RELIEF
THERAPEUTICS

PROVIDING RELIEF TO PATIENTS WITH RARE DISEASES

2024

HALF-YEAR REPORT

RELIEF
THERAPEUTICS

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DEAR SHAREHOLDERS,

Since the start of the year, we have advanced our strategic initiatives while navigating organizational changes. Our commitment to prioritizing development plans and leveraging our expertise has directed our focus toward rare dermatologic diseases while accelerating the development of RLF-OD032, a promising treatment in the rare metabolic space. Relief's current strategy is built on four key pillars: transitioning our commercialization model, partnering and licensing non-core assets, monetizing royalty streams from commercial-stage products, and concentrating on advancing our rare dermatology franchise. This approach aims to reduce costs, streamline our organization, secure non-dilutive capital, and direct resources to the development of our core assets. This refined strategy is expected to position the Company to deliver sustainable innovation and meaningful benefits for those affected by rare and debilitating disorders. Given the inherent risks and uncertainties associated with the development of our core assets and securing future capital, the Board of Directors continues to evaluate strategic options to safeguard and enhance shareholder value.

HIGHLIGHTS

RLF-TD011

We are approaching a significant milestone with RLF-TD011, our patent-protected, differentiated hypochlorous acid topical spray designed to treat epidermolysis bullosa (EB) wounds, which has previously received Orphan Drug Designation (ODD) from the U.S. FDA for this indication. The investigator-initiated trial conducted at Northwestern University has completed its enrollment and treatment phases. This study is evaluating changes in the microbiome of EB wounds treated with RLF-TD011, along with safety and improvements in wound closure. We anticipate reporting topline results in the coming weeks, following the completion of data analysis. Concurrently, we are preparing to consult with the FDA to validate our development and regulatory plan, paving the way for market approval.

RLF-TD011, if approved, could offer a fast, easy-to-use, and effective solution to the significant unmet needs in EB wound care management. The treatment targets microbial load without triggering antibiotic resistance, which is anticipated to prevent infections and reinfections while actively promoting wound healing. Its unique characteristics are also expected to enhance the efficacy and usability of emerging EB therapies.

RLF-OD032

We have initiated a proof-of-concept pharmacokinetic (PK) trial for our novel liquid formulation of sapropterin dihydrochloride, codenamed RLF-OD032. This ongoing study compares the pharmacokinetics of RLF-OD032 with a marketed reference product and assesses the effects of food and water on its bioavailability. These results may support the initiation of a subsequent pivotal PK trial and, upon successful completion of the clinical development, the submission of a 505(b)(2) NDA to the FDA in mid- to late 2025.

RLF-OD032, if approved, would be the first and only highly concentrated, portable, and ready-to-use liquid formulation of sapropterin dihydrochloride, aiming to offer significant improvements in the management, adherence, and compliance of Phenylketonuria (PKU) patients.

OLPRUVA®

Our U.S. commercialization partner for OLPRUVA, Zevra Therapeutics Inc. (Zevra), recently reported increased reimbursement coverage to 75% of covered lives, improved preferred status on formulary plans, and new patient enrollments. The full launch by Zevra earlier this year has expanded access to OLPRUVA for patients, and we are pleased with the progress being made. In August this year, building on these advancements, we secured non-dilutive financing of up to USD 11 million by monetizing a portion of OLPRUVA's future royalty stream, ensuring continued financial support for the Company's strategic initiatives.

GOLIKE®

We transitioned our rare metabolic business in the U.S. from direct commercialization to a partnership-based model. In March 2024, we granted Eton Pharmaceuticals Inc. (Eton) an exclusive license for the commercialization of the GOLIKE family of products in the U.S., and Eton has since successfully taken over the marketing of PKU GOLIKE. We are actively pursuing similar partnerships in Europe. This strategic shift has reduced our cost base while leveraging the expertise and reach of our partners, allowing greater penetration of our products within the affected communities.

