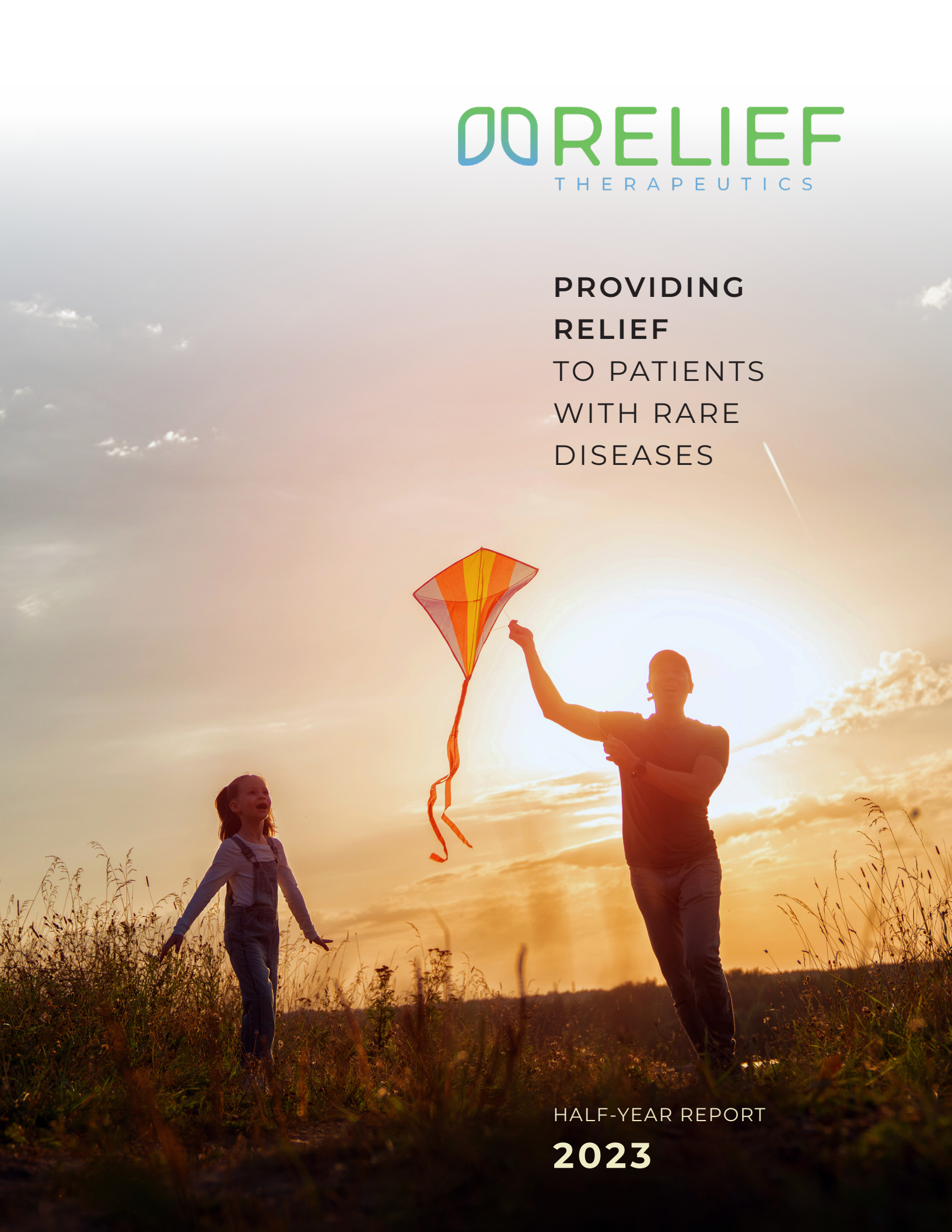
RELIEF
THERAPEUTICS

PROVIDING RELIEF TO PATIENTS WITH RARE DISEASES



HALF-YEAR REPORT

2023

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2023 TO DATE HIGHLIGHTS

JANUARY

Relief Therapeutics announced institutional review board (IRB) approval for the protocol of an IIT to evaluate **RLF-TD011**, a patent-protected hypochlorous acid topical spray, as an adjunctive treatment for patients diagnosed with cutaneous t-cell lymphoma (CTCL).

FEBRUARY

Relief Therapeutics provided an update on its financing strategy, including the Company's decision to voluntarily withdraw its Registration Statement on Form F-1 initially filed with the SEC on August 23, 2022, in order to explore alternative options for financing.

Relief Therapeutics announced the first three patients were enrolled in a proof-of-concept IIT to evaluate **RLF-TD011**, a self-administered, sprayable solution enabling targeted application while avoiding skin contact and cross-contamination, as a potential treatment for epidermolysis bullosa (EB).

Relief Therapeutics recognized Rare Disease Day 2023 and announced the U.S. availability of new **PKU GOLIKE BARS®**, a medical food for the dietary management of PKU.

MARCH

Acer provided an update on the commercial launch activities for **OLPRUVA™** (sodium phenylbutyrate; ACER-001) for oral suspension, noting progress with the build out of its commercial and medical affairs teams to support the U.S. commercial launch in Q2 2023, and drug availability anticipated by early July 2023.

Relief Therapeutics announced the availability of new **PKU GOLIKE BAR®** flavors in Europe.

Relief Therapeutics announced the results of pre-clinical research evaluating the metabolic impact of **PKU GOLIKE®** on nitrogen balance, muscle strength and glucose will be presented in a poster session at the Society for Inherited Metabolic Disorders (SIMD) 44th Annual Meeting.

Acer announced results from a survey of UCD healthcare providers identifying preferred UCD treatment attributes that were presented at SIMD. The data showed taste and odor are the most important attributes when considering treatment options and adherence.

APRIL

World-renowned gene therapy pioneer Guangping Gao, Ph.D. was appointed as the chair of Relief Therapeutics' newly formed scientific advisory board (SAB).

Relief Therapeutics announced an executive leadership team change with the departure of Nermeen Varawalla, M.D., Ph.D., chief medical officer.

Relief Therapeutics announced full-year 2022 financial results and provided a corporate update.

Relief Therapeutics announced positive 12-month stability data for inhaled and intravenous preparations of **RLF-100®**.

Relief Therapeutics announced results of its extraordinary meeting of shareholders.

MAY

Acer Therapeutics announced that the **OLPRUVA™** commercial launch was progressing ahead of schedule.

Relief Therapeutics announced the implementation timeline for a reverse split of its ordinary shares.

Relief Therapeutics announced Swissmedic approval and operation of a new, good manufacturing practice-compliant laboratory.

JUNE

Relief Therapeutics announced results of the annual general meeting of shareholders.

Relief Therapeutics announced closing of a CHF 5 million private placement.

Relief Therapeutics and World Orphan Drug Alliance announced an exclusive, long-term distribution agreement to introduce **PKU GOLIKE®** in the Middle East.

JULY

Relief Therapeutics announced extension of distribution agreement for **PKU GOLIKE®** in the U.S. with Pentec Health. Subsequently, Pentec Health announced its acquisition of ZOIA Pharma.

AUGUST

Relief Therapeutics and Acer Therapeutics announced a new exclusive definitive licensing agreement for the development and commercialization of **OLPRUVA™** for the treatment of certain UCDs and other potential indications, superseding the March 2021 collaboration and license agreement between the companies. Subsequently, Acer announced that it was being acquired by Zevra Therapeutics, Inc.

SEPTEMBER

Relief Therapeutics announced in this report that it has discontinued the position of Head of Genetic Medicine, suspended its development activities in this domain, and dissolved the recently formed scientific advisory board. This decision falls within the Company's strategy to prioritize the use of its resources over the near term, as further discussed throughout this report, including in the Corporate Strategy Update in the Management's discussion and analysis of financial condition and results of operations.

LETTER TO OUR SHAREHOLDERS

DEAR SHAREHOLDERS,

The first half of 2023 has been challenging for Relief, as it has also been for others of our peers in the biopharmaceutical and biotechnology space. New financing, including equity, debt, non-dilutive or other forms, has been much more difficult to obtain than in recent years. Nevertheless, I want to reflect on several notable accomplishments for the Company in the first half of this year including our recent successful efforts to raise financing on favorable terms, as well as provide you with insights on where I see the future of Relief and why I am so enthusiastic about our business.

We continue to be a fully integrated, international biopharmaceutical enterprise with both an unlevered, clean balance sheet and a disciplined, cost-effective, capital-efficient approach to drug development. Our primary focus remains on rare diseases, specifically those in the metabolic, dermatological, and respiratory areas with unmet medical needs. This targeted approach enables us to maintain a lean organization, led by a seasoned executive team. We have also taken steps to streamline the Company and continue to focus on optimizing the cost-effectiveness of our operations in the context of the current financing environment. Considering available financial and operational resources, I am confident we are well positioned to effectively implement and realize our strategic initiatives and objectives over the coming periods.

KEY ADVANCEMENTS IN THE FIRST HALF OF 2023

In June 2023, we concluded a CHF 5 million PIPE financing with a well-known healthcare-focused institutional investor on favorable terms. In August 2023, we re-structured our collaboration with Acer Therapeutics, Inc. (Acer). Under the terms of the revised agreement, Acer will retain development and commercialization rights for OLPRUVA™ for the treatment of urea cycle disorders (UCDs) and any potential additional indications in the U.S. and other countries worldwide, excluding geographical Europe. Acer has provided Relief with a non-contingent USD 10 million upfront cash payment and shall provide an additional non-contingent USD 1.5 million cash payment in August 2024. Relief will also receive a 10 percent continuing royalty calculated on the net sales of OLPRUVA™ in the Acer territory up to a cumulative amount of USD 45 million. At the same time, Relief will retain development and commercialization rights for OLPRUVA™ in geographical Europe. We expect that the transition from a profit-based to a revenue-based royalty stream model will deliver earlier returns and provide enhanced predictability to Relief. In addition, Acer continues to make crucial progress in securing market access and reimbursement for OLPRUVA™ with U.S. payers. Subsequent to the restructuring

of our agreement with Acer on OLPRUVA™, Acer announced that it was being acquired by Zevra Therapeutics, Inc. (Zevra). We believe that this acquisition is likely to foster the launch of OLPRUVA™ in the U.S. and the continued development of the drug across new indications, considering Zevra's expertise and track record.

We further strengthened our intellectual property for the PKU GOLIKE® line of products. Our PKU GOLIKE products are the first prolonged-release, amino acid food for special medical purposes (FSMPs), developed using our Physiomimic Technology™ drug delivery platform, for the dietary management of phenylketonuria (PKU). PKU GOLIKE has been available in Europe since 2018. Then in late October 2022, with Pentec Health Inc., a leading national distributor in place, our newly assembled commercial team initiated the U.S. launch. Recently, Pentec acquired another distributor, ZOIA Pharma, which will broaden our reach into commercial payors and greatly improve reimbursement capabilities for GOLIKE patients and their families.

Our PKU GOLIKE BAR® product, which became available this year in two flavors in the U.S. and Europe, has been well received as an exciting new addition to the limited existing options for PKU patients. In the U.S., we continue to make significant progress, meeting with new dietitians, sending out more samples and converting sample users to sustained therapy users due in no small part to our successes in obtaining reimbursement with an increasing number of state-based reimbursement agencies and private payers. I have accompanied members of our U.S. sales team to meet with patients, their parents and registered dietitians. I am very pleased to see their reaction when sampling our products as they learn and discover the variety that PKU GOLIKE® brings to their dietary options. We are excited to continue our work with the PKU community and add more flavors and other forms of PKU GOLIKE®, including savory products such as crackers and biscuits that are currently in late-stage development. In June 2023, we announced an exclusive, long-term, distribution agreement with the World Orphan Disease Alliance (WODA) to introduce PKU GOLIKE® in the Middle East region.

Our development of a novel dosage form of an already FDA-approved prescription drug for the treatment of PKU is ongoing. This improved product, codenamed RLF-OD032, is expected to increase patient acceptance and compliance as well as enable easier, self or caregiver administered metered dosing and dispensing. We are expecting to start a pilot clinical study in Q1 2024 and anticipate filing for FDA approval in Q1 – Q2 2025 via a 505(b)(2) NDA for an anticipated commercial launch in Q4 2025 – Q1 2026. In December 2022, we and our collaboration partner Acer announced the U.S. Food and Drug Administration (FDA) approval of OLPRUVA™ for oral suspension for the long-term management of patients with certain UCDs. In Q3 2023, OLPRUVA™ became available to patients in the U.S. with a strategy to price the treatment competitively against currently available products.

We also made several advancements in our rare pulmonary disease program in the first half of 2023. In April 2023, we announced twelve-month stability data for our new formulation of RLF 100® which is shelf-stable at temperatures suitable for shipping and long-term storage, thus, potentially having significant clinical and commercial value. We have filed a new provisional patent application based on those results. Our objective is to establish our proprietary and patent-protected formulation of aviptadil acetate, RLF-100®, as the standard of care for the prevention and treatment of respiratory failure and its complications in both the acute intensive care and chronic ambulatory settings. We continue exploring the development of RLF-100® for the treatment of non-COVID-19-related ARDS, checkpoint inhibitor-induced pneumonitis (CIP), chronic berylliosis and pulmonary sarcoidosis, an indication for which we received an orphan drug designation (ODD) in August of 2020.

Finally, we continue the development of RLF-TD011, a patent-protected hypochlorous acid topical spray developed with our TEHCLO Nanotechnology™ platform in rare dermatological conditions, with an emphasis on connective tissue disorders. Our efforts are primarily focused on epidermolysis bullosa (EB), a devastating rare, inherited skin disease characterized by widely distributed, painful, chronic wounds that easily become infected, resulting in an elevated risk of sepsis and death. There are no cures or currently available therapies for EB. RLF-TD011 was granted ODD by the FDA for the treatment of EB. We are progressing with our proof-of-concept, investigator-initiated trial (IIT) at Northwestern University to evaluate RLF-TD011 as a treatment for EB. Results of this study are expected sometime between Q4 2023 and Q1 2024 depending on the enrollment and treatment pace.

Our existing cash reserves of approximately USD 20.5 million as of August 31, 2023, and projected revenue are expected to provide Relief with a cash runway well into 2025. Our focus is directed on the following:

- Advancing our pipeline: we are excited about the Q3 2023 U.S. launch of OLPRUVA™ for the treatment of UCDs and the anticipated development of OLPRUVA™ for the treatment of maple syrup urine disease (MSUD). We are evaluating filing a marketing authorization application for OLPRUVA™ for the treatment of UCDs in Europe. In addition, we are moving forward with the development of RLF-OD032 for the treatment of PKU. We also intend to advance our RLF-100® and RLF-TD011 programs, which we believe have significant potential in their respective indication fields.
- Maximizing value: we continue the commercial roll out of PKU GOLIKE in the U.S. and expand the PKU GOLIKE line of product offerings. We are actively working on maintaining and developing economic benefits from our legacy products to support our operations. We are also exploring new opportunities to leverage our drug delivery platform technologies.

- Expanding our portfolio: we continue to pursue a strategy to diversify our pipeline and bring assets to patients as quickly as possible through the ongoing evaluation of potential in-licensing opportunities that fit our profile and seeking partnerships with, or acquisitions of, companies with late-stage clinical molecules with a strong human safety profile, allowing for relatively short, capital-efficient clinical trials with clear endpoints.

I thank our employees and the many other people who make our work possible including our partners and collaborators, researchers, physicians, geneticists, dieticians, nutritionists and, especially, patients and their families. I also welcome our newest institutional and individual shareholders to the Relief family, and extend my thanks to our long-term shareholders for their continued support and trust in our vision. We are confident that our continued progress will enable us to deliver significant value to our shareholders in the long term. We remain united in our commitment to provide much needed relief to those suffering from rare and debilitating disorders. Thank you.

