

Ad hoc announcement pursuant to Art. 53 LR

Relief Therapeutics Announces Full Year 2022 Financial Results and Provides Corporate Update

GENEVA, April 14, 2023 – [RELIEF THERAPEUTICS Holding SA](#) (SIX: [RLF](#), OTCQB: [RLFTF](#), [RLFTY](#)) (Relief Therapeutics, or Relief), a biopharmaceutical company committed to delivering innovative treatment options with the potential for transformative outcomes to benefit those suffering from select specialty and rare diseases and disorders, today reported its financial results for the full-year ended December 31, 2022 and provided a corporate update. The Relief Therapeutics 2022 Annual Report, including management’s discussion and analysis, financial statements and results of operations for the year ending December 31, 2022, is available for download on the company’s [website](#).

“We made substantial progress in our transformation of Relief Therapeutics into a fully integrated, commercial-stage biopharmaceutical company in 2022, strengthening our intellectual property portfolio with multiple new patents and with the launch of our PKU GOLIKE® line of products in the U.S. in October, and the subsequent launch of the new PKU GOLIKE BARS™ in the U.S. and Europe earlier this year. In late December, we announced the U.S. FDA approval of OLPRUVA™ for the treatment of patients with urea cycle disorders with our collaboration partners at Acer Therapeutics,” said Jack Weinstein, chief executive officer of Relief Therapeutics. “We also announced new stability data for RLF-100®, our novel formulation of aviptadil acetate, which has been shown to be shelf-stable at temperatures suitable for shipping and long-term storage. We believe RLF-100 has significant potential clinical and commercial value and intend to pursue development of this product candidate for treatment of several debilitating lung disease indications.”

“We also built out our U.S. commercial organization and strengthened our management team, while continuing to advance other elements of our diversified pipeline of risk-mitigated product candidates toward significant catalysts,” continued Mr. Weinstein. “In 2022 we also launched a new initiative in genetic medicine focused on inherited metabolic disorders, which is being led by [Dr. Serene Forte](#) who joined Relief in July. To support this endeavor, we also recently announced the appointment of [Dr. Guangping Gao](#), a pioneer and global thought leader in the field of molecular genetics and viral vector gene therapy, to serve as the chair of our newly established scientific advisory board. Looking ahead to the balance of 2023, we continue to execute on the revised financing and listing strategy we announced in February. We maintain a lean organization, with a strong, experienced leadership team that has the proven ability to execute our disciplined, cost-effective, capital-efficient approach to drug development and deliver growth. We look forward to concluding the remaining steps on our pathway to a dual listing of our ordinary shares on the Nasdaq Stock Market and further advancing our development plans in 2023, and to realizing the full potential of the Relief Therapeutics portfolio for patients and our shareholders,” said Mr. Weinstein.

2022 & EARLY 2023 HIGHLIGHTS

OLPRUVA™ (sodium phenylbutyrate) for oral suspension FDA Approval

- U.S. Food and Drug Administration approved OLPRUVA™ (sodium phenylbutyrate for oral suspension for the treatment of certain patients living with urea cycle disorders (UCDs) involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC) or argininosuccinic acid synthetase (AS).
 - Collaboration partner Acer Therapeutics (ACER) announced preliminary launch activities in March 2023; with commercial and medical affairs teams in place to support the U.S. launch in Q2 2023 and product availability expected in July 2023.
 - ACER presented UCD survey data at 44th annual meeting of the *Society for Inherited Metabolic Disorders (SIMD)* in March 2023. The survey data were designed to quantify preferences of healthcare providers who treat patients with UCDs, and results showed taste and odor are the most important attributes influencing overall prescription and patient adherence to UCD treatments.

PKU GOLIKE® for the Treatment of Phenylketonuria (PKU)

- Relief's newly assembled U.S. commercial team and a leading national health services company serving as exclusive distributor initiated the launch of its PKU GOLIKE® line of products in the U.S. in October. The PKU GOLIKE® family of products are next-generation, prolonged-release amino acid medical foods for the dietary management of phenylketonuria (PKU).
- In early 2023, Relief also launched the newest product in the PKU GOLIKE line, the PKU GOLIKE BAR™ in the U.S. and Europe.
- The Company presented results of pre-clinical research evaluating the metabolic impact of PKU GOLIKE® on nitrogen balance, muscle strength and glucose at SIMD 2023. Data presented in a poster session summarized acute and long-term metabolic effects of PKU GOLIKE supplementation on the utilization of amino acids and glucose metabolism in a pre-clinical rat model using biomarkers for muscle metabolism, functional muscle performance and a glucose tolerance test. Beneficial effects were observed on amino acid oxidation, muscle metabolism, grip strength and glucose tolerance in healthy rats.

RLF-100® (aviptadil acetate)

- In November, Relief announced six-month stability data for its new proprietary formulation of aviptadil acetate, RLF-100®; high-purity levels were demonstrated at all temperatures tested (refrigerated, room temperature).
 - Results demonstrate novel RLF-100® formulation to be shelf-stable at temperatures suitable for shipping and long-term storage.
- RLF-100® was granted Orphan Drug designation (ODD) for pulmonary sarcoidosis by the FDA.
- In December, Relief announced a definitive settlement agreement was reached with its former collaboration partner NeuroRx, Inc. (NRx) to resolve litigation, resulting in transfer to Relief of all assets previously used in the aviptadil development program.

