FORM 20FR12B/A

Form for initial registration of a class of securities of foreign private issuers pursuant to Section 12(b) [amend]

Filing Date: **2022-07-01**
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FILER

Relief Therapeutics Holding SA
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SIC: **2834** Pharmaceutical preparations

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As filed with the Securities and Exchange Commission on July 1, 2022

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Amendment No. 4
to
FORM 20-F

[Mark One]

☒ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☐ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the period ended

OR

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report

Commission file number: 001-41174

RELIEF THERAPEUTICS HOLDING SA
(Exact name of registrant as specified in its charter and translation of Registrant' s name into English)

Switzerland
(Jurisdiction of incorporation or organization)

Avenue de Sécheron 15
1202 Genève
Switzerland
(Address of principal executive offices)

Jack Weinstein
Chief Financial Officer
RELIEF THERAPEUTICS Holding SA
Avenue de Sécheron 15
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Switzerland
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Securities Registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class:	Name of exchange on which registered:
American Depositary Shares, representing 150 shares of Common Stock, par value CHF 0.01 per share	**NONE**
Common Stock, par value CHF 0.01 per share*	**SIX Swiss Exchange (SIX)**

* **Listed not for trading, but only in connection with the registration of the American Depositary Shares, pursuant to the requirements of the Securities & Exchange Commission**

Securities registered or to be registered pursuant to Section 12(g) of the Act: None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None

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Indicate the number of outstanding shares of each of the issuer' s classes of capital or common stock as of the close of the period covered by the annual report: N/A

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act: ☐ Yes ☒ No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934: ☐ Yes ☐ No

Note – Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those Sections.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days: ☐ Yes ☒ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files): ☒ Yes ☐ No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See the definitions of "large accelerated filer", "accelerated filer", and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Emerging growth company ☒

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act. ☐

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark whether the registrant has filed a report on and attestation to its management' s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☐ International Financial Reporting Standards as issued by the International Accounting Standards Board ☒ Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. Item 17 ☐ Item 18 ☐

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☐

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INTRODUCTION

Unless otherwise indicated or the context otherwise requires, all references in this Registration Statement on Form 20-F to the terms "Relief," "Relief Therapeutics," "the company," "we," "us" and "our" refer to RELIEF Therapeutics Holding SA together with its subsidiaries. Relief and its subsidiaries may also sometimes be referred to in this Form 20-F as the "Group."

We own trademarks for Relief Therapeutics in Switzerland. All other trade names, trademarks and service marks of other companies appearing in this Registration Statement on Form 20-F are the property of their respective holders. Solely for convenience, the trademarks and trade names in this Registration Statement on Form 20-F are referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. We do not intend to use or display other companies' trademarks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Our product candidate, RLF-100, is also known by its scientific name, aviptadil. The name for the same product used by Relief' s collaboration partner in the United States is ZYESAMI. Relief believes that all of these names refer to the same product.

Our reporting currency is the Swiss franc. The exchange rate between the Swiss franc and the U.S. dollar as of June 28, 2022 was $1.0443 per CHF 1.0. We present our consolidated financial statements in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. Readers of this Registration Statement on Form 20-F should note that there may be certain differences between the presentation of our financial position, results of operations and cash flows under IFRS and U.S. generally accepted accounting principles.

The terms "dollar," "USD" or "$" refer to U.S. dollars and the terms "Swiss francs" or "CHF" refer to the legal currency of Switzerland.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This registration statement contains forward-looking statements that involve substantial risks and uncertainties. All statements contained in this registration statement, other than statements of historical fact, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, projects, plans and objections of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend", "may," "plan," "predict," "project," "target," "potential," "would," "could," "should," "continue," and other similar expressions are intended to identify forward-looking statements, though not all forward-looking statements contain these identifying words. The forward-looking statements in this registration statement include, among other things, statements about:

- the success, cost and development of our clinical programs, including the progress of, and results from, our (and our partners') clinical trial and preclinical programs for RLF-100 and ACER-001;
- the ability of our collaboration partners to obtain authorizations to commercialize products that are the subject of the respective collaborations;
- the outcome of our lawsuit against NeuroRx for breach of our collaboration agreement with NeuroRx;
- our ability or our collaboration partners' abilities to obtain and maintain regulatory approval of our product candidates and any related restrictions, limitations or warnings on the label of any such product, if approved;
- our plans to pursue research and development of product candidates we may obtain in the future;

- our ability to compete with companies currently marketing or engaged in the development of treatments for indications that our product candidates are designed to target;
- the potential advantages or disadvantages of our product candidates;
- the rate and degree of market acceptance and clinical utility of our product candidates;
- the success of our collaborations and partnerships with third parties;
- our estimates regarding the potential market opportunities for our product candidates;
- our sales, marketing, and distribution capabilities and strategy;
- our ability to establish and maintain arrangements for the manufacture of our product candidates;
- our ability to protect and defend our intellectual property;
- whether any of our product candidates (or our collaboration partners' product candidates) will ever be approved for commercialization;
- whether we will ever achieve cash flow positive operations or profitability;
- our expectations related to our use of capital;
- the effect of the COVID-19 pandemic, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations, including, but not limited to our preclinical studies and clinical trials;
- our estimates regarding expenses, future revenues, capital requirements and our needs for additional financing;
- the impact of government laws and regulations; and
- our competitive position.

You should read this registration statement and the documents we have filed as exhibits to the registration statement completely and with the understanding that our actual future results may be materially different from what we expect. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. You should refer to the sections of this registration statement titled "Item 3. Key Information, D. Risk Factors," "Item 4. Information on the Company." and "Item 5. Operating and Financial Review and Prospects" for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

This registration statement includes statistical and other industry and market data that we obtained from industry publications and research, surveys and studies conducted by third parties. Industry publications and third-party research, surveys and studies generally indicate that their information has been obtained from sources believed to be reliable, although they do not guarantee the accuracy or completeness of such information.

PART I

ITEM 1. IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

A. DIRECTORS AND SENIOR MANAGEMENT

The following table sets forth the names, ages as of June 30, 2022 and positions of our directors and senior management:

Directors

Name	Age	Position
Dr. Raghuram (Ram) Selvaraju	43	Chairman
Dr. Tom Plitz	53	Vice-Chairman
Dr. Patrice P. Jean	51	Director
Paolo Galfetti	57	Director
Michelle Lock	53	Director

Senior Management

Name	Age	Position
Paolo Galfetti	57	President of Relief Europe
Jack Weinstein	66	Chief Financial Officer and Treasurer and President of Relief U.S.
Anthony M. Kim	50	Senior Vice President and Head of U.S. Commercial Operations
Jeremy Meinen	33	VP Finance and Administration and Chief Accounting Officer
Nermeen Varawalla	60	Chief Medical Officer
Marco Marotta	37	Chief Business Officer

Directors

Raghuram (Ram) Selvaraju, Ph.D., MBA, serves as Chairman of our Board of Directors. Dr. Selvaraju Managing Director of Equity Research at H.C. Wainwright whose research focuses on the healthcare sector. Dr. Selvaraju has over 16 years of experience on Wall Street and previously was a pharmaceutical researcher at Serono in Switzerland. In addition, Dr. Selvaraju has appeared numerous times on Bloomberg, CNBC, Business News Network and BTV where he discussed drug development trends, healthcare reform policy, and pharma and biotech M&A. Prior to joining H.C. Wainwright, Dr. Selvaraju held Senior Research positions at MLV & Co., Aegis Capital Corp. – Head of Healthcare Equity Research and Director of Equity Research, Hapoalim Securities U.S.A. and Rodman & Renshaw LLC. Dr. Selvaraju became the youngest-ever recipient of the Serono Pharmaceutical Research Institute' s Inventorship Award for exceptional innovation and creativity in 2003. Dr. Selvaraju earned his Ph.D. in cellular immunology and molecular neuroscience and an M.S. in molecular biology from the University of Geneva in Switzerland on the basis of his drug development research. He also holds an M.B.A. from the Cornell University accelerated one-year program for scientists and engineers and a B.S. in biological sciences and technical writing from Carnegie Mellon University.