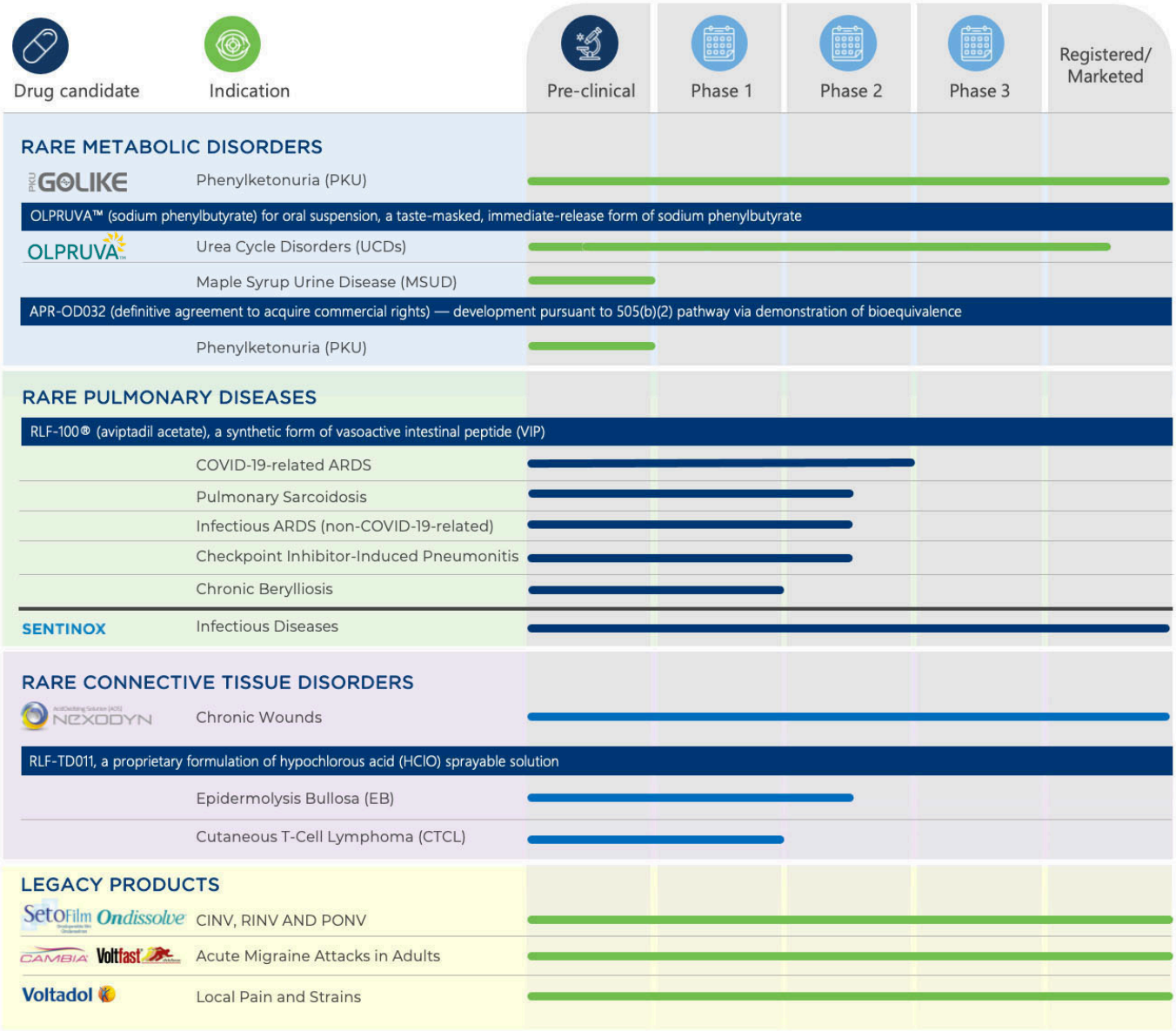
Sincerely,

Jack Weinstein
Chief Executive Officer
Relief Therapeutics

PORTFOLIO & PIPELINE

PORTFOLIO & PIPELINE

Relief's clinical development program currently focuses on pulmonary diseases and rare genetic, metabolic, and connective tissue disorders, with particular emphasis on conditions with dermatological manifestations. The diversified pipeline consists of differentiated assets that have the potential to effectively address significant unmet medical needs. In addition, the Company is commercializing several legacy products via licensing and distribution partners.



DRUG DELIVERY PLATFORM TECHNOLOGIES

Our drug delivery platform technologies enable us to optimize the therapeutic potential of established products with proven efficacy, known safety profiles or where proof-of-concept exists. These platforms have utility for development in other specialty or rare disease therapeutic areas, partnerships and out-licensing.

TEHCLO NANOTECHNOLOGY™

Our TEHCLO Nanotechnology™ platform consists of our proprietary, globally patent-protected electrode with nanocoating, the method for preparing and making highly stable aqueous solutions and our device for the electrolytic treatment of a fluid. The TEHCLO technology was used to develop RLF-TD011, Nexodyn and some of our legacy products.

Our TEHCLO intellectual property portfolio consists of four patent families. The first three families include 103 granted patents worldwide directed to systems and methods for generating APR's hypochlorous acid solution, compositions comprising APR's hypochlorous acid solution and methods for treating ocular disorders. These patents expire between October 2026 and June 2030, exclusive of any patent term adjustments or extensions, or any form of potential exclusivity. The fourth patent family will cover certain medical uses and, if granted, will expire no earlier than July 2040.

PHYSIOMIMIC TECHNOLOGY™

Our Physiomimic Technology™, used in the PKU GOLIKE® product line, is our globally patented, proprietary method to engineer amino acids to modify their release and absorption to mimic the physiological absorption of natural dietary proteins. This technology provides extended-release and taste and odor masking of the amino acids.

Our PKU GOLIKE® intellectual property portfolio consists of two patent families including 32 pending applications and 51 granted patents worldwide. Patents resulting from these families, if granted, will expire no earlier than 2036 and 2038, respectively, exclusive of any patent term adjustments or extensions, or any form of potential exclusivity.

RARE METABOLIC DISORDERS

PKU GOLIKE® FOR PHENYLKETONURIA

The PKU GOLIKE® line of products comprises phenylalanine-free foods for special medical purposes (FSMPs) for the dietary management of phenylketonuria (PKU) in both children and adults. Engineered with the Physiomimic Technology™, the Company's proprietary, patent-protected, drug delivery platform. PKU GOLIKE is the first prolonged-release amino acid mix product that mirrors the absorption profile of natural dietary proteins while offering effective taste and odor masking.

PKU is a rare, inherited disorder affecting more than 450'000 patients worldwide.[1] PKU is caused by a defect of the enzyme needed to break down phenylalanine (Phe), leading to a toxic buildup of Phe from the consumption of foods containing protein or aspartame. Untreated, PKU can result in global developmental delay or severe irreversible intellectual disability, as well as growth failure, hypopigmentation, motor deficits, ataxia and seizures.[2]

Living with PKU requires a very strict, life-long, low protein diet and precise careful management. People living with PKU do not have the ability to metabolize Phe, which is found in most foods, and they require daily and high quantity supplementation of amino acid based FSMPs to prevent protein deficiency and optimize metabolic control. Currently available FSMPs may lead to poor or suboptimal clinical outcomes and compliance because they are rapidly absorbed and are characterized by an unpleasant odor and aftertaste. Such factors contribute to barriers to social interaction for PKU patients, further limiting FSMP compliance and exposing patients to the risks of poor disease control.[3]

PKU GOLIKE granules are flavorless and can be mixed with many foods. PKU GOLIKE products contain all 19 amino acids that people with PKU need to maintain neurological and muscular health and is fortified with 27 essential vitamins and minerals, including ones normally found in protein-rich foods like iron, calcium, and vitamin B12. The PKU GOLIKE line of products is available in convenient packets (PKU GOLIKE *Plus*® 3-16 and 16+), medical food bars (PKU GOLIKE BAR®) and tablets to be chewed (PKU GOLIKE KRUNCH®). PKU GOLIKE products are uniquely differentiated, offering improved metabolic management and the opportunity for better compliance for PKU patients of all age groups.

PKU GOLIKE is currently sold by a direct sales and marketing organization in the U.S., Germany, Italy, Switzerland, and Austria, and is marketed in the UK, Spain, Portugal, Israel and certain Middle Eastern countries by local distributors. PKU GOLIKE is available by prescription only and is considered a life-saving option for PKU patients.

PKU GOLIKE products have been commercially available in Europe since 2018. Relief launched the PKU GOLIKE family of products in the U.S. in late October 2022, with its recently assembled commercial infrastructure and team. In early 2023, the Company announced the U.S. and EU availability of the new PKU GOLIKE BARs in red fruit and tropical fruit flavors. These bars contain only natural fruits and have no added artificial flavors or colorants. More flavors of the bars and other forms of PKU GOLIKE, including savory options such as crackers and biscuits, are currently in late-stage development.

On August 23, 2022, APR was issued U.S. patent number 11,419,837, which covers certain formulations of PKU GOLIKE and supplements the PKU GOLIKE intellectual property portfolio, which includes U.S. patent number 10,500,180, which was issued on December 10, 2019. The patents will expire no earlier than September 27, 2036.

In March 2023, the Company presented the findings from pre-clinical research evaluating the metabolic impact of PKU GOLIKE on nitrogen balance, muscle strength and glucose in a poster session at the Society for Inherited Metabolic Disorders (SIMD) 44th Annual Meeting. The poster summarized the 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. Due to the prolonged release of the amino acids, beneficial effects were observed on amino acid oxidation, muscle metabolism, grip strength and glucose tolerance in healthy rats. BUN (blood urine nitrogen test) was significantly lower in the acute treatment with PKU GOLIKE indicating the potential to improve amino acid utilization in PKU patients resulting in a reduction of catabolic episodes. The results from this pre-clinical research demonstrate the important body composition benefits of the physiological absorption of our prolonged-release amino acid supplement PKU GOLIKE. Detailed results from this study are available on the Relief website.

Relief plans to expand the PKU GOLIKE commercial infrastructure beyond the current countries to increase and accelerate future growth. This will be supported by newer formulations of PKU GOLIKE.

OLPRUVA™ (SODIUM PHENYLBUTYRATE, ACER-001) FOR ORAL SUSPENSION

In March 2021, Relief signed a collaboration and license agreement with Acer Therapeutics Inc. (Acer) for the worldwide development and commercialization of ACER-001 (sodium phenylbutyrate) for the treatment of various inborn errors of metabolism, including urea cycle disorders (UCDs) and maple syrup urine disease (MSUD). In August 2023, Relief and Acer announced a new exclusive definitive licensing agreement for the development and commercialization of OLPRUVA™ for the treatment of certain UCDs and other potential indications. This agreement supersedes the March 2021 collaboration and license agreement between the companies.

ACER-001 is a proprietary, coated powder formulation of sodium phenylbutyrate (NaPB) designed to be both taste-masked and immediate release. ACER-001 was developed using a multiple coating process, and the microparticles consist of an inert core center, a coated layer of active drug and a final taste-masking coating that quickly dissolves in the stomach to avoid a bitter taste while still allowing for rapid systemic absorption. ACER-001's taste-masked formulation is designed to improve the palatability of NaPB and could make it a compelling alternative to existing NaPB-based treatments, as the unpleasant taste associated with NaPB is cited as a major impediment to patient compliance with those treatments. Additionally, bioequivalence trials have shown ACER-001 to have similar relative bioavailability to BUPHENYL® under both fasted and fed conditions, along with significantly lower projected pricing compared to RAVICTI®.[4]

On December 22, 2022, the U.S. Food and Drug Administration (FDA) approved ACER-001 under the brand name OLPRUVA™ (sodium phenylbutyrate for oral suspension) as a prescription medicine for use with certain therapy, including changes in diet, for the long-term management of adults and children weighing 44 pounds (20 kg) or greater and with a body surface area (BSA) of 1.2 m^2 or greater, with UCDs, involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS). OLPRUVA™ is not used to treat rapid increase of ammonia in the blood (acute hyperammonemia), which can be life-threatening and requires emergency medical treatment.[5] Please see Important Safety Information and full Prescribing Information, including Patient Information.

On August 14, 2023, Acer announced that OLPRUVA™ kits were commercially available in all dosage strengths. Acer also announced its intention to add commercial and medical affairs resources, and the introduction of its patient support service called OLPRUVA™ Navigator.

OLPRUVA™ received FDA approval under section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (FDCA), a regulatory pathway that allows applicants to rely, at least in part, on third-party data for approval. In Acer's new drug application (NDA), the Company cited pre-clinical and clinical safety and efficacy data from the reference listed drug (RLD), BUPHENYL® powder, which is approved as adjunctive therapy in the chronic management of patients with UCDs involving deficiencies of CPS, OTC or AS. In Acer's NDA, the Company also provided additional data including studies that evaluated the bioavailability and bioequivalence of OLPRUVA™ compared to BUPHENYL® powder. The data from these studies, presented at the Society for Inherited Metabolic Disorders (SIMD) Annual Meeting in April 2022 and the Genetic Metabolic Dieticians International (GMDI) Conference in May 2022, showed that OLPRUVA™ was bioequivalent to BUPHENYL® powder.[6,7]

Acer maintains its own intellectual property portfolio. Acer's patent portfolio for ACER-001 consists of three patent families. The first family includes 41 granted patents worldwide directed towards novel sodium phenylbutyrate particle formulations and methods of use. These patents have an expiration date of October 2036, exclusive of any patent term adjustments or extensions, or any form of potential exclusivity. If granted, additional patents would expire no earlier than October 2036. Acer's patent portfolio further includes PCT/US2021/040760 and PCT/US2022/040082. Patents granted from applications claiming priority to PCT/US2021/040760 will expire in July 2041, excluding any patent term adjustments or extensions, or any form of potential exclusivity. Patents granted from applications claiming priority to PCT/US2022/040082 will expire in April 2042, excluding any patent term adjustments or extensions or any form of potential exclusivity.

OLPRUVA IN UREA CYCLE DISORDERS (UCDS)

Urea cycle disorders (UCDs) are a group of rare, genetic disorders that can cause harmful ammonia to build up in the blood, potentially resulting in brain damage and neurocognitive impairments, if ammonia levels are not controlled. Any increase in ammonia over time is serious.[8] Therefore, it is important to adhere to any dietary protein restrictions and have alternative medication options to help control ammonia levels.

UCDs are a group of disorders caused by genetic mutations that result in a deficiency in any one of the six enzymes that catalyze the urea cycle, which can lead to an excess accumulation of ammonia in the bloodstream, a condition known as hyperammonemia. Acute hyperammonemia can cause lethargy, somnolence, coma and multi-organ failure. Chronic hyperammonemia can lead to headaches, confusion, lethargy, failure to thrive, behavioral changes and learning and cognitive deficits. Common symptoms of both acute and chronic hyperammonemia also include seizures and psychiatric symptoms.

The current treatment of UCDs consists of dietary management to limit ammonia production in conjunction with medications that provide alternative pathways for removing ammonia from the bloodstream. Some patients may also require individual branched-chain amino acid supplementation. Current medical treatments for UCDs include nitrogen scavengers, RAVICTI® and BUPHENYL®, in which the active pharmaceutical ingredients are glycerol phenylbutyrate (GPB) and NaPB, respectively. Their role is to provide an alternative way to excrete excessive nitrogen. According to a 2016 study by Shchelochkov et al., published in *Molecular Genetics and Metabolism Reports*, while nitrogen scavenging medications have been shown to be effective in helping to manage ammonia levels in some patients with UCDs, non-compliance with treatment is common. Reasons referenced for non-compliance associated with some available medications include unpleasant taste, the frequency with which medication must be taken, the number of pills and the high cost of the medication.

OLPRUVA™ for oral suspension is a proprietary and novel formulation that leverages the well-established efficacy of sodium phenylbutyrate in a novel, innovative dual-coating formulation designed for improved convenience and palatability[9] and will be available in single-dose envelopes, which may help people living with UCD to manage their condition.

