, we expect that we will recognize non- cash gains or losses on our warrants or any other similar derivative instruments in each reporting period and that the amount of such gains or losses could be material. The impact of changes in fair value on earnings may have an adverse effect on the market price of our common stock. The warrants issued in connection with ~~our initial public offering, the (" IPO Warrants ") were accounted for as equity as these instruments meet all of the requirements for equity classification under ASC 815- 40. (See Note 19. Stockholders' Equity) The warrants issued in connection with~~ the private placement offerings (completed on December 1, 2021 ~~and~~ **,** May 16, 2022 ~~)~~, ~~as well as the Inducement Warrants issued on~~ July 26, 2022 **, and November 2, 2023) (collectively, the " PIPE Warrants ")** were accounted for as liabilities as these warrants provide for a ~~cashless settlement provision~~ **redemption right in the case of a fundamental transaction** which fails the requirement of the indexation guidance under ASC 815- 40 ~~(collectively " PIPE Warrants ")~~. The resulting warrant liabilities are re- measured at each balance sheet date until their exercise or expiration, and any change in fair value is recognized in the Company' s consolidated statement of operations. Refer to Note 4. Fair Value Measurements. As of the date of this Form 10- K, ~~7~~ **2** , ~~704~~ **192** , ~~715 PIPE~~ **736 liability classified** Warrants remain outstanding. See Note ~~19~~ **18** . Stockholders' Equity in our audited financial statements for the fiscal year ended December 31, **2023 and** 2022 included in this Form 10- K for more information on the Warrants. Item 1B. Unresolved Staff Comments