Tom Plitz serves as Vice Chairman of our Board of Directors and is chairperson of the Nominating and Compensation Committee of the Board. Dr. Plitz most recently has served as Chief Executive Officer of Chord Therapeutics SA, a privately held biopharmaceutical firm based in Geneva, Switzerland. Chord Therapeutics SA was acquired by Merck KGaA in January 2022 for an undisclosed amount. Prior to Chord, Dr. Plitz worked as Chief Scientific Officer of the rare disease company, Wilson Therapeutics. Wilson Therapeutics was acquired for $855 million by Alexion Pharmaceuticals in April 2018. Dr. Plitz' s previous assignments include senior roles at Serono, Merck, and Shire, where he worked across multiple therapeutic areas, including neuroinflammatory, metabolic, and rare diseases, completing more than two decades of experience in pharmaceutical R&D. Dr. Plitz holds a Ph.D. from Technical University of Munich, Germany.

Patrice Jean is a member of our Board of Directors and is chairperson of the Audit and Finance Committee. Dr. Jean is the Chair of the Life Sciences Practice at Hughes Hubbard & Reed, an international law firm based in New York City. She has over a decade of experience counselling leading and startup pharmaceutical, chemical and biotechnology companies in all areas of intellectual property law, including asserting and defending patent rights underlying core technologies and innovations. Dr. Jean serves as Vice President of the New York Intellectual Property Law Education Foundation and is a Board member of the New York Intellectual Property Law Association. Dr. Jean holds a Ph.D. in molecular biology from Princeton University, a J.D. from Columbia University School of Law, and a B.A. in biochemistry from Xavier University.

Paolo Galfetti is a member of our Board of Directors and is the chairperson of the Corporate Governance Committee. Mr. Galfetti is the Chief Executive Officer of APR Applied Pharma Research SA ("APR"). Pursuant to the contractual terms for the acquisition of APR by the Company, the then shareholders of APR were entitled to appoint a designee to serve on the Company' s Board of Directors. Mr. Galfetti has over thirty years of management experience in the pharmaceutical sector, including in the areas of business development and licensing, operational strategic management, clinical research, and pharmaceutical discovery and development. He joined APR in 1995 as head of licensing and business development and was appointed Chief Executive Officer in 2002. Prior to joining APR, Mr. Galfetti was a founding partner, CEO and board member of the Institute for Pharmacokinetic and Analytical Studies AG (IPAS), a Swiss contract research organization (CRO) as well as CEO and board member of Farma Resa s.r.l., an Italian CRO. Mr. Galfetti is a Chartered Financial Analyst (CFA) and has a bachelor' s degree in economics from the Commercial University Bocconi, Milan, Italy.

Michelle Lock is a member of our Board of Directors. Ms. Lock is the Chief Operating Officer of Covis Pharma Group, a Switzerland-based global specialty pharmaceutical company that markets therapeutic solutions for patients with life-threatening conditions and chronic illnesses. Ms. Lock' s broad biopharmaceutical industry experience spans nearly 30 years and includes leadership roles in commercialization across various therapeutic areas including oncology, hematology, cardiovascular and metabolic disease, liver disease, immunology, virology and neuroscience. Previously, Ms. Lock served as the Senior Vice President and Head of International organization at Acceleron Pharma Inc, a biopharmaceutical company dedicated to the discovery, development, and commercialization of therapeutics to treat serious and rare diseases until its acquisition by Merck & Co. for $11.5 billion. Before that, she was a consultant to biotechnology companies, providing leadership, guidance, and strategic support to managements seeking to establish or improve their international businesses based in Switzerland. Earlier, Ms. Lock was Senior Vice President & Head of International at Sage Therapeutics, a clinical-stage biopharmaceutical company committed to discovering, developing, and commercializing novel medicines to transform the lives of patients with life-altering central nervous system (CNS) disorders. During her career, Ms. Lock also spent 24 years with Bristol-Myers Squibb (BMS) in positions of increasing responsibility in sales, commercial, general management, regional leadership and business strategy. In her most recent role at BMS, she served as Vice President and General Manager for EU Country Clusters & Global Capabilities Hub leadership, Switzerland, driving the company' s leadership efforts in immuno-oncology. She has served as Honorary Ambassador between Switzerland and the U.S. since 2018, as well is a past member of the board of directors of the Swiss American Chamber of Commerce and the Interpharma Switzerland Pharmaceutical Industry. She earned a degree in Science/Nursing at Royal Melbourne University, Australia and studied General Management and Internal General Management at CEDEP, France.

Executive Officers

Paolo Galfetti. See biographical information above.

Jack Weinstein joined us in October 2020 as our U.S. based Chief Financial Officer and Treasurer, and serves as the President of Relief U.S. Mr. Weinstein has nearly 40 years of wide-ranging executive management expertise, including as a CFO, investment banker and consultant in the biopharmaceutical and life sciences industries. Prior to joining Relief, Mr. Weinstein served as Managing Director and Head of Healthcare Investment Banking at Avalon NetWorth, an independent New York-based boutique investment bank. Prior to joining Avalon, Mr. Weinstein was CFO, Treasurer and Vice President of Business Development at Catalyst Pharmaceuticals, Inc.(Nasdaq:CPRX), a biopharmaceutical company developing therapies to treat rare diseases, where he led the Company through its Initial Public Offering. Prior to joining Catalyst, Mr. Weinstein was the President and founder of The Sterlington Group, Inc., a consulting firm providing strategic, business development, regulatory and "CFO" consulting services. Mr. Weinstein received his MBA from the Harvard Business School.

Anthony M. Kim joined us in November 2021 as our Head of U.S. Commercial Operations. In that role, he will oversee the launch of PKU Golike in the United States and work closely with Acer in the launch of ACER-001 if it is approved for commercialization. Prior to joining Relief, for the past three years, Mr. Kim was Vice President, Global Commercial Development at Novocure, where he led a 21-person team in the planning and U.S. marketing execution for that company' s Optune and Optune Lua, FDA-approved, therapeutic devices that deliver alternating electrical fields to treat patients with Glioblastoma Multiforme and Mesothelioma. Further, from 2017 to 2018, Mr. Kim was Executive Director of Marketing at Ignyta (subsequently acquired by Roche), during which time he led the development of the commercial launch plan for entrectinib, an oral, oncologic agent in pan-tumor clinical trials for patients with neurotrophic tyrosine receptor kinase (NTRK) and ROS1 fusion-positive disease. From 2012 to 2017, Mr. Kim held positions of increasing responsibility at Alexion Pharmaceuticals, Inc., most recently serving as Director, Head of U.S. Marketing, Hypophosphatasia, where he managed the U.S. marketing efforts for the launch of Strensiq, a novel, first-in-class enzyme replacement therapy for the treatment of hypophosphatasia, a rare inherited metabolic bone disorder. Earlier, from 2004 to 2012, Mr. Kim held various positions at Genentech, which is a part of the Roche Group, including Product Manager, Herceptin Marketing and Divisional Sales Manager, Rituxan Hematology. Mr. Kim received his Bachelor of Arts Degree from Harvard University and a Master of Business Administration from The Wharton School.