In March 2023, Acer presented survey results at the 44th Annual Meeting of the Society for Inherited Metabolic Disorders. Data from a survey of UCD healthcare providers showed that optimizing nitrogen-binding medications for UCD treatment to facilitate and encourage increased patient adherence through masking taste/odor and/or enhancing other aspects of the patient experience may support improved outcomes in UCDs.

In accordance with Relief's exclusive license agreement with Acer, we intend to submit a marketing authorization application for approval of OLPRUVA for the treatment of UCDs in the UK and EU, subject to the performance of certain bridging studies necessary to extend the approval received in the United States into other countries of Europe where the access and reimbursement landscape is more favorable.

OLPRUVA IN MAPLE SYRUP URINE DISEASE (MSUD)

Maple syrup urine disease (MSUD) is a rare inherited disorder caused by defects in the mitochondrial branched-chain ketoacid dehydrogenase complex, which results in elevated blood levels of the branched-chain amino acids (BCAA), leucine, valine and isoleucine, as well as the associated branched-chain ketoacids (BCKA) in a patient's blood. Left untreated, this can result in neurological damage, mental disability, coma or death. There are currently no approved pharmacologic therapies in the U.S. or Europe for MSUD. Treatment of MSUD consists primarily of a severely restricted diet to limit the intake of BCAA, with aggressive medical interventions when blood levels of BCAA or BCKA become elevated.[10]

NaPB is approved for people with UCDs to control their ammonia levels in conjunction with a restricted diet. People with UCDs who are treated with NaPB have been found to have a BCAA deficiency, despite adequate dietary protein intake. Based on this clinical observation, NaPB is being explored as a treatment to lower BCAA and their corresponding BCKA in patients with MSUD.[11]

The FDA and EMA have granted orphan drug designation (ODD) to ACER-001 (OLPRUVA) for the MSUD indication.

Acer has been issued several patents protecting the usage of and composition of ACER-001. The recent approval of U.S. patent 11,202,767 covers methods of use claims related to ACER-001's multi-particulate dosage formulation for oral administration for the potential treatment of UCDs and MSUD and supplements previous issuance of U.S. patent 11,154,521 which covers pharmaceutical composition claims of ACER-001. Both patents have an expiration date in 2036. In addition, the China National Intellectual Property Administration (CNIPA) has issued Electronic Patent Certificate ZL202122004991.9 for the Utility Model patent directed to ACER-001. Specifically, the patent covers dosage form claims related to ACER-001's polymer coated formulation for oral administration as a potential treatment for UCDs and MSUD. This patent has an expiration date of August 24, 2031, and provides protection for ACER-001 in the context of potential commercialization in China. Acer has submitted an investigational new drug (IND) application to the FDA to evaluate the safety and efficacy of OLPRUVA for the potential treatment of MSUD. Acer expects to start clinical studies in MSUD, subject to available capital. It is anticipated that the data from these studies will be suitable for product registration in the U.S. and Europe and Relief expects to use such data to start the registration process in Europe.

RLF-OD032 IN PKU

In July 2022, Relief entered into a definitive agreement with the UK-based company Meta Healthcare Ltd. (Meta). Pursuant to the agreement, the Company has acquired the worldwide rights, title and interest, except in the UK, for a novel dosage form of a prescription drug already approved by the FDA and intended for the treatment of patients with phenylketonuria (PKU). This improved product is expected to increase patient acceptance and compliance as well as enable easier, self or caregiver administered metered dosing and dispensing.

According to the terms of the agreement, Meta transferred to Relief all data, know-how, as well as any intellectual property as developed or generated so far by Meta. Relief shall only be responsible for funding the remaining development work as well as for filing and prosecuting an NDA in all countries worldwide except for the UK where Relief shall grant a license back to Meta, enabling Meta to directly promote and commercialize the product in such country. Other than the initial acquisition payment and low double-digit royalty payments on net profit of the product in the various countries, Relief shall be under no obligation to fund or pay any other amount to Meta.

Relief expects to start the pilot clinical study in Q1 2024 and anticipate filing for FDA approval in Q1 – Q2 2025 via a 505(b)(2) NDA for an anticipated commercial launch in Q4 2025 – Q1 2026.

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RARE PULMONARY DISEASES

RLF-100® (AVIPTADIL ACETATE)

Aviptadil is a synthetic form of vasoactive intestinal peptide (VIP) consisting of 28 amino acids, which was first discovered in 1970. Although initially identified in the intestinal tract, human VIP is now known to be produced throughout the body and to be primarily concentrated in the lungs. VIP has shown a multimodal mechanism of action: decrease of inflammatory cytokines release leading to prevention of cytokine storm syndrome and viral replication, immunomodulating effect, vasodilating and bronchodilating effects and prevention of surfactant depletion. 70 percent of VIP in the body is bound to a less common type of cell in the lung, the alveolar epithelial type II (AT2) cell, which is critical to the absorption of oxygen into the body.

Aviptadil has a 20-year history of safe use in humans. For example, a combination of aviptadil with phentolamine is approved for the treatment of erectile dysfunction by intra-cavernous injections in countries outside the U.S.

It is our objective to establish our proprietary and patent-protected formulation of aviptadil, RLF-100® as the standard of care for the prevention and treatment of respiratory failure and its complications in both the acute intensive care and chronic ambulatory settings.

Since RLF-100's mechanism of action is not restricted to the protection of AT2 cells, we believe that its beneficial effects could extend to other types of acute lung injury (ALI) as supported by pre-clinical and preliminary clinical data in sepsis-induced ALI.

In April 2023, we announced twelve-month stability data for our new formulation of RLF-100 which is shelf-stable at all temperatures tested that are suitable for shipping and long-term storage, thus, potentially having significant clinical and commercial value. We have filed a new provisional patent application based on those results.

We continue exploring the development of RLF-100 for the treatment of COVID-19 and non-COVID-19-related ARDS, checkpoint inhibitor-induced pneumonitis (CIP), chronic berylliosis and pulmonary sarcoidosis, an indication for which we received ODD in August of 2020.

AVIPTADIL ACETATE IN COVID-19-RELATED ACUTE RESPIRATORY DISTRESS SYNDROME (ARDS)

In March 2020, at the beginning of the first wave of the pandemic in the U.S., our former collaboration partner, NeuroRx Inc. (NeuroRx), submitted an IND application to the FDA for a Phase 2b/3 trial of intravenous (IV) aviptadil for the treatment of patients with critical COVID-19 respiratory failure. Within 24 hours, the FDA issued a "Study May Proceed" letter and the first patients were treated in April 2020 at Thomas Jefferson University Hospital in Philadelphia.

In late 2020, a Phase 2b/3 clinical study with aviptadil IV in patients with COVID-19-induced acute respiratory distress syndrome (ARDS) was completed in the U.S. by NeuroRx. In its press release reporting those results, NeuroRx announced that across all patients and sites, the aviptadil IV treated cohort met the primary endpoint for successful recovery from respiratory failure at days 28 (p=0.14) and 60 (p=0.13) and had a meaningful survival benefit after controlling for ventilation status and clinical site. However, they also reported that the trial did not demonstrate a statistically significant difference on the study's primary endpoint without statistical adjustment for these pre-specified covariates. Based on these findings, NeuroRx announced on June 1, 2021, the company applied to the FDA for Emergency Use Authorization (EUA) for aviptadil IV for the treatment of acute respiratory failure due to critical COVID-19 and that it planned to submit an NDA with the FDA. On November 5, 2021, NeuroRx announced the FDA declined its application for EUA of aviptadil IV for the treatment of acute respiratory failure due to critical COVID-19. Subsequent applications filed by NeuroRx with the FDA seeking EUA for more limited use of the product for the treatment of COVID-19 and for breakthrough therapy designation for the product were also denied in the first half of 2022.

In March 2021, NeuroRx announced that aviptadil IV was included in a National Institute of Health (NIH)-sponsored Phase 3 ACTIV-3b/TESICO clinical trial in severely ill patients with COVID-19. In May 2022, Relief learned trial was discontinued by its Data Safety Monitoring Board (DSMB) based on futility.

In December 2022, NeuroRx transferred to Relief all of the assets it used in the NRx aviptadil development program, including the regulatory filings, patent applications, clinical data, and the formulation of the aviptadil product it was previously developing. Relief now has the exclusive right and control going forward and the obligation to use commercially reasonable efforts to develop and commercialize an aviptadil product. NeuroRx has agreed not to compete in the development of an aviptadil product in the future.

While regulatory approval for aviptadil IV to treat COVID-19-induced ARDS has not been granted in the U.S., an unrelated pharmaceutical company received approval for this indication in India in early 2022 for their formulation of aviptadil, thereby substantiating Relief's original hypothesis.

Inhaled RLF-100® is being evaluated in an investigator-initiated trial at a site in Switzerland for the treatment of ARDS associated with COVID-19 (Leuppi/NCT04536350). While the study is in an advanced stage of recruitment, changing disease patterns have hindered the completion of patient recruitment. The lead investigator has reported that top-line data is now expected in the first quarter of 2024, subject to successful completion of patient enrolment, which remains challenging.

RLF-100® ADDITIONAL OPPORTUNITIES

RLF-100® is under development in both inhaled and IV formulations for other acute and chronic lung diseases, including as a potential treatment of pulmonary sarcoidosis, non-COVID-19-related acute respiratory distress syndrome (ARDS), checkpoint inhibitor-induced pneumonitis (CIP) and chronic berylliosis.

PULMONARY SARCOIDOSIS

Sarcoidosis is an inflammatory disease characterized by the formation of granulomas—tiny clumps of inflammatory cells that can develop in any part of the body. When the disease occurs in the lungs, it is called pulmonary sarcoidosis and is a form of interstitial lung disease (ILD) which are a group of immune-mediated disorders that cause progressive fibrosis of the lung interstitium (the extravascular and extracellular space between cells in tissue). The granulomas disrupt the intake of oxygen and can cause scarring on the lungs, preventing the lungs stretching fully, and therefore limiting their capacity. The prognosis for patients with pulmonary sarcoidosis ranges from benign and self-limiting to chronic, debilitating disease and death. Despite increasing advances in research, pulmonary sarcoidosis remains difficult to diagnose with limited treatment options to manage symptoms and no known cure. According to the Foundation for Sarcoidosis Research, approximately 200'000 Americans live with pulmonary sarcoidosis. Relief was granted ODD by the FDA for inhaled RLF-100 for the treatment of pulmonary sarcoidosis in August 2021.

CHECKPOINT INHIBITOR-INDUCED PNEUMONITIS (CIP)

Checkpoint inhibitor-induced pneumonitis (CIP) is a rare, potentially fatal form of lung inflammation following treatment with immune checkpoint inhibitors (ICIs). ICIs are a type of immune therapy used to treat cancer. CIP can result in cough, dyspnea, fever, chest pain, and in severe cases, lack of oxygen in the lungs (hypoxia) and respiratory distress. The use of inhaled RLF-100 for this indication will be further evaluated to explore whether such use could enhance compliance with chemotherapy and improve outcomes for cancer patients. Relief received a Swiss method-of-use patent protection related to the inhaled formulation of RLF-100 for the potential treatment of CIP extending into at least 2039.

BERYLLIOSIS / CHRONIC BERYLLIUM DISEASE (CBD)

Chronic beryllium disease (CBD) is an orphan lung disease caused by the inhalation of beryllium particles, dust or fumes in the workplace, resulting in severe inflammation of the lungs, coughing and increasing breathlessness (dyspnea). CBD is a clinical phenocopy of sarcoidosis. Currently there are no treatments approved for berylliosis. The *ex-vivo* effect of RLF-100 on mononuclear cells in the setting of CBD is currently being evaluated. Together with the results from the Phase 2b sarcoidosis trial, these results would justify the therapeutic use of inhaled RLF-100 in CBD, providing a rationale for the clinical trial design in this indication.

NON-COVID-19-RELATED, INFECTIOUS ACUTE RESPIRATORY DISTRESS SYNDROME (ARDS)

Infectious acute respiratory distress syndrome (ARDS) is a potentially life-threatening condition in which the lungs become severely inflamed, leading to buildup of fluid in the lungs, preventing oxygen from getting to the bloodstream and the rest of the body. Infectious ARDS results from an injury or an infection (such as pneumonia, severe flu, sepsis, etc.) of the air sacs in the lung. Plans for clinical trials of RLF-100 for the treatment of infectious ARDS are in development.

SENTINOX

Sentinox, is a novel, acid-oxidizing solution containing hypochlorous acid in a nasal spray formulation that was developed by APR. Sentinox was certified in Europe on February 16, 2021, as a Class III medical device (certificate number EPT 0477.MDD21/4200.1). Sentinox is intended for irrigation, cleansing and moistening of the nasal cavities and is indicated to reduce the risk of infections caused by bacteria and viruses, including SARS-CoV-2, by lowering the nasal microbial load; symptomatic nasal care; and nasal care in cases of minor lesions/ alterations of the nasal mucosa.

Sentinox was evaluated in a randomized, controlled clinical trial to establish the efficacy and safety of the product in reducing viral load in the upper respiratory airways in recently COVID-19 infected individuals. The results were reported in March 2022. Considering the small sample size and the high variability in the baseline viral load observed within study groups, the primary endpoint was not reached; however, the results suggest the potential efficacy of Sentinox in the reduction of the nasal viral load, negativization and infectivity and confirmed its safety and tolerability. As a result, we initiated a confirmatory, controlled clinical trial in the prevention of viral and bacterial airborne infections in the fourth quarter of 2022. However, due to funding constraints and currently limited market potential given the evolution of the COVID-19 pandemic, we halted research and development activities related to Sentinox in the first half of 2023. Resumption may be implemented upon securing additional funding or collaborative partnerships.

RARE CONNECTIVE TISSUE DISORDERS

NEXODYN®

Nexodyn® acid-oxidizing solution (AOS) is proven to restart healing in chronic wounds by creating an ideal microenvironment to sustain the physiological healing process. A wealth of evidence and real-world experience has consistently shown accelerated wound closure with reduced infection rates and less wound-associated pain.

Nexodyn was developed using APR's proprietary TEHCLO Nanotechnology® and is a highly pure and stabilized hypochlorous acid (HClO >95% of free chlorine species), with acidic pH (2.5 - 3.0) and high reduction-oxidation potential (ORP 1.000 – 1.200 mV). The product is a self-administered sprayable solution with ancillary antimicrobial properties intended for use in the debridement, irrigation, cleansing and moistening of acute and chronic wounds (e.g., diabetic foot ulcers, pressure ulcers and vascular ulcers), post-surgical wounds, burns and other lesions. The product is certified in Europe as a Class III medical device and is certified as a 510(k) medical device in the U.S.

The anti-microbial and anti-inflammatory properties of Nexodyn AOS, along with its tolerability, absence of systemic exposure and convenient contactless delivery for topical applications could make this an attractive treatment candidate for the management of wounds in epidermolysis bullosa (EB), with the potential to be the only product approved for the control of wound infection in this disease, thereby reducing long-term antibiotic use, while assisting wound healing and decreasing wound-related pain, all of which would significantly benefit quality of life in patients with this genetic disorder.

RLF-TD011 IN EPIDERMOLYSIS BULLOSA

RLF-TD011 is a differentiated acid oxidizing solution of hypochlorous acid (HCIO) that combines strong antimicrobial action with anti-inflammatory properties, thereby allowing for infection control, reduction of wound colonization, alleviation of pain and itching and improved wound healing.

Developed with APR's proprietary, patent-protected TEHCLO Nanotechnology®, RLF-TD011 employs an exclusive combination of three physio-chemical properties – high-purity HCIO, hypotonic low pH and high oxidation-reduction potential (ORP), which is believed to support a faster physiological healing of wounds by creating a favorable wound microenvironment. HCIO is well known as a broad-spectrum, fast acting antimicrobial agent, which reinforced by low pH and high ORP contributes to the prevention and treatment of skin infections.