SSF AGREEMENT

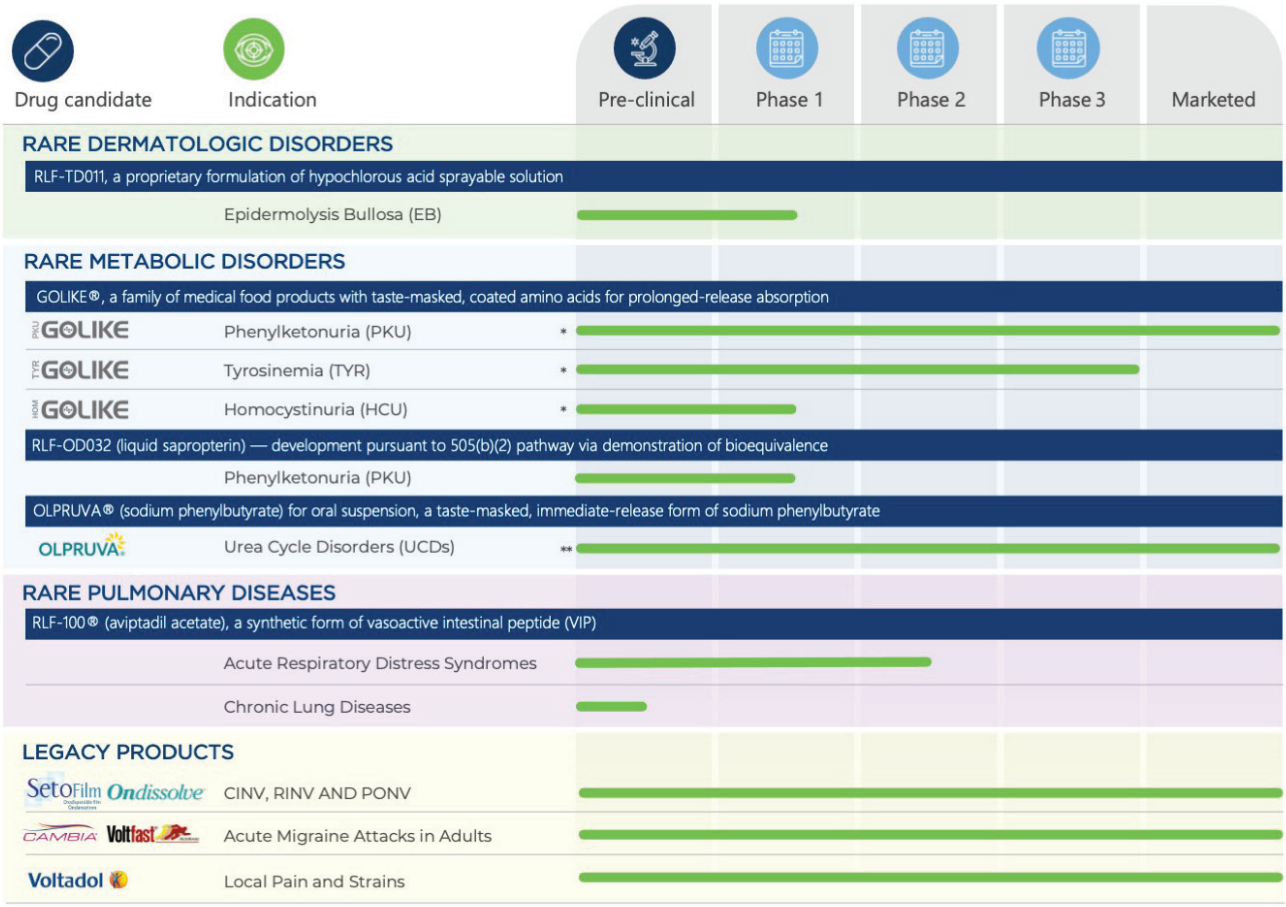
In February 2024, we renewed our CHF 50 million Share Subscription Facility (SSF) agreement with GEM Global Emerging Markets, Relief's largest shareholder since 2016. This renewal extends the agreement for an additional three-year period, providing us with enhanced financial flexibility.

CORPORATE DEVELOPMENTS

We underwent several changes within our Board of Directors and executive team. In April 2024, our shareholders elected to the Board of Directors three new members representing our principal investor, GEM Global Emerging Markets. In June 2024, we announced that our former interim Chief Executive Officer completed her transitional mandate, leaving this role currently vacant as the Company evaluates long-term leadership options. In the interim, operations are being effectively managed under the supervision of Relief's Board of Directors by a strong executive team, including Paolo Galfetti (Chief Business Officer), Giorgio Reiner (Chief Scientific Officer), Jeremy Meinen (Chief Financial Officer), and Vincenzo Gallo (Head of Legal and Compliance). Their collective expertise ensures continuity and drives our strategic initiatives forward.