Jeremy Meinen has been our Vice President Finance and Administration since October 2020 and our Chief Accounting Officer since December 2021. He joined Relief as ad-interim Chief Financial Officer in April 2020. Prior to joining Relief, Jeremy provided financial consulting, controlling and auditing services to companies in various industries. He began his career in an international audit firm, where he held positions of increasing responsibility and scope over more than six years. Mr. Meinen holds a Master of Science in finance from Bocconi University and a Bachelor of Arts degree in Business Administration from the University of Geneva. He is a Swiss certified public accountant and former licensed audit expert.

Nermeen Varawalla, MD, PhD, MBA joined us as our Chief Medical Officer in December 2021. Prior to joining Relief, Dr. Varawalla served as Chief Medical Officer and Head of Clinical Development with Atlantic Healthcare plc, a specialist pharmaceutical company with late-stage clinical assets for inflammatory bowel disease and gastrointestinal dysmotility in rare diseases. Before that, Dr. Varawalla was Managing Director of Clinstrat Ltd., a life science and business consultancy, where, among other projects, she worked with private equity firms to develop the investment thesis and business plan for the buy-out of BTG plc' s specialty pharmaceutical business unit, valued at approximately $1 billion. Before that, Dr. Varawalla was Senior Vice President and Head of Clinical Development and BTG International plc, where she led a global team responsible for clinical development of the company' s product portfolio across both pharmaceutical and medical device business units before it was acquired by Boston Scientific for $4.4 billion in 2019. Earlier, Dr. Varawalla was Chief Medical Officer at Accord Healthcare UK, an international division of Intas Pharmaceuticals and Executive Vice President of Lambda Therapeutic Research, Intas' full-service contract research organization. She began her career as a physician in obstetrics and gynecology at KEM Group of University Hospitals, Mumbai before continuing her specialist training at NHS University Hospitals in the United Kingdom. She is the current President of the INSEAD UK Alumni Association and is presently Chair, Medical Advisory Group, Atorvia Health Technologies and a member of the International Advisory Council of the Oxford India Centre for Sustainable Development. Dr. Varawalla received her MBBS (Bachelor of Medicine and Bachelor of Surgery) and MD degree from the University of Mumbai, her PhD from the University of Oxford where she was a Rhodes Research Fellow, and her MBA from INSEAD.

Marco Marotta became our Chief Business Officer in December 2021. Mr. Marotta joined us as part of our acquisition of APR, where he served as Corporate Director, Business Development and Licensing. Mr. Marotta joined APR in January 2015, where he was initially in charge to reshape and optimize APR' s end-to-end supply chain process, and afterwards, he joined the licensing and business development department, establishing and consolidating APR' s presence in emerging markets like the Asia-Pacific and Latin American regions. From 2019, Mr. Marotta led APR Business Development as a director, with responsibility of out-licensing proprietary products worldwide, divesting non-strategic assets and maximizing monetization as well as merging APR' s business with Relief. Mr. Marotta received a Master of Science in Engineering from the University Federico II in Napoli and an Executive MBA from Commercial University Bocconi in Milan.

B. ADVISERS

Our principal Swiss legal advisor is VISCHER AG, located at Schuetzengasse 1, PO Box, CH-8021 Zurich, Switzerland and our principal United States legal adviser is Akerman LLP, located at 201 East Las Olas Boulevard, Suite 1800, Fort Lauderdale, Florida 33301.

C. AUDITORS

MAZARS SA has been our auditor since 2017. The address for MAZARS SA is Chemin de Blandonnet 2, 1214 Vernier-Geneva, Switzerland.

ITEM 2. OFFER STATISTICS AND EXPECTED TIMELINE

Not applicable.

ITEM 3. KEY INFORMATION

A. SELECTED FINANCIAL DATA

Relief Financial Information

The following tables, which have been derived from our audited financial statements for the years ended December 31, 2021 and 2020, summarizes our balance sheet and results of our operations at the date and for the periods indicated, together with the changes for those items in thousands of CHF (TCHF).

(in TCHF)	December 31,		
Statement of Operations Data	**2021**	**2020**	**Change (2021 to 2020)**
Revenue	3,321	–	3,321
Other gains	1,171	273	898
Total income	4,492	273	4,219
Raw materials and consumables expense	(750)	–	(750)
External selling and distribution expense	(365)	–	(365)
External research and development expense	(19,024)	(13,672)	(5,352)
Personnel expense	(9,121)	(2,627)	(6,494)
Other administrative expense	(6,750)	(2,999)	(3,751)
Other losses	(752)	(1,260)	508
EBITDA	(32,270)	(20,285)	(11,985)
Reversal of impairment losses on intangible assets	–	11,200	(11,200)
Amortization and depreciation expense	(2,036)	–	(2,036)
Operating Result	(34,306)	(9,085)	(25,221)
Gain from disposal of a subsidiary	–	3,382	(3,382)
Financial income	97	7	90
Financial expense	(1,316)	(565)	(751)
Result before income taxes	(35,525)	(6,261)	(29,264)
Income taxes	820	(1,567)	2,387
Results for the Period	(34,705)	(7,828)	26,877

Balance Sheet Data	**December 31, 2021**
Current Assets	54,970
Total Assets	251,618
Equity	181,530
Non-Current Liabilities	50,355
Current Liabilities	19,733
Total equity and liabilities	251,618

The following tables, which have been derived from APR' s audited financial statements for the year ended December 31, 2020 summarizes the result of APR' s operations for the period indicated, in TCHF.

In TCHF	**Fiscal Year Ended December 31, 2020**
Statement of Operations Data:	
Revenue	10,100
Other gains	3,943
Total income	**14,043**
Goods and service expense	(6,069)
Personnel expense	(4,809)
Net impairment losses on financial and contract assets	(657)
General and administrative expense	(1,019)
Operating result	**1,489**
Depreciation and amortization expense	(1,053)
Profit before interest and taxes	**436**

Financial income and expense, net	(327)
Profit before income taxes	**109**
Income taxes	(315)
Loss for the year	**(206)**

Summary Unaudited Pro Forma Financial Information of Relief and APR

The unaudited pro forma condensed combined statements of operations assume that the acquisition of APR was consummated on January 1, 2021 instead of its actual date (June 28, 2021) and combines the historical results of Relief and APR for the six months ended June 30, 2021 (as to APR) and the year ended December 31, 2021 (as to Relief). The historical financial statements of Relief and APR, which are provided elsewhere in this Registration Statement on Form 20-F, have been adjusted to give pro forma effect to events that are (i) directly attributable to the acquisition, (ii) factually supportable, and (iii) with respect to the statements of operations, expected to have a continuing impact on the combined results. A more detailed version of the pro forma financial statements is included in this registration statement in "Operating Results-Unaudited Pro Forma Financial Information for Relief and APR."