RLF-TD011 is an investigational drug candidate that has the potential for the treatment of wounds in epidermolysis bullosa (EB) as it is a self-administered, sprayable solution enabling targeted application while avoiding skin contact and cross-contamination. EB, also known as "Butterfly Skin," is a group of rare, genetic, life-threatening connective tissue disorders characterized by skin fragility and blistering, which may appear in response to minor injury, even from heat, rubbing or scratching. These widely distributed, painful, chronic wounds can easily become infected, resulting in an elevated risk of sepsis and death. A crucial element of patient management involves rigorous and timely wound care.

Subject to clinical demonstration of efficacy and safety in clinical trials, RLF-TD011 could play an important role in the reduction of inflammation by inhibiting the NF-kB pro-inflammatory pathway and, at the same time, may offer a faster wound healing in EB patients and by reducing the itching and pain linked to infections and inflammation. RLF-TD011 has consistently been shown to accelerate wound closure with reduced infection rates in clinical trials.[1,2,3] In a preliminary clinical trial, EB patients who administered RLF-TD011 demonstrated improvement in skin blistering and tissue repair within just two weeks of treatment, and the product candidate was shown to be well tolerated with a favorable safety profile.

In February 2023, Relief Therapeutics announced the first three patients were enrolled in a proof-of-concept, investigator-initiated study to evaluate RLF-TD011 as a treatment for EB (NCT05533866). Results of this study are expected sometime between Q4 2023 and Q1 2024 depending on the enrollment and treatment pace. The primary aim of this study will be to assess changes in the skin microbiome *(Staphylococcus aureus, Pseudomonas aeruginosa,* commensal organisms*)* before, during and after treatment with RLF-TD011.

RLF-TD011 was granted ODD by the FDA for the treatment of EB, which qualifies the sponsor of the treatment for certain development incentives, including seven-year marketing exclusivity after FDA marketing approval is received. Relief Therapeutics intends to seek qualified infectious disease product (QIDP) designation status for RLF-TD011, which may confer up to an additional five years of market exclusivity regardless of patent protection status. Good Manufacturing Practice (GMP) grade product is being prepared for clinical development under an FDA-authorized IND.

There are four main types of EB, which are classified based on the depth, or level, of blister formation: EB simplex (EBS), junctional EB (JEB), dystrophic EB (DEB) and Kindler syndrome.[4] In severe cases, the blisters may develop into chronic wounds or occur inside the body, such as the lining of the mouth or stomach. Patients with JEB and DEB are at increased risk for serious complications, including aggressive squamous cell carcinoma.[5] The National Epidermolysis Bullosa Registry (NEBR) reports, based on 16 years of data, that the incidence of EB in the U.S. is 19.57 per 1 million live births and the prevalence is 11.07 per 1 million population.[6] Worldwide, EB impacts 500'000 lives.[7] Currently there is no cure or approved

treatments for EB in the U.S. and RLF-TD011 could represent the first product specifically indicated for EB patients that provides a comprehensive solution to prevent or reduce wound colonization and infection. This, along with its anti-inflammatory action, could provide symptom relief and wound healing. The Company estimates the global market opportunity for EB to exceed USD 1.0 billion.

RLF-TD011 IN ONCOLOGY SUPPORTIVE CARE

RLF-TD011 is currently approved in Europe as a Class III medical device for the treatment of skin lesions and toxicities induced by cancer treatments, including anti-epidermal growth factor receptors (anti-EGFR) monoclonal antibodies, such as Cetuximab. The use of anti-EGFR inhibitors causes papulopustular manifestations due to their interference of epidermal growth factor receptor (EGFR) signaling in the skin with a high risk of secondary infections. Following commercial assessment, the company is planning to conduct a follow-on clinical study to renew product approval in Europe as a Class III medical device beyond 2024, when the new EU device regulations will apply. This clinical study will be a multi-center, post-market, double-blinded, placebo-controlled trial to evaluate the efficacy, safety and tolerability of RLF-TD011 in the management of skin lesions and reactions resulting from anti-EGFR monoclonal antibodies and/or radiotherapy treatments in oncology patients.

In January 2023, Relief Therapeutics announced that an independent institutional review board (IRB) approved the protocol of an investigator-initiated trial to evaluate RLF-TD011 as an adjunctive treatment for patients diagnosed with cutaneous T-cell lymphoma (CTCL) (NCT05728879). The study is designed to evaluate the effect of RLF-TD011, on the microbiome of CTCL skin lesions and determine tolerability, symptom improvement, and potential for reducing lesion size and skin disease activity. Relief plans to seek external funding or collaborative partnerships to conduct further evaluation of RLF-TD011 in this arena.

CTCL is a rare, heterogeneous group of non-Hodgkin's lymphomas characterized by abnormal accumulation of malignant t-cells in the skin that can result in the development of rashes, plaques and tumors. Because CTCL is rare and often looks like eczema or another common skin disease, it can be difficult to diagnose.[8] Advanced CTCL lesions harbor *Staphylococcus aureus*, which release toxins that stimulate malignant cells and drive disease progression. This often leads to recurrent skin infections with a high risk for sepsis and death. Treatment of advanced CTCL remains a challenge, with five-year disease-specific survival rates ranging from 70 percent for early stage to 24 percent for advanced disease, with the greatest mortality stemming from bacterial infections.

While there are many types of CTCLs, the most common diagnoses are mycosis fungoides, primary CTCL and primary cutaneous anaplastic large cell lymphoma.[9] The overall incidence rate of CTCL was 8.55 per 1 million with MF being the subtype with the highest incidence, at 5.42 per 1 million.[10] The overall incidence of CTCL in the U.S. and Europe has increased, a reflection of better diagnostic tools and increased awareness among physicians and patients, which has led to improved disease detection.[11]

According to Fortune Business Insights, the North American CTCL therapeutics market size is projected to reach an annual valuation of USD 587.4 million by 2028, registering a 13.6 percent compound annual growth rate (CAGR) in the 2021-2028 period.[12] The market value was estimated to be worth USD 225.9 million in 2020 and reached USD 240.9 million in 2021. The increasing burden of CTCL in the region is slated to increase the demand for novel CTCL therapeutics solutions. Cleveland Clinic reports that more than 3'000 new CTCL patients are diagnosed in the U.S. each year and about 16'000-20'000 individuals suffer from mycosis fungoides, the most common form of CTCL that is linked to skin-localized immune cell stimulation.

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OTHER COLLABORATIONS

INVENIAI

On November 23, 2021, we entered into a collaboration agreement with InveniAI LLC (InveniAI), a U.S.-based company that has pioneered the application of artificial intelligence (AI) and machine learning across the biopharmaceutical and other industries, in order to identify promising drug candidates to treat rare and specialty diseases (the Collaboration Agreement).

Under the terms of the Collaboration Agreement, InveniAI will use its proprietary platform for the identification of potential pharmaceutical product opportunities and the related development pathway in select therapeutic areas by using its Pharma Big Innovation Data Lab, consisting of (i) its proprietary AlphaMeld platform, a cloud-based AI platform that uses its proprietary machine learning and deep learning based neural networks to identify product opportunities in therapeutic areas, (ii) its cross-functional teams at its Integrated Center of Excellence, and (iii) domain expertise, to generate novel pharmaceutical opportunities and the related development pathway for the development of such concepts.

In the collaboration it is expected that InveniAI will use its platform to navigate the volume of data for all regulatory agency approved drugs and their associated active ingredients to identify potential rare and specialty disease indications for development and commercialization by Relief Therapeutics (product concepts). InveniAI will seek to prioritize top product concepts, associated diseases, scientific packages and evidence to support the potential drug development opportunities for Relief Therapeutics. We anticipate the InveniAI platform will complement our existing capabilities in research and development and in drug reformulation. Based on product leads developed by InveniAI, we hope to develop proprietary versions of existing drugs, and to protect those drugs with long-lived intellectual property and defensible product claims.

Under the terms of the Collaboration Agreement, Relief Therapeutics paid InveniAI an initial up-front fee of USD 500’000. We will be required to pay success milestones for any products brought to us in connection with the InveniAI Collaboration Agreement ranging from USD 200’000 per product candidate for which we exercise our option to acquire intellectual property (IP) rights to USD 50 million for any required product reaching USD 1 billion per year in net sales. We will also be required to pay royalties on any such commercialized product in certain countries, a royalty of approximately 3 percent. We are not currently developing any product brought to us by InveniAI, and there can be no assurance that our collaboration with InveniAI will result in the development of new product candidates or product concepts.

LEGACY PRODUCTS

Our legacy products are revenue-generating, approved products marketed in various countries and regions of the world including the U.S. and Europe, originally developed and patented by APR and subsequently licensed to third parties for commercialization in the different territories. The rights on the legacy products were acquired by Relief Therapeutics as part of the 2021 acquisition of APR.

SETOFILM/ONDISSOLVE

SETOFILM is the first prescription-only medicine approved in Europe and Canada, developed as an orodispersible film (ODF) formulation. The product is available in 4 mg and 8 mg doses. Once placed on the tongue, it dissolves in a few seconds and is swallowed with saliva without the need for water. The innovative ODF form may reduce the patient pill burden and enable patients to take their medication virtually anywhere.

The product is indicated for radiotherapy induced nausea and vomiting (RINV), chemotherapy induced nausea and vomiting (CINV) as well as postoperative induced nausea and vomiting (PONV) in both adults and children of 6 months of age or older. The product has been formulated and developed using the RapidFilm drug delivery technology platform and is the form of a soluble film to be placed on the tongue where it dissolves in few seconds thus greatly improving patient compliance and avoiding possible risks of suffocation in kids.

The product is approved in Europe and Canada as prescription a drug, and it is marketed by Norgine B.V. and Takeda Pharmaceuticals respectively under license from APR.

CAMBIA™

Diclofenac potassium is an off-patent, potent non-steroidal anti-inflammatory drug (NSAID) widely used for treating inflammatory conditions and pain management. By applying its patented Dynamic Buffering Technology (DBT), APR developed the first and only NSAID approved by the FDA for the treatment of acute migraine attacks with or without aura in adults. The product is currently marketed as CAMBIA™ by Assertio Therapeutics Inc. (Nasdaq: ASRT) in the U.S. and Miravo Healthcare (formerly Nuvo Pharmaceuticals Inc.) in Canada, under an exclusive, royalty-bearing license agreement with APR.

In January 2022, APR received a notice of allowance from the U.S. Patent and Trademark Office (USPTO) for patent application number 16/713,052 entitled, “Ready to Use Diclofenac Packs” with an expiration date in 2039.

On February 28, 2022, Unimedica Laboratories Pvt. Ltd., India, sent APR a Notice of Certification under the Federal Food, Drug, and Cosmetic Act (FFDCA) related to the filing of an abbreviated new drug application (ANDA) for CAMBIA. While there can be no assurance, it is unlikely that Unimedica will get accelerated approval, and we reserve the right to seek to enforce our patents.

DBT and CAMBIA are currently protected by a family of four patents listed in the FDA Orange Book, all expiring in 2026. In 2023, based on litigation settlements between Assertio and specific generic filers, generic versions of CAMBIA became available in the U.S., significantly reducing our royalty income from CAMBIA. CAMBIA is currently available in the form of a dry powder packed into a single dose envelope to be poured and dissolved in water before administration.

VOLTADOL

Voltadol is a topical, locally applied and locally acting patch delivering diclofenac sodium, an off-patent, potent non-steroidal anti-inflammatory drug (NSAID) for the local treatment of painful, acute conditions such as muscle and joint strains. Unlike heat plaster, the patch contains an anti-inflammatory. It penetrates deep to the source of pain to provide powerful pain relief. The medicated patch provides up to two times more powerful deep pain relief, compared to a non-medicated, non-heated placebo patch. The patch also provides 12 hours continuous release of the active ingredient (diclofenac) to the site of pain. This means the patch only needs to be applied once in the morning and once in the evening to provide effective pain relief. The product is marketed in various countries as an over-the-counter medicine by GlaxoSmithKline (GSK) which recently spun-off the rights to Haleon.

Forward-looking statements: This report contains forward-looking statements, all of which involve certain assumptions, risks and uncertainties that are beyond the control of Relief Therapeutics and could cause our actual results to differ materially from the statements described. Forward-looking statements involve significant risks and uncertainties and actual results may vary materially. Please refer to our Cautionary Statement at the end of the management's discussion and analysis contained within this report.

RELIEF THERAPEUTICS HOLDING SA

Condensed consolidated interim financial statements for the half-year ended June 30, 2023 (unaudited)

CONSOLIDATED INTERIM BALANCE SHEET

in CHF thousands	Notes	June 30, 2023	December 31, 2022
ASSETS			
Intangible assets	6	105'576	162'915
Right-of-use assets	7	2'829	2'642
Property and equipment	8	390	49
Other non-current assets		118	114
Deferred tax assets		506	495
Non-current assets		**109'419**	**166'215**
Inventories	9	450	227
Trade receivables		1'012	1'321
Other current assets	10	2'106	1'798
Cash and cash equivalents		12'792	19'237
Current assets		**16'360**	**22'583**
Total assets		**125'779**	**188'798**
EQUITY AND LIABILITIES			
Share capital	11	56'163	56'163
Reserves		221'590	220'961
Treasury shares		(7'289)	(12'108)
Accumulated losses		(176'098)	(119'599)
Equity		**94'366**	**145'417**
Non-current lease liabilities	7	2'334	2'232
Non-current borrowings	12	13	16
Defined benefit obligations		1'764	1'772
Provisions	13	7'032	7'909
Deferred tax liabilities	24	13'145	20'736
Non-current liabilities		**24'288**	**32'665**
Current lease liabilities	7	531	444
Current borrowings	12	361	372
Trade payables		2'173	1'625
Financial liabilities due to related parties	14	1'313	1'280
Provisions	13	-	3'094
Other current payables and liabilities	15	2'747	3'901
Current liabilities		**7'125**	**10'716**
Total equity and liabilities		**125'779**	**188'798**

The accompanying notes form an integral part of these consolidated interim financial statements.

CONSOLIDATED INTERIM STATEMENT OF COMPREHENSIVE LOSS

in CHF thousands	Notes	Six-month period ended June 30, 2023	2022
Revenue	5	3'023	3'242
Other gains	16	66	563
Total income		**3'089**	**3'805**
Raw materials and consumables expenses	17	(779)	(669)
External selling and distribution expenses	17	(1'442)	(465)
External research and development expenses	18	(933)	(10'637)
Personnel expenses	19	(6'259)	(5'767)
Other administrative expenses	20	(3'462)	(3'963)
Change in fair value of contingent consideration	13	3'962	740
EBITDA		**(5'824)**	**(16'956)**
Impairment expense	21	(55'824)	(8'226)
Amortization and depreciation expense	22	(1'704)	(2'033)
Operating result		**(63'352)**	**(27'215)**
Financial income	23	-	162
Financial expense	23	(790)	(1'056)
Net loss before taxes		**(64'142)**	**(28'109)**
Income taxes	24	7'643	1'609
Net loss for the period		**(56'499)**	**(26'500)**
OTHER COMPREHENSIVE INCOME			
Remeasurement of defined benefit obligation		-	-
Items that will not be reclassified to profit or loss		**-**	**-**
Currency translation differences		415	191
Items that may be reclassified to profit or loss		**415**	**191**
Other comprehensive income for the period, net of tax		**415**	**191**
Total comprehensive loss for the period		**(56'084)**	**(26'309)**
EARNINGS PER SHARE			
Basic and diluted loss per share (in CHF)	25	(5.098)	(2.551)

The accompanying notes form an integral part of these consolidated interim financial statements.