RELIEF'S PORTFOLIO AND PIPELINE

Our portfolio ranges from marketed, revenue-generating products to those in various stages of development. It includes a diversified pipeline of risk-mitigated assets, optimized to enhance efficacy, safety, or convenience, with the goal of improving the lives of patients suffering from rare dermatology, metabolic and pulmonary disorders.



* GOLIKE product lines, as foods for special medical purposes, are not subject to the traditional drug development and approval process. Consequently, they do not undergo the phase development stages as illustrated. The progression visualization is intended solely for indicative purposes and should not be interpreted as a regulatory pathway.

** OLPRUVA is approved and marketed in the U.S. by Zevra Therapeutics Inc. Relief holds exclusive commercialization rights for Europe, where the product is currently not approved or marketed.

We continue to evaluate business development opportunities to expand our portfolio in the rare dermatological therapeutic area. We are considering partnerships or acquisitions of late-stage clinical assets with strong safety and efficacy profiles. By leveraging our development expertise and platform technologies, we aim to efficiently advance and commercialize these product candidates.

FINANCIAL OVERVIEW

The first half of 2024 marks a significant improvement for Relief, with several financial indicators showing positive trends, reflecting the effectiveness of the Company's cost-saving measures and strategic realignment.

Revenue rose to CHF 5.6 million in the six months ended June 30, 2024, up 85% from CHF 3.0 million in the same period of 2023. This growth was primarily driven by licensing income from the Eton license and supply agreement, as well as by increased contract development services and product sales.

Operational expenditures for the period, excluding manufacturing costs, were CHF 6.6 million, down 45% compared to CHF 12.1 million in the first half of the prior year. This decrease was largely due to reductions in personnel and SG&A expenses, resulting from the Company's strategic shift in commercial operations and other cost reduction initiatives. Investments in internal and external R&D, however, remained stable.

Based on the Group's consolidated financial statements, EBITDA for the six months ended June 30, 2024, was a loss of CHF 2.5 million, a 74% decrease compared to the loss of CHF 9.8 million in the first half of 2023. The net loss for the period was CHF 4.6 million, compared to CHF 56.5 million in the first half of 2023.

Our focus remains on controlling our burn rate and preserving cash to advance critical strategic milestones. Our existing cash reserves of CHF 15.1 million as of August 30, 2024, and projected revenue are expected to provide Relief with a cash runway into at least 2026.

We remain committed to delivering value for all our stakeholders and, as we move forward, we are optimistic and confident in our ability to overcome challenges and capitalize on opportunities before us.

Sincerely,

Raghuram Selvaraju, Ph.D., M.B.A.
Chairman of the Board of Directors

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This half-year report contains statements that constitute forward-looking statements. All statements other than statements of historical facts contained in this report, including statements regarding our future results of operations and financial position, business strategy, product candidates, marketed products, ongoing and planned clinical studies, regulatory approvals, research and development costs, timing and likelihood of success, as well as plans and objectives of management for future operations are forward-looking statements. Many of the forward-looking statements contained in this report can be identified by the use of forward-looking words such as “anticipate,” “believe,” “could,” “expect,” “should,” “plan,” “intend,” “estimate,” “will” and “potential,” among others. Forward-looking statements appear in a number of places in this report and include, but are not limited to, statements regarding our intent, belief or current expectations. Forward-looking statements are based on our management’s beliefs and assumptions and on information currently available to our management. Such statements speak only as of the date of this report and are subject to risks and uncertainties. Actual results may differ materially from those expressed or implied in the forward-looking statements due to various factors, including, but not limited to, those identified under the section entitled “Risk Factors” in our 2023 annual report on Form 20-F filed with the U.S. Securities and Exchange Commission. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur, and actual results could differ materially from those projected in the forward-looking statements. Moreover, we operate in an evolving environment. New risk factors and uncertainties may emerge from time to time, and it is not possible for management to predict all risk factors and uncertainties. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.