Statement of Operations Data:	December 31, 2021
Revenue	6,911
Other gains	1,183
Total income	8,094
Raw materials and consumables expense	(1,501)
External selling and distribution expense	(559)
External research and development expense	(19,765)
Personnel expense	(12,053)
Other administrative expense	(7,064)
Other losses	(752)
Net impairment reversal gain on financial and contract assets	117
EBITDA	(33,483)
Amortization and depreciation expense	(4,079)
Operating result	(37,562)
Financial income	166
Financial expense	(1,411)
Net result before taxes	(38,807)
Income taxes	(1,126)
Net result for the period	(37,681)

B. CAPITALIZATION AND INDEBTEDNESS

The table below sets forth our cash and cash equivalents and shows our capitalization as of March 31, 2022. You should read this table in conjunction with our consolidated financial statements for the year ended December 31, 2021, together with the accompanying notes and the other information appearing under the heading "Item 5. Operating and Financial Review and Prospects." All amounts below are in Swiss Francs (CHF) and are in thousands. The indebtedness set forth below is unsecured and non-guaranteed.

(in thousands, except per-share data)	March 31, 2022
Cash and Cash Equivalents	36,965
Debt	
Interest bearing loans and borrowings	1,732
Capitalization	
Share Capital	44,163
Treasury Shares	(2,565)
Reserves	213,837
Accumulated deficit	(77,476)
Total Capitalization	177,959
Total Capitalization and Indebtedness	179,691

As of March 31, 2022, 4,159,788,621 of our ordinary shares were outstanding, excluding 256,545,996 shares that were held in treasury.

As of June 28, 2022, our cash and cash equivalents were approximately CHF 30.0 million and 4,416,334,617 of our ordinary shares were outstanding, including 227,108,394 shares that were held in treasury.

C. REASONS FOR THE OFFER AND USE OF PROCEEDS

Not applicable

D. RISK FACTORS

Risk Factors Summary

We are providing the following summary of the risk factors contained in our Form 20-F to enhance the readability and accessibility of our risk factor disclosures. We encourage our stockholders to carefully review the full risk factors contained in this Form 20-F in their entirety for additional information regarding the risks and uncertainties that could cause our actual results to vary materially from our recent results or from our anticipated future results.

Risks Related to our Business

We depend heavily on the success of our product candidates. If our clinical studies are unsuccessful, if we or our collaboration partners do not obtain regulatory approval or if we or our collaboration partners are unable to commercialize our product candidates, or if we experience significant delays in doing so, our business, financial condition and results of operations will be materially adversely affected.

The potential success of RLF-100 for the treatment of critical COVID-19 patients is dependent on the unpredictable trajectory of the virus and effects of the availability of other treatments.

Our business is subject to significant regulation from governments and regulatory bodies, including marketing approval requirements, which could lengthen the development time, increase the cost of developing RLF-100 and our other drug product candidates or delay, prevent or limit the commercialization of our product candidates.

Results of early clinical studies may not be predictive of future study results.

The successful commercialization of our product candidates will depend on the extent to which governmental authorities and health insurers establish adequate coverage and reimbursement levels and pricing policies.

Our products may not gain market acceptance, in which case we or our collaboration partners may not be able to generate product revenues, which would materially adversely affect our business, financial condition and results of operations.

We depend on enrollment of patients in our clinical studies for our product candidates. If we are unable to enroll patients in our clinical studies, our research and development efforts could be materially adversely affected.

If serious adverse, undesirable or unacceptable side effects are identified during the development of our product candidates or following approval, if any, we may need to abandon our development of such product candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval, if any.

We operate in highly competitive and rapidly changing industries, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

Our business is subject to additional risks associated with international operations.

The COVID-19 pandemic may impact our business.

Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel.

We may become exposed to costly and damaging liability claims, either when testing our product candidates or at the commercial stage or as a result of claims against our directors and officers, and our liability insurance may not cover all damages from such claims.

A breakdown or breach of our information technology systems and cybersecurity efforts, or those of our key business partners or service providers, could subject us to liability or reputational damage or interrupt the operation of our business.

Changes in laws, rules or regulations relating to data privacy and security, or any actual or perceived failure by us to comply with such laws, rules, regulations and standards, or contractual or other obligations relating to data privacy and security, could have a material adverse effect on our reputation, results of operations, financial condition and cash flows.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs.

We have little history of commercializing pharmaceutical products, which may make it difficult to evaluate our future viability.

We may not be able to formulate or manufacture RLF-100 to the standards needed for sustained commercial supply.

Risks related to our Relationships with Third Parties

We are in litigation with NeuroRx, and there can be no assurance as to the result of that litigation.

If we fail to maintain our strategic relationships with any of our current or future strategic partners, our business, commercialization prospects and financial condition may be materially adversely affected.

We rely on third parties to conduct our nonclinical and clinical studies and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates, and our business could be substantially harmed.

We currently rely on third-party suppliers and other third parties for production of our product candidates and our dependence on these third parties may impair the advancement of our research and development programs and the development of our product candidates.

Risks related to Intellectual Property

We may not have sufficient patent terms to protect our products and business effectively.

We or our licensing or collaboration partners may become subject to intellectual property-related litigation or other proceedings to protect or enforce our patents or the patents of our licensors or licensees and collaborators, any of which could be expensive, time-consuming, and unsuccessful, and may ultimately result in our loss of ownership of intellectual property.

If we or our licensing or collaboration partners are unable to obtain and maintain effective patent rights for our technologies, product candidates or any future product candidates, or if the scope of the patent rights obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our, or our collaboration partners' ability to successfully commercialize our products and technology may be adversely affected.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

Patent policy and rule changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, thereby impairing our ability to protect our technologies and products.

If we are unable to maintain effective proprietary rights for our technologies, product candidates or any future product candidates, we may not be able to compete effectively in our markets.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document-submission, fee-payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

The patent protection and patent prosecution for some of our product candidates could be dependent on third parties.

Third-party claims of intellectual property infringement may expose us to substantial liability or may prevent or delay our or our collaboration partners' development and commercialization efforts.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We may not be able to protect our intellectual property rights throughout the world.

We may be unable to protect our trade secrets, know-how and technologies.

Risks related to our Financial Condition and Results of Operations

We are a commercial-stage biopharmaceutical company with a history of operating losses. While we currently believe that we have sufficient funds for our planned operations well into 2023, there can be no assurance that we will be able to obtain the funds necessary to continue our operations beyond that point.

If we fail to obtain additional funding required for our planned activities, we may not have sufficient funds to continue our operations and may have to delay, reduce or eliminate one or more of our product development programs or commercialization efforts.

Raising additional capital will likely cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our intellectual property or future revenue streams.

Our ability to use tax loss carry-forwards may be limited.

Exchange rate fluctuations may materially affect our results of operations and financial condition.

Risks related to regulation of our business

The SIX Exchange Regulation AG has launched an investigation into Relief, the results of which are uncertain.

We cannot give any assurance that any of our product candidates in development will receive regulatory approval, which is necessary before they can be commercialized.

Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes. If clinical studies of our product candidates are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our product candidates on a timely basis or at all.

Even if we obtain and maintain approval for certain of our drug candidates from one jurisdiction, we may never obtain approval for our drug candidates in other jurisdictions, which would limit our market opportunities and adversely affect our business.