CONSOLIDATED INTERIM STATEMENT OF CASH FLOW

in CHF thousands	Notes	Six-month period ended June 30, 2023	2022
Net loss for the period		(56'499)	(26'500)
Adjustments:			
Income tax gain	24	(7'643)	(1'609)
Amortization and depreciation expense	22	1'704	2'033
Impairment of intangible assets	6	55'734	8'226
Impairment of receivables and inventories		98	77
Reversal of impairment loss on receivables		-	(453)
Gain from fair value adjustments to contingent payments	13	(3'962)	(740)
Finance expenses	23	790	1'056
Finance income	23	-	(12)
Interest expenses on borrowings and lease liabilities		(255)	(166)
Change in defined benefit obligations		-	23
Share-based payment expense	19	511	1'288
Changes in working capital:			
Decrease/(Increase) in inventories		(223)	147
Decrease/(Increase) in trade receivables		301	166
Decrease/(Increase) in other assets		(312)	4'498
(Decrease)/increase in trade payables		577	(146)
(Decrease)/increase in provisions		(136)	(622)
(Decrease)/increase in other payables and liabilities		(1'151)	(1'997)
Cash flow used in operating activities		**(10'466)**	**(14'731)**
Payments for property, plant and equipment		(369)	(25)
Payments for intangible assets	6	-	(107)
Reimbursement for price adjustment on intangible assets	6	149	-
Proceeds from other financial assets		-	469
Milestone payments related to acquisition of subsidiaries		-	(5'120)
Interest received		-	19
Cash flow used in investing activities		**(220)**	**(4'764)**
Proceeds from capital increase	11	4'992	60
Sale of treasury shares	11	17	4'933
Equity transaction costs	11	(487)	(78)
Repayment of lease liabilities		(344)	(178)
Repayment of borrowings		(4)	(75)
Cash flow from financing activities		**4'174**	**4'662**
Net decrease in cash and cash equivalents		**(6'512)**	**(14'833)**
Cash and cash equivalents at beginning of period		19'237	44'761
Exchange difference on cash and cash equivalents		67	(57)
Cash and cash equivalents at end of period		**12'792**	**29'871**

The accompanying notes form an integral part of these consolidated interim financial statements.

CONSOLIDATED INTERIM STATEMENT OF CHANGES IN EQUITY

in CHF thousands	Share capital	Treasury shares	Reserves	Accumulated loss	Total equity
Balance at January 1, 2022	**44'133**	**(2'999)**	**210'147**	**(69'751)**	**181'530**
Result for the period	-	-	-	(26'500)	(26'500)
Other comprehensive income for the period	-	-	191	-	191
Total comprehensive result for the period	**-**	**-**	**191**	**(26'500)**	**(26'309)**
Direct Share Placement program	-	764	4'169	-	4'933
Transaction cost in relation to capital increases	-	-	(78)	-	(78)
Exercise of stock options	30	-	30	-	60
Share-based compensation cost	-	-	1'288	-	1'288
Balance at June 30, 2022	**44'163**	**(2'235)**	**215'747**	**(96'251)**	**161'424**
Balance at January 1, 2023	**56'163**	**(12'108)**	**220'961**	**(119'599)**	**145'417**
Result for the period	-	-	-	(56'499)	(56'499)
Other comprehensive income for the period	-	-	415	-	415
Total comprehensive result for the period	**-**	**-**	**415**	**(56'499)**	**(56'084)**
Direct Share Placement program	-	12	5	-	17
Private placement	-	4'800	195	-	4'995
Withdrawal of fractional shares	-	(12)	(10)	-	(22)
Transaction cost in relation to capital increases	-	-	(487)	-	(487)
Exercise of stock options	-	19	-	-	19
Share-based compensation cost	-	-	511	-	511
Balance at June 30, 2023	**56'163**	**(7'289)**	**221'590**	**(176'098)**	**94'366**

The accompanying notes form an integral part of these consolidated interim financial statements.

1. General information

RELIEF THERAPEUTICS Holding SA ("Relief", the "Company" or the "Group") is a Swiss stock corporation domiciled at 15 Avenue de Sécheron, 1202 Geneva, Switzerland. The Company's shares are listed on the SIX Swiss Exchange (ticker: RLF) and quoted in the U.S. on OTCQB (tickers: RLFTF, RLFTY).

The Group focuses on identification, development and commercialization of novel, patent protected products intended for the treatment of metabolic, dermatological and pulmonary rare diseases with a portfolio of clinical and marketed products that serve unmet patient needs.

In March 2021, Relief signed a collaboration and license agreement with Acer Therapeutics, Inc. ("Acer") for the worldwide development and commercialization of ACER-001 (OLPRUVA™) for the treatment of urea cycle disorders ("UCDs") and maple syrup urine disease ("MSUD"). In December 2022, the FDA approved ACER-001 for the treatment of UCDs in the U.S. In August 2023, Relief and Acer terminated the March 2021 collaboration and license agreement and entered into a new exclusive license agreement for the development and commercialization of ACER-001 for the treatment of UCDs, MSUD, and other potential indications. Under the terms of the new agreement, Acer retains development and commercialization rights worldwide, excluding Europe where Relief retains these rights.

In June 2021, the Group acquired APR Applied Pharma Research SA ("APR"), a privately held Swiss pharmaceutical company specialized in formulating, developing, and commercializing known molecules designed with proprietary drug delivery systems for niche and specialty diseases. The acquisition transformed Relief into a fully integrated commercial-stage biopharmaceutical group. The acquisition further diversified Relief's pipeline and portfolio with both commercial products and clinical-stage programs, provided a commercial infrastructure in Europe and strengthened internal research and development ("R&D") capabilities.

In July 2021, the Group acquired AdVita Lifescience GmbH ("AdVita"). The acquisition strengthened the Group's expertise and intellectual property rights around the inhaled formulation and delivery of aviptadil.

In 2022, Relief established a commercial unit in the U.S. to launch PKU Golike in October 2022 and market potential future products in the U.S. market.

These unaudited condensed consolidated interim financial statements were approved for publication by the Board of Directors on September 14, 2023.

2. New and revised International Financial Reporting Standards (IFRS)

There were no new standards or amendments to existing standards that have a significant impact on the Group's accounting policies and interim financial statements.

3. Summary of significant accounting policies

3.1 Basis of preparation

These condensed consolidated interim financial statements were prepared in accordance with IAS 34 'Interim Financial Reporting' as issued by the International Accounting Standards Board (IASB). They do not include all disclosures that would otherwise be required in a complete set of financial statements and should therefore be read in conjunction with the Group's annual consolidated financial statements for the year ended December 31, 2022. They have been prepared under the historical cost convention, as modified by the revaluation of financial instruments at fair value, and are presented in Swiss francs (CHF). All values are rounded to the nearest thousand (TCHF), except when otherwise indicated.

3.2 Reclassifications

A gain of TCHF 740 on fair value remeasurement of contingent consideration in the comparative period of the consolidated interim statement of comprehensive loss has been reclassified from 'Other gains' to a distinct line 'Change in fair value of contingent consideration' to conform with the current period presentation. This reclassification had no impact on the Group's previously reported financial position or result of operations.

3.3 Significant accounting policies

The accounting policies used in the preparation and presentation of the condensed interim consolidated financial statements are consistent with those applied for the Group's last annual consolidated financial statements for the year ended December 31, 2022.

3.4 Interim measurement note

The business is not subject to any seasonality. Expenses largely depend on the phase of the respective projects, particularly with regard to external research and development procedures.

Costs that incur unevenly during the financial year are anticipated or deferred in the interim report only if it would also be appropriate to anticipate or defer such costs at the end of the financial year.

4. Summary of critical accounting judgments and key sources of estimation uncertainty

The preparation of the consolidated financial statements in conformity with IFRS requires management to make estimates and assumptions that affect the application of policies and reported amounts of assets, liabilities, income, expenses and related disclosures. The estimates and underlying assumptions are based on historical experience and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making the judgments about carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates.

4.1 Critical judgments in applying accounting policies

Critical judgments in applying accounting policies were the same as those applied to the consolidated financial statements for the year ended December 31, 2022.

4.2 Key sources of estimation uncertainty

Key sources of estimation uncertainty were the same as those applied to the consolidated financial statements for the year ended December 31, 2022.

Going concern

These consolidated financial statements have been prepared assuming the Group will continue as a going concern which contemplates the continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business.

As of August 31, 2023, the Group had CHF 18.3 million cash in hand, which includes proceeds of USD 10 million from the renegotiation of licensing terms with Acer (refer to note 29). Based on liquidity forecasts and development plans, existing cash was expected to be sufficient to meet the Group's cash needs for at least the next 12 months.

The Group has primarily relied on external financing to fund its cash needs and has experienced recurring losses. The Group may continue to generate operating losses in the foreseeable future. The Group's long-term viability depends on its ability to raise additional capital until it generates positive cash flows to support its operations. The Group may never achieve sustainable profitability and is exposed to all the risks inherent in establishing a business. Management intends to continue to explore options to obtain additional funding, including public or private financing, or license and collaboration agreements. However, there can be no assurance that capital will be available in sufficient amounts or on acceptable terms. If Relief is unable to obtain the required funding, it will be forced to delay, reduce or eliminate some or all of its research and development programs and of its product portfolio expansion or commercialization efforts, which could adversely affect its business prospects or result in the Group's inability to continue operations.

5. Segment information

5.1 Information on revenue

The disaggregation of the Group's revenue is presented in the following table:

TCHF	01.01.-30.06.2023	01.01.-30.06.2022
Revenue streams		
Royalties	812	1'246
Product sales	2'042	1'369
Licensing fees	-	211
Revenue from research and development services	169	416
Total revenue	**3'023**	**3'242**
Geographical area		
Switzerland	237	639
Europe (excluding Switzerland)	1'319	1'609
North America	735	630
Rest of the world	732	364
Total revenue	**3'023**	**3'242**
Timing of revenue recognition		
Point in time	3'023	3'242
Over time	-	-
Total revenue	**3'023**	**3'242**

5.2 Geographical location of non-current assets

TCHF	June 30, 2023	December 31, 2022
Switzerland	108'565	165'484
Rest of the world	230	122
Total non-current assets *	**108'795**	**165'606**

* Without financial assets and deferred tax assets

6. Intangible assets

TCHF	Technologies, patents and trademarks	Licenses	In-process research and development	Goodwill	Total
Historical cost					
January 1, 2022	**39'357**	**13'729**	**132'395**	**8'658**	**194'139**
Addition	174	-	314	-	**488**
December 31, 2022	**39'531**	**13'729**	**132'709**	**8'658**	**194'627**
Acquisition price adjustment	-	-	(149)	-	**(149)**
June 30, 2023	**39'531**	**13'729**	**132'560**	**8'658**	**194'478**
Accumulated amortization and impairment					
January 1, 2022	**(1'840)**	**-**	**-**	**-**	**(1'840)**
Amortization	(3'448)	-	-	-	**(3'448)**
Impairment	(24'255)	-	(529)	(1'640)	**(26'424)**
December 31, 2022	**(29'543)**	**-**	**(529)**	**(1'640)**	**(31'712)**
Amortization	(965)	(491)	-	-	**(1'456)**
Impairment	-	-	(49'717)	(6'017)	**(55'734)**
June 30, 2023	**(30'508)**	**(491)**	**(50'246)**	**(7'657)**	**(88'902)**
Carrying amount per class					
December 31, 2022	9'988	13'729	132'180	7'018	162'915
June 30, 2023	**9'023**	**13'238**	**82'314**	**1'001**	**105'576**
Carrying amount per asset					
PKU Golike	4'511	-	-	-	**4'511**
Diclofenac	4'512	-	-	360	**4'872**
ACER-001	-	13'238	-	641	**13'879**
RLF-100	-	-	57'290	-	**57'290**
RLF-TD011	-	-	24'858	-	**24'858**
Sentinox	-	-	-	-	**-**
RLF-OD032	-	-	166	-	**166**
June 30, 2023	**9'023**	**13'238**	**82'314**	**1'001**	**105'576**
PKU Golike	4'678	-	-	-	**4'678**
Diclofenac	5'310	-	-	360	**5'670**
ACER-001	-	13'729	-	641	**14'370**
RLF-100	-	-	81'516	3'805	**85'321**
RLF-TD011	-	-	47'392	2'212	**49'604**
Sentinox	-	-	2'958	-	**2'958**
RLF-OD032	-	-	314	-	**314**
December 31, 2022	**9'988**	**13'729**	**132'180**	**7'018**	**162'915**

In December 2022, ACER-001 was approved in the U.S. by the Food and Drug Administration (FDA) for the treatment of Urea Cycle Disorders under the trademark OLPRUVA™. The intangible asset associated with the ACER-001 license is amortized from January 1, 2023, on a straight-line basis over its estimated useful life of 14 years.

Impairment test

Intangible assets with finite lives are amortized over the useful economic life and assessed for impairment whenever there is an indication that the intangible asset may be impaired. Intangible assets with indefinite useful lives are not amortized but are tested for impairment either individually or at the cash-generating unit level. The Group generally tests its intangible assets for impairment at the end of the year, or more frequently if events or changes in circumstances indicate that intangible assets may be impaired. The Group considers the relationship between its market capitalization and its equity book value, among other factors, when reviewing for indication of impairment. As of June 30, 2023, Relief's market capitalization was CHF 33.7 million, representing a significant decrease from CHF 132.2 million as of December 31, 2022, and a large discount to the carrying amount of its net assets, indicating a potential impairment of Relief's intangible assets. Additionally, the Group identified circumstances that negatively affected the recoverable value of its in-development assets. Consequently, the Group carried out impairment tests of its intangible assets and goodwill as of June 30, 2023.

For the purpose of impairment testing, goodwill was allocated to each CGU constituting the sole operating segment of the Group. The recoverable amount of the group of CGUs is based on the cumulated value in use estimated for each CGU or group of CGUs. The Group's material CGUs relate to on-market drugs and drug candidates referred to above. The impairment test was performed by determining the recoverable amount of each CGU as the risk-adjusted net present value of future cashflows.

Key assumptions used in value in use calculations

The estimation of recoverable amounts involves significant management judgment. The values assigned to each assumption on an asset basis are based on historical data from external and internal sources and on management's estimates. The key assumptions used in the valuation models were determined as follows:

- Cash flow projections were based on a financial forecast developed by management, which includes projections for net sales, cost of sales, and development costs. These projections are periodically reviewed and updated by management.
- Revenue projections were based on a product-specific analysis that considered relevant market sizes, disease prevalence, incidence rates, expected market share, expected patent life, and the expected year of regulatory approval for unapproved product candidates based on the current stage of development and expected development plan.
- Forecast periods were defined on a product basis and based on product life cycles. For on-market products, cash flows were projected for each CGU over a period of five years and cash flows beyond the forecast period were extrapolated using an attrition rate of 5% until the expected end of the exclusivity period of each product. For in-process projects, cash flows were projected over a period of up to 20 years, reflecting the length of the development and subsequent commercialization period. Relief's approach to compiling development and commercial forecasts is based on a combination of external sources and internal estimates, which includes the use of patient-based models. This methodology is commonly employed in the pharmaceutical industry and has demonstrated satisfactory results over time. No terminal value was considered.
- Probabilities of success for in-process projects to reach final development and commercialization ranged from 15% to 35%. These probabilities were based on empirical success rate analysis of multi-stage studies for comparable indications, or if this approach could not be applied, management exercised its judgment.
- The pre-tax discount rate was 17.61% based on the assumed cost of capital for the Group (December 31, 2022: 16.54%).

Impairment test conclusion

For the six-month ended June 30, 2023, the Group recognized a non-cash impairment charge of TCHF 55'734 to write down the carrying value of intangible assets associated with RLF-100®, RLF-TD011 and Sentinox™. The impairment charge was recorded in the comprehensive statement of loss under the heading 'Impairment expense'.

As part of a comprehensive strategic review conducted in the second and third quarters of 2023, the Group prioritized certain development programs to ensure resource efficiency amid constrained funding conditions and revised its development plans. Under the revised strategic plan, resource allocation to development programs related to drug candidates RLF-100, RLF-TD011 and Sentinox was scaled back. The de-prioritization of these programs is expected to postpone potential economic returns while reducing required short-term investments. The Group plans to primarily allocate available resources to the ongoing development of its metabolic disorder programs, including RLF-OD032, PKU Golike and ACER-001. It aims to resume the accelerated development of RLF-100, RLF-TD011 and Sentinox once adequate financing or strategic partnerships are secured for their completion. Clinical programs with RLF-100 and RLF-TD011 remained ongoing as of June 30, 2023.