RLF-TD011

- Patient enrollment was initiated in a proof-of-concept, investigator-initiated clinical trial of RLF-TD011 for the treatment of epidermolysis bullosa (EB), a rare, inherited skin disease characterized by widely distributed, painful, chronic wounds that easily become infected, resulting in an elevated risk of sepsis and death.
 - The study ([NCT05533866](#)) is currently enrolling up to 17 patients diagnosed with junctional epidermolysis bullosa (JEB) or dystrophic epidermolysis bullosa (DEB) with *S. aureus* or *P. aeruginosa* culture-positive wounds at Ann & Robert H. Lurie Children's Hospital of Chicago.
- Relief received the approval of an independent IRB for an investigator-initiated trial evaluating RLF-TD011 as an adjunctive treatment for cutaneous t-cell lymphoma (CTCL) ([NCT05728879](#)); the study will evaluate the effect of RLF-TD011, a patent-protected hypochlorous acid topical spray, on the microbiome of CTCL skin lesions and determine tolerability, symptom improvement and potential for reducing lesion size and skin disease activity.

RLF-OD032 for the Treatment of PKU

- In July, Relief acquired the worldwide commercialization rights (except in the United Kingdom) for a novel dosage form of an already FDA-approved prescription drug for the treatment of PKU from Meta Healthcare Ltd. Relief continues to work on the FDA investigational new drug (IND) application for submission during the second half of 2023 and anticipate filing for U.S. approval through a 505(b)(2) NDA in 2024.

Genetic Medicines Initiative

- In early 2022, Relief Therapeutics launched a [genetic medicine initiative](#) with the objective of developing life-altering, potentially curative treatments for patients suffering from for devastating, as-yet-unaddressed, rare monogenetic diseases.
- Serene Forte, Ph.D., MPH, was welcomed to Relief in July 2022 to lead the genetic medicines initiative as the company pursues efforts to establish a pipeline of genetic medicine programs.
- Internationally recognized gene therapy expert Guangping Gao, Ph.D. was appointed as the chair of Relief's newly formed scientific advisory board in April 2023.

Key Leadership Appointments

- We expanded our board of directors with the appointment of life science industry veteran [Michelle Lock](#) in January 2022.
- [Serene Forte](#), Ph.D., MPH, joined Relief in July as the senior vice president, head of genetic medicine, to lead Relief's new genetic medicines initiative.
- [Paolo Galfetti](#) was promoted to the role of chief operating officer at RELIEF THERAPEUTICS Holding SA in October 2022, continuing his responsibilities as chief executive officer of APR Applied Pharma Research SA (APR) and as a member of Relief's board of directors.
- [Jack Weinstein](#), MBA, was promoted as the chief executive officer at Relief, and [Jeremy Meinen](#), CPA, as the Relief's chief financial officer, in December 2022.

Business Update

- In July, Relief's Registration Statement on Form 20-F under the Securities Exchange Act of 1934 became effective, making Relief Therapeutics a publicly reporting company in the U.S.
- In early 2023, Relief Therapeutics announced that in furtherance of its efforts to listing the Company's shares on the Nasdaq Stock Market, Relief will hold an extraordinary general meeting (EGM) of shareholders asking them to consider and vote on the proposal to consolidate (or reverse split) the company's ordinary shares. The EGM will take place on April 28, 2023 in Geneva. The full details of the proposal and proposed revised Articles of Association are enclosed in the [EGM invitation](#) available on the Relief Therapeutics website, where additional information is also provided in a [Q&A list](#).

About Relief Therapeutics

[Relief Therapeutics](#) is a commercial-stage biopharmaceutical company committed to advancing treatment paradigms and delivering improvements in efficacy, safety and convenience to benefit the lives of patients living with select specialty and rare diseases and disorders. Our portfolio offers a balanced mix of marketed, revenue-generating products, our proprietary, globally patented Physiomimic™ and TEHCLO™ drug delivery platform technologies and a highly targeted clinical development pipeline consisting of risk-mitigated assets to address rare metabolic disorders, rare skin diseases and rare respiratory diseases. In addition, the company is commercializing several legacy products via licensing and distribution partners. Our mission to provide therapeutic relief to those suffering from rare diseases and disorders is being advanced by an international team of well-established, experienced biopharma industry leaders with extensive research, development and rare disease expertise. Relief Therapeutics' headquarters are located in Geneva, with additional offices in Balerna, Switzerland, Offenbach am Main, Germany and Rome. The Company is listed on the SIX Swiss Exchange under the symbol RLF and quoted in the U.S. on OTCQB under the symbols RLFTF and RLFTY. For more information, please visit our website at www.relieftherapeutics.com or follow Relief Therapeutics on [LinkedIn](#) and [Twitter](#).

FOR MEDIA/INVESTOR INQUIRIES CONTACT:

RELIEF THERAPEUTICS Holding SA
Catherine Day
Vice President, IR & Communications
contact@relieftherapeutics.com

LifeSci Advisors
Irina Koffler
+1-917-734-7387
ikoffler@lifesciadvisors.com

Disclaimer

This press release contains forward-looking statements. Forward-looking statements involve known and unknown risks, uncertainties, and other factors, which could cause the actual results, financial condition, performance or achievements of Relief Therapeutics to be materially different from any future results, performance or achievements expressed or implied by such forward-looking statements. A number of factors, including those described in Relief Therapeutics' filings with the SIX Swiss Exchange and the U.S. Securities and Exchange Commission (SEC), could adversely affect Relief Therapeutics. Copies of Relief Therapeutics' filings with the SEC are available on the SEC EDGAR database at www.sec.gov. Relief Therapeutics does not undertake any obligation to update the information contained herein, which speaks only as of this date.