Even if certain of our product candidates obtain regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expenses. Additionally, our additional product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

We have conducted and may in the future conduct clinical studies for our drug candidates outside the U.S., Europe and Switzerland, and the FDA, EMA and Swissmedic and applicable foreign regulatory authorities may not accept data from such studies.

Our business is subject to complex and evolving U.S. and international laws and regulations regarding clinical trials reimbursement and privacy and data protection. Many of these laws and regulations are subject to change and uncertain interpretation and could result in claims, changes to our business practices, penalties, increased cost of operations, or declines in user growth or engagement, or otherwise harm our business.

We could be subject to liabilities under environmental, health and safety laws or regulations, or fines, penalties or other sanctions, if we fail to comply with such laws or regulations or otherwise incur costs that could have a material adverse effect on the success of our business.

Risks from the improper conduct of employees, agents, contractors, or collaborators could adversely affect our reputation and our business, prospects, operating results, and financial condition.

Our business activities may be subject to the Foreign Corrupt Practices Act (FCPA) and similar anti-bribery and anti-corruption laws.

Risks related to our common shares and our ADRs

We do not know whether an active, liquid and ordinary trading market will develop for our ADRs or what the market price of our ADRs will be if a market develops. As a result, it may be difficult for you to sell your ADRs.

The market price of our ADRs may be volatile and may fluctuate due to factors beyond our control.

Future sales, or the possibility of future sales, of a substantial number of our common shares could adversely affect the price of our common shares.

Holders of ADRs are not treated as holders of our ordinary shares.

You will not have the same voting rights as holders of our ordinary shares and may not receive voting materials in time to exercise your right to vote.

You may not receive distributions on our ordinary shares represented by ADRs or any value for them if it is illegal or impractical to make them available to holders of ADRs.

We are a foreign private issuer and, as a result, we are not subject to U.S. proxy rules and are subject to Exchange Act reporting obligations that, to some extent, are more lenient and less frequent than those of a U.S. domestic public company.

We are an "emerging growth company," and there are reduced disclosure requirements applicable to emerging growth companies, above and beyond the reduced disclosure requirements we have as a Foreign Private Issuer.

One of our principal shareholders has a significant holding in the company which may give them influence in certain matters requiring approval by shareholders, including approval of significant corporate transactions in certain circumstances.

We have broad discretion in the use of our cash and cash equivalents and short-term financial assets and may not use them effectively.

We have not in the past paid dividends and we do not expect to pay dividends in the foreseeable future.

We are a Swiss corporation. The rights of our shareholders are different from the rights of shareholders in companies governed by the laws of U.S. jurisdictions.

Our status as a Swiss corporation may limit our flexibility with respect to certain aspects of capital management and may cause us to be unable to make distributions without subjecting our shareholders to Swiss withholding tax.

U.S. shareholders may not be able to obtain judgments or enforce civil liabilities against us or our executive officers or members of our board of directors.

Our status as a Swiss corporation means that our shareholders enjoy certain rights that may limit our flexibility to raise capital, issue dividends and otherwise manage ongoing capital needs.

Swiss law restricts our ability to pay dividends.

As a foreign private issuer and as permitted by the listing requirements of Nasdaq, we rely on certain home country governance practices rather than the corporate governance requirements of Nasdaq.

We may lose our foreign private issuer status, which would then require us to comply with the Exchange Act' s domestic reporting regime and cause us to incur significant legal, accounting and other expenses.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common shares.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, the price of our common shares and our trading volume could decline.

Risk Factors

You should carefully consider the risks and uncertainties described below and the other information in this Registration Statement before making an investment. Our business, financial condition or results of operations could be materially and adversely affected if any of these risks occur, and as a result, the market price of our shares could decline. This Registration Statement also contains forward-looking statements that involve risks and uncertainties. See "Forward-Looking Statements." Our actual results could differ materially and adversely from those anticipated in these forward-looking statements as a result of certain factors.

Risks Related to our Business

We depend heavily on the success of our product candidates. If our clinical studies are unsuccessful, if we or our collaboration partners do not obtain regulatory approval or if we or our collaboration partners are unable to commercialize our product candidates, or if we experience significant delays in doing so, our business, financial condition and results of operations will be materially adversely affected.

We currently have a small number of products approved for sale, all of which were acquired in the business combination with APR, generating a limited volume of sales. We have invested a significant portion of our efforts and financial resources in the development of RLF-100, have recently licensed ACER-001, and have added additional products to our portfolio through our acquisitions of AdVita and APR. Our ability to generate significantly higher product revenues will depend heavily on successful clinical development, obtaining regulatory approval and eventual commercialization of these product candidates. The success of our current and future product candidates will depend on several factors, including the following:

- completing preclinical studies and clinical studies that demonstrate the efficacy, safety and clinical utility of our product candidates;
- receiving marketing approvals from applicable regulatory authorities;
- developing product formulations with sufficiently long-term stability and chemistry, manufacturing and controls that meet governmental regulatory standards;
- establishing commercial manufacturing capabilities;
- launching commercial sales, marketing and distribution operations;
- acceptance of our product candidates by patients, the medical community and third-party payors;
- a continued acceptable safety profile following approval;
- competing effectively with other therapies; and
- obtaining, maintaining, enforcing and defending our intellectual property rights and claims and not infringing on third parties' intellectual property rights.

If we or our collaborators do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully commercialize our current or future product candidates, which would materially adversely affect our business, financial conditions and results of operations.

The potential success of RLF-100 for the treatment of critical COVID-19 patients is dependent on the unpredictable trajectory of the virus and effects of other treatments.

In March 2021, NeuroRx, Inc. ("NeuroRx") announced top-line 60-day results from phase 2b/3 intravenous ("IV") trial. According to a press release issued by NeuroRx, across all patients and sites aviptadil IV met the primary endpoint for successful recovery from respiratory failure at days 28 (p=0.14) and 60 (p=0.13) and also demonstrated a meaningful benefit in survival after controlling for ventilation status and treatment site. However, they also reported that the study did not demonstrate a statistically-significant difference on the study' s primary endpoint without statistical adjustment for these pre-specified covariates. On the basis of these findings, NeuroRx announced on June 1, 2021 that it had applied to the FDA for Emergency Use Authorization ("EUA") and subsequently planned to submit a New Drug Application ("NDA") with the United States Food and Drug Administration ("FDA").

On November 5, 2021, NRx Pharmaceuticals, Inc. ("NRx"), which became the parent corporation of NeuroRx on its merger with Big Rock Partners Acquisition Corp, in May 2021, announced in a press release that the FDA had declined EUA for the use of aviptadil for the treatment of acute respiratory failure due to critical COVID-19. In its press release, NRx stated that in the letter from the FDA denying EUA, the FDA noted that it has only reviewed safety data on 131 patients treated with aviptadil. NRx further reported in its press release that it will attempt to coordinate a review by the FDA of 150 or more additional patients treated with aviptadil through other trials. Additionally, NRx stated in its press release that the study' s Data Safety and Monitoring Board reviewing the trial found no new safety issues.