The postponement of estimated future net cash flows from these assets, as well as an increase of the discount rate compared to December 31, 2022, resulted in impairment charges of TCHF 24'225, TCHF 22'534 and TCHF 2'958 recognized against the intangible assets associated with RLF-100, RLF-TD011 and Sentinox, respectively. In addition, goodwill allocated to these assets was entirely impaired for a total amount of TCHF 6'017.

For other intangible assets and remaining goodwill, the Group determined based on the results of the impairment test that their estimated value in use exceeded their respective carrying amounts as of the measurement date. Therefore, the Group did not record an impairment charge on these other assets for the period ended June 30, 2023.

Sensitivity to changes in assumptions

The Group performed a sensitivity analysis taking into account reasonably possible changes in the assumptions the value in use is most sensitive to, as listed in the key assumptions section above, including higher discount rate, lower projected income, increased development budget, and postponed market launch when applicable. The results of the sensitivity analysis as of June 30, 2023, are presented hereafter.

- The intangible assets associated with PKU Golike had an estimated recoverable amount that exceeded by TCHF 307 the carrying amount of TCHF 4'511. However, changes in assumptions such as an increase in the pre-tax discount rate by 50 basis points, or a 6% reduction in expected gross margins during the remaining expected commercialization period would trigger an impairment. For instance, a reduction of 30% in expected gross margins throughout the commercialization period would cause an impairment of TCHF 1'273, assuming other assumptions remain constant. No other reasonably possible change of key assumptions would cause the carrying amount to exceed the recoverable amount.
- The intangible assets associated with Diclofenac had an estimated recoverable amount that exceeded by TCHF 1'271 the carrying amount of TCHF 4'872. However, a reduction of 22% in expected gross margins during the remaining expected commercialization period would trigger an impairment. For instance, a reduction of 30% in expected gross margins throughout the commercialization period would cause an impairment of TCHF 501, assuming other assumptions remain constant. No other reasonably possible change of key assumptions would cause the carrying amount to exceed the recoverable amount.
- The intangible assets associated with RLF-100 and RLF-TD011 had estimated recoverable amounts that exactly matched their carrying amounts due to the impairment recognized at the end of the current reporting period. They are inherently sensitive to any changes in assumptions which would result in future impairments.

For intangible assets associated with the ACER-001 license, the Group concluded that no reasonably possible change of key assumptions would cause the carrying amount to exceed the recoverable amount.

While management believes the assumptions used are reasonable, changes in these assumptions could result in a future material impairment. The completion of the development of IPR&D assets and the ongoing commercialization of on-market products are subject to the availability of capital, which is uncertain as discussed in note 4.2 of these interim consolidated financial statements. If the Group is unable to secure sufficient capital, it will be forced to delay or abandon certain development and commercialization activities, which could lead to a material impairment of the affected assets.

7. Leases

7.1 Right-of-use assets

TCHF	Building	Equipment	Total
Historical cost			
January 1, 2022	**2'538**	**139**	**2'677**
Addition	-	549	**549**
Foreign exchange difference	(9)	(2)	**(11)**
December 31, 2022	**2'529**	**686**	**3'215**
Addition	86	454	**540**
Disposal	(89)	(44)	**(133)**
Foreign exchange difference	(1)	1	-
June 30, 2023	**2'525**	**1'097**	**3'622**
Accumulated depreciation			
January 1, 2022	**(147)**	**(32)**	**(179)**
Depreciation	(292)	(105)	**(397)**
Foreign exchange difference	3	-	**3**
December 31, 2022	**(436)**	**(137)**	**(573)**
Depreciation	(104)	(116)	**(220)**
Foreign exchange difference	-	-	-
June 30, 2023	**(540)**	**(253)**	**(793)**
Carrying amount			
at December 31, 2022	2'093	549	2'642
at June 30, 2023	**1'985**	**844**	**2'829**

7.2 Maturity of lease liabilities

TCHF	June 30, 2023	December 31, 2022
< 1 year	531	444
1-5 years	1'674	1'455
> 5 years	660	777
Total	**2'865**	**2'676**

7.3 Amounts recognized in profit or loss

TCHF	01.01.-30.06.2023	01.01.-30.06.2022
Lease expense for short-term and low value leases	25	19
Depreciation expense on right-of-use assets (note 22)	220	183
Interest expense on lease liabilities (note 23)	13	13

8. Property and equipment

The net carrying amount of property and equipment increased to TCHF 390 as of June 30, 2023, from TCHF 49 as of December 31, 2022, primarily in relation to the acquisition of laboratory equipment and office material.

9. Inventories

TCHF	June 30, 2023	December 31, 2022
Raw material	2'753	2'758
Finished goods	457	139
Gross inventories	3'210	2'897
Valuation allowance	(2'760)	(2'670)
Total	**450**	**227**

10. Other current assets

TCHF	June 30, 2023	December 31, 2022
Prepaid expenses	1'040	836
Accrued revenue	915	723
VAT receivable	120	147
Deposits	10	28
Other current receivables	21	64
Total	**2'106**	**1'798**

11. Share capital

	Number of shares		
	Common shares	Treasury shares	Total
Balance at January 1, 2022	**11'033'337**	**(749'668)**	**10'283'668**
Issuance of treasury shares	3'000'000	(3'000'000)	-
Direct Share Placement program	-	347'145	347'145
Milestone payments	-	375'500	375'500
Exercises of options	7'500	-	7'500
Balance at December 31, 2022	**14'040'837**	**(3'027'024)**	**11'013'813**
Balance at January 1, 2023	**14'040'837**	**(3'027'024)**	**11'013'813**
Direct Share Placement program	-	2'947	2'947
Private placements	-	1'200'000	1'200'000
Withdrawal of fractional shares	-	(3'009)	(3'009)
Exercises of options	-	4'688	4'688
Balance at June 30, 2023	**14'040'837**	**(1'822'398)**	**12'218'439**

11.1 Issued share capital

As of June 30, 2023, the share capital consisted of 14'040'837 issued shares with a par value of CHF 4.00 each. The Company held 1'822'398 shares in treasury as of June 30, 2023.

Reverse stock split

On May 5, 2023, RELIEF THERAPEUTICS Holding SA effected a 1-for-400 reverse stock split, whereby every 400 shares of the pre-reverse split share capital were combined and reclassified into one share. A total of 5'616'334'800 pre-reverse split ordinary shares were combined and reclassified into 14'040'837 ordinary shares post-reverse stock split. The par value of each share was multiplied by 400 from CHF 0.01 to CHF 4.00. The Company paid in cash fractional shares, and accordingly, no fractional shares were issued in connection with the reverse stock split.

As a result of the reverse stock split, all references in these financial statements to units of shares or per share amounts are reflective of the reverse split for all periods presented. In addition, the exercise prices and the numbers of shares issuable upon the exercise of any outstanding options, warrants, and other securities entitling their holders to purchase or receive Relief shares were proportionally adjusted.

Equity transactions in 2023

During the first semester of 2023, the following transactions resulted in cash gross proceeds of TCHF 5'030 before deducting transaction costs of TCHF 487.

- June 2023 private placement:

  On June 15, 2023, the Company entered into a securities purchase agreement pursuant to which the Company agreed to sell in a private placement 1'200'000 ordinary shares, pre-funded warrants to purchase up to 300'000 ordinary shares (the "Pre-Funded Warrants") and warrants to purchase up to 1'500'000 ordinary shares (the "Warrants"). The Company received total gross proceeds of TCHF 4'995 before deducting placement agent fees and related expenses.

  The Warrants are exercisable until June 21, 2028, at an exercise price of CHF 3.40 per share. The Pre-Funded Warrants were prefunded at CHF 3.329 per share and are exercisable with no expiration date at an exercise price of CHF 0.001 per share. Each of the Warrants and Pre-Funded Warrants represents the right to purchase one ordinary share of the Company. Relief committed to reserving from its treasury shares reserve the maximum number of shares to be issued upon exercise of the Warrants and Pre-Funded Warrants. As of June 30, 2023, none of the Warrants and Pre-Funded Warrants had been exercised.

- DSP program: sale of 2'947 shares at an average price per share of CHF 5.52 for total gross proceeds of TCHF 17.

- Exercises of options: issuance upon exercise of 4'688 shares at CHF 4.00 per share for gross proceeds of TCHF 19.

The Company retired fractional shares upon completion of the reverse stock split. Fractional shares representing 3'009 shares post-reverse stock split were acquired in May 2023 for a total cost of TCHF 22.

11.2 Capital band

Pursuant to changes in the Swiss Code of Obligations effective January 1, 2023, and the decision of the extraordinary general meeting held on April 28, 2023, the Company's authorized capital was replaced by a capital band. The capital range can be used for issuance of shares for strategic acquisitions and financing transactions.

As of June 30, 2023, the Board of Directors was authorized, at any time until 30 May 2024, to increase the share capital by the issuance of up to 2'500'000 ordinary shares with a nominal value of CHF 4.00, under the terms and conditions set forth in Article 3a^{ter} of Relief's Articles of Association.

11.3 Conditional share capital

The conditional share capital of the Company as of June 30, 2023, was TCHF 16'688, consisting of 4'171'924 shares with a par value of CHF 4.00 each, of which 264'424 shares to be used for stock options and 3'907'500 shares for grant of option rights in connection with bonds, notes or similar financial instruments issued by the Company.

11.4 Outstanding options and warrants

As of June 30, 2023, there were 182'283 outstanding stock options under the Company's stock option plans and 1'800'000 outstanding warrants as issued in the June 2023 private placement. Each option allows its holder to acquire one share at a predetermined price, subject to certain vesting conditions.

12. Borrowings

TCHF	June 30, 2023		December 31, 2022	
	Non-current	Current	Non-current	Current
Bank loans	13	361	16	372
Other financial liability	-	-	-	-
Total	**13**	**361**	**16**	**372**

As of June 30, 2023, the company had two outstanding bank loans: a TCHF 355 loan from a German bank carrying interest at 2.7% per year until December 30, 2023, and a TCHF 19 loan that is interest-free and repayable in monthly installments until 2026.

13. Provisions

TCHF	Contingent consideration (i)	Legal and regulatory (ii)	Total
Balance at December 31, 2022	**10'867**	**136**	**11'003**
Unwinding of discount on provisions	171	-	171
Variation due to assumption adjustment	(3'962)	-	(3'962)
Foreign exchange difference	(44)	-	(44)
Utilization	-	(136)	(136)
Balance at June 30, 2023	**7'032**	**-**	**7'032**

(i) Contingent consideration for business acquisitions

As of June 30, 2023, the Group recognized provisions of TCHF 7'032 for contingent payments that may become due to the former shareholders of APR and AdVita upon completion of pre-agreed milestones. As a result of changes in its development strategy (note 6), the Group reevaluated its assessment of contingent payments related to the affected programs. Consistent with assumptions underlying the impairment of the carrying value of the associated intangible assets, the expected settlement dates of the contingent payments were postponed. The resulting gain of TCHF 3'962 from fair value remeasurement was recorded in the income statement for the six months ended June 30, 2023.

Contingent consideration for the acquisition of APR

As of June 30, 2023, remaining milestone payments under the acquisition agreement were (i) the execution of a definitive agreement for the commercialization of Sentinox™, (ii) the launch of Sentinox in the first of France, Germany, Spain, Italy, and the United Kingdom, and (iii) the launch of RLF-TD011 in the first of France, Germany, Spain, Italy and the United Kingdom. Contingent payments aggregate to a maximum amount of CHF 28 million, in a combination of cash and Relief shares.

Contingent consideration for the acquisition of AdVita

As of June 30, 2023, remaining milestone payments under the acquisition agreement were (i) the approval in the U.S. or Europe of the inhaled form of aviptadil for the treatment of sarcoidosis or berylliosis, and (ii) the conduct of a phase II clinical study for the inhaled form of aviptadil in the treatment of checkpoint inhibitor-induced pneumonitis. Contingent payments aggregate to a maximum amount of EUR 10 million (CHF 9.8 million), in cash.

Provisioned amounts are calculated at the end of each reporting period by determining the probability-weighted present value of potential payments. As of June 30, 2023, probabilities ranged from 15% to 90% based on the estimated likelihood of completion for each underlying milestone. These probabilities are consistent with those estimated for the impairment test conducted for intangible assets and goodwill (note 6). Time to completion of each milestone ranged from approximately five years to nine years. A discount rate of 5% was determined based on the estimated time value of comparable liabilities, excluding risks factored into the probabilities of success.

(ii) Legal and regulatory proceedings

A provision of TCHF 136 recorded as of December 31, 2022, was released upon the conclusion of an investigation initiated in June 2021 by SIX Exchange Regulation AG. The actual cost amounted to TCHF 142.

14. Financial liabilities due to related parties

In January 2021, the Company signed a financing agreement with its largest shareholder, GEM Global Yield LLC ("GEM"), for the implementation of a share subscription facility (the "SSF") in the amount of up to CHF 50 million until January 20, 2024. As of June 30, 2023, the Company had not drawn on the SSF.

The Company agreed to pay GEM a commitment fee (the "Fee") of TCHF 1'250 plus accrued interest. As of June 30, 2023, the Fee was payable on demand and bore interest at 1% above the base rate of Barclays Bank plc. As the obligation to pay the Fee arose with the execution of the agreement, the Company recorded it in full as a liability on the signature date. The corresponding expense is recognized as financial expense (note 23) over the SSF commitment period of three years ending January 20, 2024.

15. Other current payables and liabilities

TCHF	June 30, 2023	December 31, 2022
Accrued expenses	1'558	2'138
Payable to social security institutions	498	497
Stamp duty and capital tax liabilities	136	347
Deferred revenue	80	776
Other current liabilities	475	143
Total	**2'747**	**3'901**

16. Other gains

TCHF	01.01.-30.06.2023	01.01.-30.06.2022
Gain from reversal of impairment on financial assets	-	453
Income from sublease agreements	50	47
Various others	16	63
Total other gains	**66**	**563**

17. Cost of sales

Expenses incurred with third parties in relation to the purchase and manufacturing of drug products for sale, as well as laboratory supplies in connection with research and development services provided to customers, are classified in 'raw materials and consumables expenses'. Expenses incurred with third parties in relation to advertising, marketing, sales promotion, shipping, distribution and commission on sales, are classified as 'external selling and distribution expenses'.

The increase in 'raw materials and consumables expenses' correlates with the increase in revenue from product sales. A change in the product mix, with a higher proportion of sales stemming from higher-margin products, reduced the ratio of raw materials and consumables expenses over product sales. The increase in 'external selling and distribution expenses' is primarily due to marketing activities subsequent to the launch of PKU Golike in the U.S. in October 2022.

18. External research and development expenses

External research and development expenses include costs associated with outsourced clinical research organization activities, sponsored research studies, clinical trial costs, process development, and product manufacturing expenses in relation to research and development programs.

In the first six months of 2023, external research and development expenses mainly comprised the clinical and drug product development costs associated with RLF-OD032, RLF-100 and RLF-TD011, complemented by the continued development of the PKU Golike products franchise. In the comparative period, these expenses mainly related to costs incurred by Acer under the license and collaboration agreement for development and premarketing activities for ACER-001.

19. Personnel expenses

TCHF	01.01.-30.06.2023	01.01.-30.06.2022
Salaries and social security expense	5'735	4'277
Independent contractors fees	-	178
Share-based payment expense	511	1'288
Service cost for other benefit obligations	13	24
Total personnel expenses	**6'259**	**5'767**

20. Other administrative expenses

TCHF	01.01.-30.06.2023	01.01.-30.06.2022
Professional services	1'947	3'306
Other administrative expenses	1'515	657
Total other administrative expenses	**3'462**	**3'963**

21. Impairment expense

TCHF	01.01.-30.06.2023	01.01.-30.06.2022
Impairment losses on intangible assets (note 6)	(55'734)	(8'226)
Impairment losses on inventories (note 9)	(90)	-
Total impairment expense	**(55'824)**	**(8'226)**

22. Amortization and depreciation expense

TCHF	01.01.-30.06.2023	01.01.-30.06.2022
Amortization of intangible assets (note 6)	1'456	1'840
Depreciation of rights-of-use assets (note 7)	220	183
Depreciation of property and equipment (note 8)	28	10
Total amortization and depreciation expense	**1'704**	**2'033**

23. Financial income and expense

TCHF	01.01.-30.06.2023	01.01.-30.06.2022
Interest income	-	12
Foreign exchange gain, net	-	150
Total financial income	**-**	**162**
Unwinding of discount on provisions (note 13)	(171)	(676)
SSF commitment fee (note 14)	(207)	(205)
Negative interest on cash deposits	-	(92)
Interest expense related to leases	(13)	(13)
Bank charges	(17)	(16)
Foreign exchange loss, net	(323)	-
Other financial expenses	(59)	(54)
Total financial expense	**(790)**	**(1'056)**

24. Income taxes

The income tax gain of TCHF 7'643 is primarily related to a reduction in deferred tax liabilities resulting from the impairment and amortization expenses recognized against intangible assets (note 6).

25. Earnings per share

	01.01.-30.06.2023	01.01.-30.06.2022
Loss attributable to shareholders (in TCHF)	(56'499)	(26'500)
Weighted average number of shares	11'082'004	10'388'747
Total basic and diluted loss per share (in CHF)	**(5.098)**	**(2.551)**

Basic and diluted result per share is calculated by dividing the net result attributable to the shareholders of the parent company by the weighted average of shares outstanding during the period. In 2023 and 2022, the number of shares outstanding varied as a result of different transactions on the share capital structure of the Company. References to shares and per share amounts for the comparative period have been restated to reflect the reverse stock split (note 11).

Neither outstanding options and warrants nor effects from the contingent liabilities payable in shares have been considered in the diluted loss calculation as their effect is anti-dilutive.

26. Related party transactions

26.1 Related party transactions

During the six-month period ending on June 30, 2023, the Company did not engage in any related party transactions, except for compensation provided to its management.

26.2 Related party balances

As of June 30, 2023, the liability of TCHF 1'313 due to GEM (December 31, 2022: TCHF 1'280) was the only material related party balance.

27. Non-cash transactions

In the first semester of 2023 and 2022, the Group engaged in non-cash investing or financing activities that are not reflected in the consolidated statement of cash flow. These activities mainly included the execution of new leasing contracts for office material and laboratory equipment (note 7).

28. Contingent liabilities

28.1 Business combinations with APR and AdVita

The acquisition agreements for APR and AdVita contain remaining contingent milestone payments in the aggregate maximum amounts of CHF 28 million and EUR 10 million (CHF 9.8 million), respectively, payable upon achievement of pre-agreed objectives. As of June 30, 2023, a provision totaling CHF 7.0 million was recognized to account for the probability-weighted present value at balance sheet date of these possible future payments. Refer to note 13 for further details.

28.2 Acquisition of RLF-OD032

Under the agreement and subsequent amendments concluded with Meta Healthcare Ltd. for the acquisition of RLF-OD032, Relief may issue additional payments of approximately TCHF 250 contingent to pre-specified development milestones. Relief also committed to paying Meta Healthcare Ltd. royalties on net commercialization profit of a low double-digit percentage.

28.3 Settlement agreement with NeuroRx

In November 2022, Relief agreed to a settlement with NRx Pharmaceuticals, Inc. ("NRx"), the parent company of NeuroRx, to terminate their collaboration in the development of aviptadil and resolve their legal dispute. As part of the agreement, Relief committed to pay NRx up to USD 13 million (CHF 11.6 million) in aggregate as milestone payments upon marketing approval of an aviptadil product. Relief also agreed to pay single-digit percentage royalties on possible future sales of an aviptadil product, up to a maximum of USD 30 million (CHF 26.8 million) in aggregate. Finally, Relief agreed to use commercially reasonable efforts to maintain the Right to Try Program in the U.S. until December 2024.

29. Events after the reporting period

Restructured license agreement with Acer

On August 30, 2023, Relief announced the termination of the March 2021 collaboration and license agreement and the execution of a new exclusive license agreement with Acer for the development and commercialization of ACER-001 (OLPRUVA™) for the treatment of UCDs, MSUD, and other potential indications. Under the terms of the new agreement, Acer retains development and commercialization rights worldwide, excluding Europe where Relief retains these rights.

Relief received a non-contingent USD 10 million upfront cash payment and will receive an additional non-contingent USD 1.5 million cash payment on the one-year anniversary of the agreement. Relief is also entitled to receive from Acer a 10% continuing royalty on net sales in the Acer territory, and 20% of any value received by Acer from licensing or divestment transactions relating to OLPRUVA™, up to a cumulative amount of an additional USD 45 million. Relief committed to paying Acer a variable, continuing royalty up to a maximum of 10% of the net sales of OLPRUVA™ and 20% of any value received by Relief from sublicensing transactions relating to OLPRUVA™ in the Relief territory.

There were no other material events after the balance sheet date that would require adjustment to these consolidated financial statements or disclosure under this heading.

RELIEF THERAPEUTICS HOLDING SA

Management's discussion and analysis of financial condition and results of operations

The following discussion and analysis should be read in conjunction with the unaudited interim condensed consolidated financial statements as of and for the six months ended June 30, 2023, which were prepared in accordance with International Accounting Standard 34 'Interim Financial Reporting'. Our consolidated financial statements are prepared in accordance with the International Financial Reporting Standards (IFRS), as issued by the International Accounting Standards Board (IASB) and are presented in Swiss francs (CHF).

Unless otherwise indicated or the context otherwise requires, the terms "Company," "Relief," "Group," "we," "our," "ours," or "us" refer to RELIEF THERAPEUTICS Holding SA together with its consolidated subsidiaries.

In addition to historical data, this discussion contains forward-looking statements regarding our business and financial performance based on current expectations that involve risks, uncertainties, and assumptions. Actual results may differ materially from those discussed in the forward-looking statements as a result of various factors.

Overview

We are a Swiss, commercial-stage biopharmaceutical company committed to delivering innovative treatment options with the potential for transformative outcomes to benefit those suffering from debilitating conditions that have no or limited treatment options to help them live their best possible lives and achieve their full potential. Our cost-effective, capital-efficient approach to drug development and commercialization is focused on rare metabolic disorders, rare skin diseases, rare respiratory diseases and rare monogenetic diseases.

We mitigate development risk by focusing on programs that can be advanced via the 505(b)(2) regulatory pathway, which relies on established products with a proven history of safety and efficacy and either initial human therapeutic activity, proof-of-concept or a strong scientific rationale. We concentrate our global skills and internal R&D resources toward optimizing the therapeutic potential of these assets through the application of our proprietary platform technologies, drug delivery systems or novel dosage forms.

Our portfolio offers a balanced mix of marketed, revenue-generating products, our proprietary, globally patented drug delivery platform technologies that have utility for development in other specialty or rare disease therapeutic areas and a highly targeted clinical development pipeline consisting of risk-mitigated assets that have been engineered for improvements in efficacy, safety or convenience to benefit the lives of patients. In addition, the Company is commercializing several legacy products via licensing and distribution partners. A description of our portfolio is provided in the Portfolio & Pipeline section of our 2023 half year report.

We are actively pursuing a strategy to diversify our portfolio through the ongoing evaluation of potential in-licensing opportunities. To bring treatments to patients as quickly as possible, we are seeking partnerships with, or acquisitions of, companies that have late-stage clinical molecules with a strong human safety profile, allowing for relatively short, capital-efficient clinical trials with clear endpoints. We are also evaluating prospective opportunities that fit within our genetic medicine initiative for devastating, as-yet-unaddressed, rare monogenetic diseases.

Our mission to provide therapeutic relief to those suffering from rare diseases and disorders is being advanced by an international team of well-established biopharma industry leaders with extensive research, development and rare disease expertise. Our focus on rare diseases with significant unmet medical need allows us to maintain a lean organization, with strong, experienced leadership able to deliver growth by effectively managing partnerships and efficiently allocating capital across our business.

Corporate Strategy Update

After conducting a comprehensive evaluation of Relief's business, we continue to refine our corporate strategy to enhance operational efficiency and focus on near term, pivotal value drivers.

We intend to concentrate in the near term the Company's resources on advanced, lower-risk R&D programs in the metabolic therapeutic area with substantial value-generating potential. Relief will continue to advance the development of RLF-OD032, which, if successful, may significantly bolster revenues. Concurrently, we will pursue the development of ACER-001 in Europe and of our PKU Golike products franchise.

Collaboration and license agreement with Acer Therapeutics, Inc.

In March 2021, we entered into a collaboration and license agreement with Acer Therapeutics, Inc. (Acer) for the worldwide development and commercialization of ACER-001 (sodium phenylbutyrate, OLPRUVA™). In December 2022, the U.S. Food and Drug Administration (FDA) approved ACER-001 as a prescription medicine for the treatment of certain Urea Cycle Disorders (UCDs). In August 2023, Relief and Acer terminated the March 2021 collaboration and license agreement and entered into a new exclusive license agreement for the development and commercialization of ACER-001 for the treatment of UCDs, MSUD, and other potential indications. Under the terms of the new agreement, Acer retains development and commercialization rights worldwide, excluding Europe where we retain these rights.

Acer provided us in August 2023 with a non-contingent USD 10 million upfront cash payment and will provide an additional non-contingent USD 1.5 million cash payment on the one-year anniversary of the agreement. We will also receive a 10% continuing royalty calculated on the net sales of OLPRUVA™ in the Acer territory, and 20% of any value received by Acer from licensing or divestment transactions relating to OLPRUVA™, up to a cumulative amount of an additional USD 45 million. Acer will receive from us a variable, continuing royalty up to a maximum of 10% of the net sales of OLPRUVA™ and 20% of any value received by us from sublicensing transactions relating to OLPRUVA™ in geographical Europe. However, there can be no assurance as to whether Relief and Acer will be successful in their respective development and commercialization efforts.

Collaboration agreement with InveniAI LLC

In November 2021, we entered into a collaboration agreement with InveniAI LLC (InveniAI), a U.S. based company that has pioneered the application of artificial intelligence and machine learning across the biopharmaceutical and other industries, in order to identify promising drug candidates to treat rare and specialty diseases. Under the terms of the agreement, we paid InveniAI an initial up-front fee of USD 0.5 million. We will be required to pay success milestones for any products brought to us in connection with the InveniAI Collaboration Agreement ranging from approximately USD 0.2 million per product candidate for which we exercise our option to acquire IP rights to USD 50 million for any required product reaching USD 1 billion per year in net sales. We will also be required to pay royalties in certain countries of approximately 3% on any such commercialized product. We are not currently developing any product brought to us by InveniAI.

Termination of the collaboration agreement with NeuroRx, Inc.

In September 2020, we entered into a collaboration agreement with NeuroRx, Inc. (NeuroRx) to develop and commercialize aviptadil acetate, for the treatment of COVID-19 related conditions and other pulmonary indications. In October 2021, we filed a lawsuit against NeuroRx and its former chief executive officer for multiple breaches of the agreement. In January 2022, NeuroRx filed a complaint against us alleging that we were in breach of the agreement.

In November 2022, Relief and NeuroRx (along with NeuroRx's parent company NRx Pharmaceuticals, Inc.) executed an asset purchase agreement and a settlement agreement to resolve all matters relating to the pending litigation. As part of the settlement, at a closing that was held on December 19, 2022, (i) NeuroRx transferred to Relief all of the assets that it previously used in its aviptadil development program, including its regulatory filings, patent applications, clinical data, and the formulation of the aviptadil product it was previously developing, (ii) Relief has the exclusive right and control vis à vis NeuroRx going forward to develop and commercialize an aviptadil product, (iii) Relief has agreed to use commercially reasonable efforts to continue the existing Right to Try Program for aviptadil in the U.S. for at least two years, (iv) Relief will pay NeuroRx milestone payments if it can successfully obtain commercial approval of an aviptadil product (whether for COVID-19 or any other indication), up to a maximum of USD 13 million in the aggregate, (v) Relief will pay NeuroRx royalties based on a single-digit percentage of future sales of an aviptadil product (whether for COVID-19 or any other indication), up to a maximum of USD 30 million in the aggregate, (vi) NeuroRx has agreed not to compete in the development of an aviptadil product in the future, (vii) the collaboration agreement between the parties has been cancelled, (viii) the parties have exchanged mutual release of all claims between the parties, and (ix) Relief and NeuroRx have each dismissed their pending litigation.

In September 2023, we received a copy of a complaint filed in Israel by Jonathan Javitt, former chief executive officer and current chief scientist of NRx Pharmaceuticals, Inc., against Relief and certain of its current and former directors, officers and consultants. The complaint alleges, among other matters, that statements made by Relief and other defendants regarding Dr. Javitt were defamatory, causing material harm to Dr. Javitt. Dr. Javitt also appears to be seeking financial damages, an injunction against future alleged defamatory statements, and for Relief to turn over global rights to ZYESAMI to Dr. Javitt. While we deny all allegations in the complaint and consider them to be without merit and lacking both factual

and legal foundation, we intend to dispute whether Dr. Javitt has properly served the defendants and whether there is jurisdiction in the courts of Israel over these alleged claims. While there can be no assurance, we believe that the possibility of any financial damage to Relief, its directors, officers and associated parties resulting from this claim is remote.

Recent business combinations

In June 2021, we acquired APR Applied Pharma Research SA (APR), a privately held Swiss pharmaceutical company specialized in identifying, developing and commercializing known molecules engineered with drug delivery systems in niche and rare diseases on a global basis. The integration of the two companies established Relief as a fully integrated, international biopharmaceutical enterprise, further diversifying Relief's pipeline and portfolio with both commercial products and clinical-stage programs, provided a commercial infrastructure in Europe and strengthened our internal R&D capabilities.

In July 2021, we acquired AdVita Lifescience GmbH (AdVita), a Germany-based privately held pharmaceutical company developing products for the treatment and diagnosis of rare lung diseases. The acquisition strengthened our expertise and ability to progress with the development of RLF-100.

Components of Results of Operations

Revenue

Revenue is primarily derived from our portfolio of marketed products and the provision of R&D services to third parties. We generate revenue from product sales, licensing fees, and royalties since the date of acquisition of APR in June 2021. Prior to the acquisition, Relief did not generate any revenue from commercial activities.

To date, our revenue has been substantially less than our operating expenses. Accordingly, we rely on external funding to continue operations and fund our clinical and commercial development plan. We expect the expansion of our PKU GOLIKE® franchise as a medical food in the U.S. and other territories, as well as the commercialization of Olpruva™ by Acer (for which we may receive royalty payments in the amount of 10% of net sales) will contribute to increases in future revenues. We do not expect to generate revenue from product candidates unless and until we complete their development and obtain regulatory approvals.

Other gains

Other gains generally consist of income from facility subleasing, gains on disposal of intangible assets, write-offs of liabilities and adjustments in fair value of certain assets and liabilities.

Raw materials and consumables expenses

Raw materials and consumables expenses are comprised of expenditures incurred with third parties in relation to the purchase and manufacturing of medical food and drug products for sale, as well as laboratory supplies in connection with R&D services provided to customers.

External selling and distribution expenses

External selling and distribution expenses are comprised of expenditures incurred with third parties in relation to advertising, marketing, sales promotion, shipping, distribution, and commission on sales, for the sale of products and R&D services.

External research and development expenses

External research and development expenses include costs associated with outsourced clinical research organization activities, sponsored research studies, clinical trial costs, process development, drug candidate manufacturing expenses, license fees, and investigator-sponsored trials, including licensing fees and milestone payments charged by licensors or collaboration partners, as well as expenses related to laboratory supplies and materials.

Costs for certain development activities, such as clinical trials, are recognized based on an evaluation of the progress to completion of specific tasks using information from the clinical sites and our vendors. Costs associated with the development activity under collaboration agreements are recognized based on actual expenses reported by our collaboration partners.