On November 29, 2021, NRx issued a press release announcing the results of a subsequent statistical analysis it commissioned from Dr. David Schoenfeld, a statistician with expertise in life-threatening diseases of the lung. According to the press release, Dr. Schoenfeld analyzed the subgroup of patients in the Phase 2b/3 trial that remained in respiratory failure despite treatment with remdesivir and stated that the analysis identified a statistically significant (p=0.03) 2.5-fold increased odds of a patient having survived and being free of respiratory failure at 60 days (the primary endpoint) and a statistically significant (p=0.006) four-fold higher odds of 60-day survival among patients treated with ZYESAMI compared to those treated with placebo.

On January 5, 2022 NRx reported in a press release that it had submitted an additional application to the FDA seeking EUA for the use of aviptadil to treat patients with critical COVID-19 who are at immediate risk for death from respiratory failure despite treatment with approved therapy, including Remdesivir. There can be no assurance as to whether this additional EUA application will be approved.

On March 3, 2022, two U.S. Senators and two members of the House of Representatives sent a letter to Dr. Robert Califf, Commissioner of the FDA, and Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Disease regarding the results of the right-to-try administration of ZYESAMI. The letter discusses the results and seeks comment on the FDA' s review of the ZYESAMI EUA application and the FDA' s stance that the EUA will not be reviewed until the completion of clinical trials later this year. There can be no assurance as to what effect the letter will have on the review and consideration of the EUA application.

Vaccines for COVID-19 have been available since November 2020. In addition, other medications have been approved on an emergency use basis, including Gilead Sciences' Veklury (Remdesivir), which has been approved for use in adult and certain pediatric patients requiring hospitalization for COVID-19, which has been approved by the FDA and the European Medicines Agency ("EMA"), Pfizer' s Paxlovid, by the FDA, the EMA and the United Kingdom' s Medicines and Healthcare Products Regulatory Agency ("MHPRA"), and Merck' s Lagevrio, which has been approved by the MHPRA. Paxlovid and Lagevrio are both oral treatments for COVID-19 that may significantly reduce serious illness or death from COVID-19 if treatment is started early enough in the progression of the disease. It is not yet known how current treatments will affect the future of the pandemic, including the number of cases and their severity, which increases the uncertainty regarding the future medical need for aviptadil for the treatment of COVID-19.

Then can be no assurance that RLF-100 will ever be approved by the FDA as a treatment for COVID-19 or as a treatment for any other indication.

Our business is subject to significant regulation from governments and regulatory bodies, including marketing approval requirements, which could lengthen the development time, increase the cost of developing RLF-100 and our other drug product candidates or delay, prevent or limit the commercialization of our product candidates.

Prior to marketing, RLF-100 must undergo a comprehensive regulatory approval procedure by the relevant authorities, including the EMA for Europe, the FDA for the U.S., and other national health agencies, including the Swiss agency for therapeutic products ("Swissmedic"; *Schweizerisches Heilmittelinstitut*). Such procedures may last several years and require considerable financial expenditure. These procedures can only start after providing the agencies with all data generated when testing RLF-100, including pre-clinical and clinical data from extensive clinical trials to demonstrate the safety and efficacy in humans. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is uncertain as to the outcome. A failure of one or more clinical trials can occur at any stage of testing. It is hence impossible to predict when or if the FDA will determine that RLF-100 is effective or safe in humans and will receive regulatory approval.

To date, NeuroRx has refused to provide us with the data from the Phase 2b/3 trial of IV aviptadil that they reported in March 2021 and their correspondence with the FDA as to their EUA applications. This failure to provide the data has made it impossible for us to file an application for conditional marketing approval of RLF-100 in Europe. This failure to provide data is part of the claims we have made in our lawsuit against NeuroRx. There can be no assurance as to when or if we will receive the data we need to make the required filings with European authorities.

When a medicinal product candidate receives regulatory approval, the approval can nonetheless be subject to limitations, e.g., with regard to the indications for which it may be marketed. The approval may also be given subject to conditions, such as additional proof of the medicinal product' s effectiveness and safety. Even after approval is granted, manufacturing, safety, efficacy, recordkeeping, labeling, marketing, sales and distribution of its product candidates are regulated by government agencies in countries where we intend to market our products. All these activities are subject to recurring scrutiny and regular inspections by the relevant agencies. As a consequence, if previously unknown problems are discovered in connection with an approved product, its manufacturer or the manufacturing facilities, this can result in restrictions on the product, the manufacturer or the manufacturing facilities, up to the requirement to withdraw the product from the market. In any event, changes in existing regulations or adoption of new regulations could prevent the Group and/or its commercialization partners from obtaining or maintaining, or affect the timing of, future regulatory approvals.

These and other factors, alone or together, may have a material adverse effect on the Group' s business, financial condition, results of operations and growth prospects as well as the Share price.

Results of early clinical studies may not be predictive of future study results.

Positive or timely results from preclinical or early-stage clinical studies do not ensure positive or timely results in late-stage clinical studies or product approval by the FDA, the EMA, or comparable foreign regulatory authorities. Products that show positive preclinical or early clinical results may not show sufficient safety or efficacy in later-stage clinical studies and therefore may fail to obtain regulatory approvals. In addition, preclinical and clinical data are often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical and clinical studies have nonetheless failed to obtain marketing approval for the product candidates. The FDA, the EMA and comparable foreign regulatory authorities have substantial discretion in the approval process and in determining when or whether regulatory approval will be obtained for any of our product candidates. Even if we believe that the data collected from clinical studies of our product candidates are promising, such data may not be sufficient to support approval by the FDA, the EMA or any other regulatory authority.

In some instances, there can be significant variability in safety and/or efficacy results between different studies of the same product candidate due to numerous factors, including changes in study procedures set forth in protocols, differences in the size and type of the patient populations, adherence to the dosing regimen and other study protocols, and the rate of dropout among clinical study participants. In the case of our later-stage clinical product candidates, results may differ in general on the basis of the larger number of clinical study sites and the additional countries and languages involved in these clinical studies.

Clinical studies may include subject-reported outcomes, some of which may be captured with electronic diaries. We have no assurance and cannot rely on past experience that the high frequency of questioning is not influencing the measured outcome. In addition, low compliance with daily reporting requirements may impact the studies' validity or statistical power. We cannot assure that any Phase 1, phase 2, phase 3 or other clinical studies that either we or our collaboration partners may conduct will demonstrate consistent or adequate efficacy and safety to obtain regulatory approval to market our product candidates.

If we or our collaboration partners are required to conduct additional clinical studies or other testing of any of our current or future product candidates that we or our collaboration partners develop, beyond the studies and testing that we or our collaboration partners contemplate, if we or our collaboration partners are unable to successfully complete clinical studies of our product candidates or other testing, if the results of these studies or tests are unfavorable or are only modestly favorable, or if there are safety concerns associated with our current or future product candidates, we may:

- be delayed in obtaining marketing approval for our product candidates;

not obtain marketing approval;

obtain approval for indications or patient populations that are not as broad as intended or desired;

obtain approval with labeling that includes significant use or distribution restrictions or significant safety warnings, including boxed warnings;

be subject to conditional approval or otherwise to additional post-marketing studies or other requirements; or

remove the product from market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or receiving marketing approvals and we may be required to obtain additional funds to complete clinical studies. We cannot assure that our clinical studies will begin as planned or be completed on schedule, if at all, or that we will not need to amend our studies after they have begun. Significant clinical study delays could also shorten any periods during which we or our collaboration partners may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which may harm our business and results of operations. In addition, some of the factors that cause, or lead to, clinical study delays may ultimately lead to the denial of regulatory approval of our product candidates.