Personnel expenses

Personnel expenses consist of employee-related expenses, including salaries, benefits, share-based compensation, and other personnel-related costs.

Other administrative expenses

Other administrative expenses consist primarily of corporate facility costs, fees for legal and audit services, insurance costs, and consulting fees not otherwise included in research and development expenses.

Change in fair value of contingent consideration

Under the APR and AdVita acquisition agreements, Relief agreed to pay additional consideration upon completion of specific milestones. The fair value of the contingent consideration is recorded as a liability on our balance sheet and adjusted at the end of each reporting period based on the estimated probability of occurrence and the time factor. Any changes in fair value of the contingent liability due to assumption adjustments are recorded in the income statement.

Financial income

Financial income consists mainly of foreign exchange net result, when positive. Foreign exchange net result is allocated to financial expense when negative.

Financial expense

Financial expense consists mainly of interest expense associated with the discounting overtime of provisions for contingent payments measured at fair value. The commitment fee that became due upon execution of our current share subscription facility agreement with GEM in January 2021 is expensed over the period of effectiveness of the instrument. In addition, we incurred negative interest charge on our Swiss franc and Euro cash deposits until year-end 2022.

Income taxes

We are subject to corporate income taxation in Switzerland, the U.S., Italy, and Germany. We are also subject to corporate capital tax for our parent company and subsidiaries located in Switzerland. Unless and until the Group becomes profitable in certain tax jurisdictions, we expect income tax losses and gains will primarily arise from variations of deferred tax assets and liabilities.

Comparison of the six months ended June 30, 2023 and 2022

The following table summarizes our results of operations for the six months ended June 30, 2023 and 2022:

	For the six months ended June 30,		
in CHF thousands (unaudited)	**2023**	**2022**	**Change**
Revenue	3'023	3'242	(219)
Other gains	66	563	(497)
Total income	**3'089**	**3'805**	**(716)**
Raw materials and consumables expenses	(779)	(669)	(110)
External selling and distribution expenses	(1'442)	(465)	(977)
External research and development expenses	(933)	(10'637)	9'704
Personnel expenses	(6'259)	(5'767)	(492)
Other administrative expenses	(3'462)	(3'963)	501
Change in fair value of contingent consideration	3'962	740	3'222
EBITDA	**(5'824)**	**(16'956)**	**11'132**
Impairment expense	(55'824)	(8'226)	(47'598)
Amortization and depreciation expense	(1'704)	(2'033)	329
Operating loss	**(63'352)**	**(27'215)**	**(36'137)**
Financial income	-	162	(162)
Financial expense	(790)	(1'056)	266
Net loss before taxes	**(64'142)**	**(28'109)**	**(36'033)**
Income taxes	7'643	1'609	6'034
Net loss for the period	**(56'499)**	**(26'500)**	**(29'999)**

Revenue

In the first six months of 2023, we generated CHF 3.02 million in revenue from product sales, licensing fees, royalties and contract services, compared to CHF 3.24 million for the six months ended June 30, 2022.

Revenue from product sales increased from CHF 1.37 million to CHF 2.04 million, largely driven by sales of our PKU Golike products. The overall reduction in revenue is partly explained by the absence of one-time license fees we recognized in the prior year's six-month period, amounting to CHF 0.21 million. Contract services revenue also contracted from CHF 0.42 million to CHF 0.17 million. Further, our royalty revenue decreased from CHF 1.25 million to CHF 0.81 million, impacted by lower royalties on the U.S. sales of a Diclofenac-based product by a licensing partner, due to the introduction this year of generic competitors in the market.

Other gains

Other gains were CHF 0.07 million for the six months ended June 30, 2023, compared to CHF 0.56 million for the six months ended June 30, 2022. In the current period, these gains were primarily constituted by income from facility sublease agreements. The prior period also included an impairment reversal related to a financial asset, contributing CHF 0.45 million.

Raw materials and consumables expenses

Raw materials and consumables expenses increased 16% for the six months ended June 30, 2023 as compared to the prior year period. The increase in expenses correlates with the increase in revenue from product sales of 49%. A change in the product mix, with a higher proportion of sales stemming from higher-margin products, reduced the ratio of raw materials and consumables expenses over product sales revenue.

External selling and distribution expenses

External selling and distribution expenses increased to CHF 1.44 million for the six-month period ended June 30, 2023, from CHF 0.46 million for the six-month period ended June 30, 2022, an increase of CHF 0.98 million primarily due to marketing activities for the launch and subsequent commercialization of PKU Golike in the U.S. from October 2022.

External research and development expenses

External research and development expenses decreased to CHF 0.93 million for the six-month period ended June 30, 2023, from CHF 10.64 million for the six months ended June 30, 2022. In the comparative period, these expenses mainly related to costs incurred by Acer under our former license and collaboration agreement for development and premarketing activities for ACER-001. In the first six months of 2023, external development expenses were mainly directed towards the development of RLF-OD032, RLF-TD011 and RLF-100, complemented by the continued development of our PKU Golike products franchise.

Personnel expenses

Personnel expenses increased to CHF 6.26 million in the six-month period ended June 30, 2023, compared to CHF 5.77 million for the six-month period ended June 30, 2022, an increase of CHF 0.49 million mainly due to an increase in employee headcount resulting from the progressive formation of our U.S. sales force in 2022. Non-cash expenses resulting from grants of stock options, which are included in personnel expenses, amounted to CHF 0.51 million and CHF 1.29 million in the six-month periods ended June 30, 2023 and 2022, respectively.

As of June 30, 2023, Relief had 64 full-time equivalents on its payroll (December 31, 2022: 69).

Other administrative expenses

Other administrative expenses decreased to CHF 3.46 million in the six-month period ended June 30, 2023, compared to CHF 3.96 million for the six-month period ended June 30, 2022, a decrease of CHF 0.50 million mainly tied to lower expenses incurred for legal and regulatory affairs, reflecting non-recurring events from 2022 including the closed litigation with NeuroRx.

Change in fair value of contingent consideration

During the six months ended June 30, 2023, we recognized a CHF 3.96 million gain from the fair value adjustment of contingent consideration. The reduction in the estimated present value of potential future milestone payments is attributable to the postponement of expected completion dates due to strategic decisions concerning our RLF-100, RLF-TD011 and Sentinox development programs.

In the consolidated statement of loss for the six months ended June 30, 2022, a gain of CHF 0.74 million on fair value remeasurement of contingent consideration was recorded within the 'Other gains' line item. In the comparative period of the consolidated statement of loss for the six months ended June 30, 2023, this gain was reclassified to a distinct line 'Change in fair value of contingent consideration' to conform with the current period presentation.

Impairment expense

We conducted an impairment test of our intangible assets and goodwill as of June 30, 2023, and concluded that the carrying amount intangible assets and goodwill associated with RLF-100®, RLF-TD011 and Sentinox™, were impaired. As a result, we recognized a non-cash impairment charge on intangible assets of CHF 55.73 million in the current period. The impairment charge is attributable to the Company's revised development strategy. Refer to note 6 of our interim consolidated financial statements for further information on intangible assets and related impairment.

Amortization and depreciation expenses

Amortization and depreciation expenses were CHF 1.70 million for the six-month ended June 30, 2023, compared to CHF 2.03 million for the six months ended June 30, 2022. Amortization and depreciation expenses predominantly pertain to the amortization of our intangible assets.

Financial income

There was no financial income in the six-month period ended June 30, 2023, compared to CHF 0.16 million for the six-month period ended June 30, 2022. In the comparative period, financial income was primarily constituted by a net foreign exchange gain.

Financial expense

Financial expense decreased to CHF 0.79 million in the six-month period ended June 30, 2023, compared to CHF 1.06 million for the six-month period ended June 30, 2022. This reduction resulted from two main factors: the decrease of interest costs associated with the unwinding of the time discount on provisions for contingent considerations, from CHF 0.68 million to CHF 0.17 million, resulting from a decreased provisioned amount; and the end of negative interest rates that were previously charged on our cash deposits in Swiss francs and Euros. In contrast, we recognized a net foreign exchange loss of CHF 0.32 million in the six-month period ended June 30, 2023, compared to a net foreign exchange gain of CHF 0.15 million recorded during the same period in 2022.

Income taxes

Income taxes were a gain of CHF 7.64 million in the six months ended June 2023, compared to an income tax gain of CHF 1.61 million for the six-month period ended June 30, 2022. The income tax gains resulted mainly from the amortization and impairment of intangible assets and a corresponding reduction in the temporary difference between the carrying amount of these assets and their tax base.

Liquidity and Capital Resources

To date, we have funded our operations primarily through private placements, at-the-market sales of treasury shares, equity offerings, and loans from our largest shareholder, GEM. We have never been profitable and have incurred operating losses in each year since inception. We have an accumulated deficit of CHF 176.1 million as of June 30, 2023, and may incur further losses over the foreseeable future as we develop our business. We have spent, and expect to continue to spend, a substantial amount of funds in connection with implementing our business strategy, including our planned product development and commercialization efforts.

As Relief continues to incur significant operating losses, our ability to pursue and finance our operations and our intended development plans depends on our ability to continue to raise additional financing. Our primary uses of capital are R&D expenses, personnel compensation expenses, and administrative expenses. We expect to continue to incur substantial expenses in connection with our product candidates at various stages of development and for working capital requirements. We expect to continue to raise financing through the sale of equity and debt financing. We intend to use future expected proceeds, together with cash on hand, to finance our development and commercial activities and the diversification of our pipeline, as well as to fund our outstanding liabilities and other commitments. We expect our expenses to increase in

connection with our ongoing activities, particularly as we continue to advance our portfolio of product candidates, initiate further clinical trials, and seek marketing approval for our product candidates, contingent upon the availability of financing. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur additional commercialization expenses related to program sales, marketing, manufacturing, and distribution to the extent that such sales, marketing and distribution are not the responsibility of potential partners. Accordingly, we may need to obtain substantial additional funding in connection with our continuing operations.

Going concern

As of August 31, 2023, we had cash and cash equivalents of CHF 18.3 million, which includes proceeds of USD 10 million from the renegotiation of licensing terms with Acer Therapeutics in August 2023. Based on current operating plans, we expect that we have sufficient resources to fund operations for at least the next 12 months from the date of issuance of this report.

Our future capital requirements will depend on many factors, including:

- the scope, progress, results and costs of our ongoing and planned preclinical studies and clinical trials;
- the number and development requirements of other product candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our product candidates;
- the timing amount of milestone payments we may have to pay in relation to the acquisitions of APR and AdVita;
- the extent to which we in-license or acquire other product candidates and technologies;
- the costs and timing of future commercialization activities, including drug manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive or have received marketing approval;
- the timing of repayment of the Relief's borrowings; and
- the funding necessary to sustain our commercial operations until we attain the breakeven point.

Our long-term viability depends on our ability to raise additional capital until we generate positive cash flows to support our operations. We may not be successful in our efforts to raise additional funds or achieve profitable operations. We intend to continue to explore potential opportunities to obtain the additional resources that will be necessary to support our operations, including raising additional capital through either private or public equity or debt financing, or additional program collaborations or non-dilutive funding, as well as using our treasury share sales program or our shares subscription facility with GEM.

If we are unable to obtain additional funding to support our current or proposed activities and operations, we may not be able to continue our operations as proposed, which may require us to suspend or terminate any ongoing development activities, modify our business plan, curtail various aspects of our operations, cease operations, or seek relief under applicable bankruptcy laws. In such event, our stockholders may lose a substantial portion or even all of their investment.

The following table summarizes our cash flows for each of the periods indicated:

	For the six months ended June 30,		
in CHF thousands (unaudited)	**2023**	**2022**	**Change**
Cash and cash equivalents at beginning of period	**19'237**	**44'761**	**(25'524)**
Cash flow used in operating activities	(10'466)	(14'731)	4'265
Cash flow used in investing activities	(220)	(4'764)	4'544
Cash flow from financing activities	4'174	4'662	(488)
Decrease in cash and cash equivalents	**(6'512)**	**(14'833)**	**8'321**
Effect of exchange rates	67	(57)	124
Cash and cash equivalents at end of period	**12'792**	**29'871**	**(17'079)**

Operating Activities

Net cash used in operating activities was CHF 10.47 million for the six months ended June 30, 2023, compared to CHF 14.73 million for the six months ended June 30, 2022. This decrease is mainly due to reduced external R&D expense payouts, while cash inflows and outflows related to revenues and other expenses, as well as our net working capital, remained relatively constant.

Investing Activities

Net cash used in investing activities was CHF 0.22 million for the six months ended June 30, 2023, compared to CHF 4.76 million for the six months ended June 30, 2022. In the current period, cash used in investing activities was mainly for the acquisition of property and equipment. In the comparative period, cash used in investing activities consisted mainly of a payment to the former shareholders of AdVita for the completion of a contractual milestone.

Financing Activities

Net cash from financing activities was CHF 4.17 million for the six months ended June 30, 2023, compared to CHF 4.66 million for the six months ended June 30, 2022. In the current period, funds were primarily derived from a CHF 5 million private placement, before deduction of transaction costs. In the previous period, net cash from financing activities originated primarily from our Direct Share Placement program.

Main contractual obligations and commitments

Under our license agreements with Acer Therapeutics Inc., NeuroRx Inc., and Meta Healthcare Ltd., we may be required to pay royalties and milestone payments. In addition, under the acquisition agreements with the former shareholders of APR and AdVita, we may be required to make payments upon achievement of pre-agreed objectives. Refer to note 28 of our interim consolidated financial statements for further information on contingent liabilities.

In January 2021, we signed a financing agreement with GEM for the implementation of a share subscription facility. We agreed to pay GEM a commitment fee of CHF 1.25 million plus accrued annual interest at 1% above the base rate of Barclays Bank plc. As of June 30, 2023, the outstanding balance payable to GEM on demand was CHF 1.31 million.

We enter into contracts in the normal course of business with clinical research organizations for clinical trials, nonclinical studies, manufacturing and other services and products for operating purposes. These contracts generally provide for termination upon notice, and we believe that our non-cancelable obligations under these agreements are not material.

Critical Accounting Policies and Significant Judgments and Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our interim consolidated financial statements, which we have prepared in accordance with the International Financial Reporting Standards (IFRS), as issued by the International Accounting Standards Board (IASB). The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of revenues, expenses, assets, liabilities, and disclosures at the reporting date. We base our estimates and assumptions on historical experience and other factors that we believe to be reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates.

Recent Accounting Pronouncements

The adoption of IFRS as issued by the IASB and interpretations issued by the IFRS Interpretations Committee that are effective for the first time for our financial year beginning on January 1, 2023, had no material impact on our financial position or disclosures made in our interim consolidated financial statements.

JOBS Act Exemptions

We qualify as an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act") in the U.S. Subject to certain conditions, we are relying on certain of exemptions under the JOBS Act, including without limitation, (1) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (2) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earlier to occur of (1) the last day of the fiscal year (a) following the fifth anniversary of the completion of our initial public offering in the U.S., (b) in which we have total annual gross revenues of at least USD 1.07 billion, or (c) in which we are deemed to be a "large accelerated filer" under the rules of the U.S. Securities and Exchange Commission, which means the market value of our common shares held by non-affiliates exceeds USD 700 million as of the prior June 30, and (2) the date on which we have issued more than USD 1.0 billion in non-convertible debt during the prior three-year period.

Cautionary Statement Regarding Forward Looking Statements

This half-year report, including this discussion and analysis, contains statements that constitute forward-looking statements. All statements other than statements of historical facts contained in this discussion and analysis, including statements regarding our future results of operations and financial position, business strategy, product candidates, product pipeline, ongoing and planned clinical studies, including those of our collaboration partners, 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 discussion and analysis 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 are subject to risks and uncertainties, and 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 Annual Report on Form 20-F. These forward-looking statements speak only as of the date of this discussion and analysis, and are subject to a number of risks, uncertainties and assumptions as described under the sections in our Annual Report on Form 20-F entitled "Risk Factors" and in this discussion and analysis. 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 such as the global pandemic originating with COVID-19, 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.