The successful commercialization of our product candidates will depend on the extent to which governmental authorities and health insurers establish adequate coverage and reimbursement levels and pricing policies.

The successful commercialization of our product candidates will depend, in part, on the extent to which coverage and reimbursement for our products will be available from government and health administration authorities, private health insurers and other third-party payors. To manage healthcare costs, many governments and third-party payors increasingly scrutinize the pricing of new technologies and require greater levels of evidence of favorable clinical outcomes and cost-effectiveness before extending coverage. In light of such challenges to prices and the requirement for increasing levels of evidence of the benefits and clinical outcomes of new technologies, we cannot be sure that coverage will be available for any of our current or future product candidates that we or our collaboration partners will commercialize or, if available, that the reimbursement rates will be adequate in each respective region. If we are unable to obtain adequate levels of coverage and reimbursement for our product candidates, their marketability will be negatively and materially impacted.

Third-party payors may deny coverage and reimbursement status altogether for a given drug product, or may cover the product but also establish prices at levels that are too low to enable us to realize an appropriate return on our investment in product development. Because the rules and regulations regarding coverage and reimbursement change frequently, in some cases at short notice, even when there is favorable coverage and reimbursement, future changes may occur that adversely impact the favorable status. Further, the net reimbursement for drug products may be subject to additional reductions in the future depending on policy changes enacted by the national regulatory bodies.

The unavailability or inadequacy and variability of third-party coverage and reimbursement could have a material adverse effect on the market acceptance of our product candidates and the future revenues we may expect to receive from those products. In addition, we are unable to predict what additional legislation or regulation relating to the healthcare industry or third-party coverage and reimbursement may be enacted in the future, or what effect such legislation or regulation would have on our business.

Our products may not gain market acceptance, in which case we or our collaboration partners may not be able to generate product revenues, which would materially adversely affect our business, financial condition and results of operations.

Even if the FDA, the EMA or any other regulatory authority approves the marketing of any product candidates that we develop, physicians, healthcare providers, patients or the medical community may not accept or use them. Efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may not be successful. If any of our current or future product candidates does not achieve an adequate level of acceptance, we or our collaboration partners may not generate significant product or royalty revenues or any profits from operations. The degree of market acceptance of our product candidates that are approved for commercial sale will depend on a variety of factors, including:

- how clinicians and potential patients perceive our novel products;
- the timing of market introduction;
- the number and clinical profile of competing products;
- our ability to provide acceptable evidence of safety and efficacy;
- the prevalence and severity of any side effects;
- relative convenience and ease of administration;
- cost-effectiveness;
- patient diagnostics and screening infrastructure in each market;
- marketing and distribution support;
- availability of coverage, reimbursement and adequate payment from third party payors, both public and private; and
- other potential advantages over alternative treatment methods.

If our product candidates fail to gain market acceptance, this will have a material adverse impact on our ability to generate revenues to provide a satisfactory, or any, return on our investments. Even if some products achieve market acceptance, the market may prove to not be large enough to allow us to generate significant revenues.

In addition, the potential market opportunity of our product candidates is difficult to estimate precisely. Our estimates of the potential market opportunity are predicated on several key assumptions such as industry knowledge and publications, third-party research reports and other surveys. These assumptions involve the exercise of significant judgment on the part of our management and are inherently uncertain, and the reasonableness of these assumptions could not have been assessed by an independent source in every detail. If any of the assumptions proves to be inaccurate, then the actual market for our product candidates could be smaller than our estimates of the potential market opportunity. If the actual market for our product candidates is smaller than we expect, or if any approved products fail to achieve an adequate level of acceptance by physicians, healthcare payors and patients, our product or royalty revenue may be limited, and it may be more difficult for us to achieve or maintain profitability.

We depend on enrollment of patients in our clinical studies for our product candidates. If we are unable to enroll patients in our clinical studies, our research and development efforts could be materially adversely affected.

If our product candidates are associated with serious adverse, undesirable or unacceptable side effects, we may need to abandon their development or limit development to certain uses or subpopulations in which such side effects are less prevalent, less severe or more acceptable from a risk‑benefit perspective. Many compounds that initially showed promise in preclinical or early-stage testing were later found to cause side effects that restricted their use and prevented further development of the compound for larger indications.

Generally, the specific target population of patients and therapeutic time windows may make it difficult for us to enroll enough patients to complete clinical studies for our products in a timely and cost-effective manner. Delays in the completion of any clinical study of our product candidates will increase our costs, slow down our product candidate development and approval process, and delay or potentially jeopardize our or our collaboration partners' ability to commence product sales and generate revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical studies may also ultimately lead to the denial of regulatory approval of our product candidates.

If serious adverse, undesirable or unacceptable side effects are identified during the development of our product candidates or following approval, if any, we may need to abandon our development of such product candidates, the commercial profile of any approved label may be limited, or we may be subject to other significant negative consequences following marketing approval, if any.

If our product candidates are associated with serious adverse, undesirable or unacceptable side effects, we may need to abandon their development or limit development to certain uses or subpopulations in which such side effects are less prevalent, less severe or more acceptable from a risk‑benefit perspective. Many compounds that initially showed promise in preclinical or early-stage testing were later found to cause side effects that restricted their use and prevented further development of the compound for larger indications.

Occurrence of serious side effects could impede clinical study enrollment and receipt of marketing approval from the U.S. FDA, the EMA and comparable other national regulatory authorities. Adverse events ("AEs") and/or serious adverse events ("SAEs") could also adversely affect physician or patient acceptance of our product candidates.

Additionally, if one or more of our product candidates receives marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including the following:

- regulatory authorities may withdraw approvals of such product and require us or our collaboration partners to take any approved products off the market;
- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication or field alerts to physicians and pharmacies;
- we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
- we may be required to change the way the product is administered, to conduct additional studies or to change the labeling of the product;
- we or our collaboration partners may be subject to limitations in how we promote the product;
- sales of the product may decrease significantly;

we could be sued and held liable for harm caused to patients; and

our reputation and physician or patient acceptance of our products may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the particular product candidate, if approved, and could significantly harm our business, results of operations and prospects.

We operate in highly competitive and rapidly changing industries, which may result in others discovering, developing or commercializing competing products before or more successfully than we do.

The biopharmaceutical and pharmaceutical industries are highly competitive and subject to significant and rapid technological change. Our success is highly dependent on our ability to discover, develop and obtain marketing approval for new and innovative products on a cost-effective basis and to market them successfully. In doing so, we face and will continue to face intense competition from a variety of businesses, including large, fully integrated pharmaceutical companies, specialty pharmaceutical companies and biopharmaceutical companies, academic institutions, government agencies and other private and public research institutions in Europe, the U.S. and other jurisdictions. Many of our potential competitors, alone or with their strategic partners, have substantially greater financial, technical and human resources than we do and significantly greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of treatments, and the commercialization of those treatments. Mergers and acquisitions in the pharmaceutical and biopharmaceutical industries may result in even more resources being concentrated among a smaller number of our competitors.

The highly competitive nature of and rapid technological changes in the pharmaceutical and biopharmaceutical industries could render our product candidates or our technology obsolete or noncompetitive. The commercial opportunity for our products could be reduced or eliminated if our competitors:

develop and commercialize products that are safer, more effective, less expensive, or more convenient or easier to administer;

obtain quicker FDA or other regulatory approval for their products;

establish superior intellectual property and proprietary positions;

have access to more manufacturing capacity;

implement more effective approaches to sales, marketing and distribution; or

form more advantageous strategic alliances.

Should any of these occur, our business, financial condition and results of operations could be materially adversely affected.

Our business is subject to additional risks associated with international operations.

Our business is subject to risks associated with conducting business internationally. Accordingly, our future results could be harmed by a variety of factors, including:

potentially reduced protection for intellectual property rights;

changes in a specific country’ s or region’ s political or economic environment;

trade protection measures, import or export licensing requirements or other restrictive actions such as sanctions governments;

negative consequences from changes in tax laws;

compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;

difficulties associated with staffing and managing international operations, including differing labor relations;

production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and

business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

The COVID-19 pandemic may impact our business.

In December 2019, a novel strain of coronavirus, COVID-19, surfaced in Wuhan, Hubei Province, China. By March 2020, COVID-19 had spread to other countries, including Switzerland and the United States, and was declared a pandemic by the World Health Organization on March 11, 2020. Since the beginning of the pandemic, governments, public institutions, and other organizations in countries and localities where COVID-19 cases have been identified have taken certain preventative or protective measures to combat the transmission of the virus, including implementation of travel restrictions or bans, closures of non-essential businesses, limitations of public gatherings, other social distancing and shelter-in-place measures, and delays or cancellations of elective surgeries. The COVID-19 pandemic continues to pose the risk that the Company, our employees, contractors, suppliers, and other partners may be prevented from conducting business activities for an indefinite period of time due to shutdowns that may be requested or mandated by state and federal governmental authorities.

As the COVID-19 pandemic continues, we may experience disruptions that could materially impact our business and planned clinical trials, including:

delays or difficulties in conducting preclinical and clinical trials;

interruption in global manufacturing and shipping that may affect the manufacturing and/or transport of clinical trial materials and other materials, including testing equipment; and

changes in local regulations as a response to COVID-19 that may require us to change the way we perform our trials.

Our future growth and ability to compete depends on retaining our key personnel and recruiting additional qualified personnel.

Our success depends upon the continued contributions of our key management, scientific and technical personnel, many of whom have substantial experience with or been instrumental for us and our projects. The loss of our key managers and senior scientists could delay our research and development activities. Laws and regulations on executive compensation, including legislation in Switzerland, may restrict our ability to attract, motivate and retain the required level of qualified personnel. In Switzerland, legislation affecting public companies has been passed that, among other things, imposes an annual binding shareholder “say on pay” vote with respect to the compensation of the executive management, including executive officers and the members of the board of directors. In addition, the competition for qualified personnel in the pharmaceutical and biopharmaceutical field is intense, and our future success depends upon our ability to attract, retain and motivate highly skilled scientific, technical and managerial employees. We face competition for personnel from other companies, universities, public and private research institutions and other organizations. If our recruitment and retention efforts are unsuccessful in the future, it may be difficult for us to implement our business strategy, which could have a material adverse effect on our business.

We may become exposed to costly and damaging liability claims, either when testing our product candidates or at the commercial stage or as a result of claims against our directors and officers, and our liability insurance may not cover all damages from such claims.

We are exposed to potential product liability and professional indemnity risks that are inherent in the research, development, manufacturing, marketing and use of pharmaceutical or biopharmaceutical products. Currently we have no products that have been approved for commercial sale; however, our current and future use of product candidates in clinical studies, and the sale of any approved products in the future, may expose us to liability claims. These claims might be made by patients that use the product, by healthcare providers, or by pharmaceutical or biopharmaceutical companies or others selling such products. Any claims against us, regardless of their merit, could be difficult and costly to defend and could materially adversely affect the market for our product candidates or any prospects for commercialization of our product candidates.

Although the clinical trial process is designed to identify and assess potential side effects, it is always possible that a drug, even after regulatory approval, may exhibit unforeseen side effects. If any of our product candidates were to cause adverse side effects during clinical studies or after approval of the product candidate, we may be exposed to substantial liabilities. Physicians and patients may not comply with any warnings that identify known potential adverse effects and patients who should not use our product candidates.

We continuously seek to maintain appropriate and cost-effective liability insurance coverage in connection with our products and for purposes of indemnifying our directors and officers for claims against them. It is, however, possible that our liabilities could exceed our insurance coverage. For example, we intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for any of our product candidates. However, we may not be able to maintain insurance coverage at a reasonable cost or obtain insurance coverage that will be adequate to satisfy any liability that may arise. If a successful liability claim or series of claims is brought against us for uninsured liabilities or in excess of insured liabilities, our assets may not be sufficient to cover such claims and our business operations could be impaired.

Should any of the events described above occur, this could have a material adverse effect on our business, financial condition and results of operations.

A breakdown or breach of our information technology systems and cybersecurity efforts, or those of our key business partners or service providers, could subject us to liability or reputational damage or interrupt the operation of our business.

Despite the implementation of security measures, our internal computer systems and those of our contractors and consultants may be vulnerable to damage from computer viruses and unauthorized access. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Our ability to monitor our partners' data security practices are limited, and due to applicable laws and regulations or contractual obligations, we may be held responsible for any security breaches or cybersecurity attack attributed to them as they relate to the information we share with them. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary information or personal data of our employees, partners or study subjects, we could incur liability and the further development and commercialization of our product candidates could be delayed.

We are increasingly dependent upon technology systems and data. Our computer systems continue to increase in multitude and complexity due to the growth in our business, making them potentially vulnerable to breakdown, malicious intrusion and random attack. Data privacy or security breaches, including those by individuals authorized to access our technology systems or others may pose a risk that sensitive data, including intellectual property, trade secrets or personal information belonging to us, our patients, study subjects or other business partners, may be exposed to unauthorized persons or to the public. Cyber-attacks are increasing in their frequency, sophistication and intensity, and are becoming increasingly difficult to detect. They are often carried out by motivated, well-resourced, skilled and persistent actors, including nation states, organized crime groups, "hacktivists" and employees or contractors acting with malicious intent. Cyber-attacks could include the deployment of harmful malware and key loggers, ransomware, a denial-of-service attack, a malicious website, phishing attacks, computer viruses, social engineering and other means to affect the confidentiality, integrity and availability of our technology systems and data. Our key business partners face similar risks and any security breach of their systems could adversely affect our security posture. Although we continue to build and improve our systems and infrastructure, and believe we have taken appropriate security measures to reduce these risks to our data and information technology systems, there can be no assurance that our efforts will prevent, detect or appropriately respond to breakdowns or breaches in our systems that could adversely affect our business and operations and/or result in the loss of critical or sensitive information, including personal information, which could result in financial, legal, business or reputational harm to us. We continue to invest in industry standard IS/IT solutions and managed services that often include the relevant, layered protection and monitoring practices surrounding our data and IT systems and related infrastructure. These investments reduce further these risks in that they enable organizations such as ours to leverage the resources necessary to monitor IT systems and infrastructure for any current or potential threats. These investments can be costly, and as cyber threats continue to evolve, we may be required to expend significant, additional resources to continue to modify and/or enhance our protective, detective and responsive measures required to remediate any identified information security vulnerabilities. Claims related to security breaches, cyber-attacks and other related breaches may result in significant fines, penalties and payment of damages. We may be required to expend significant capital and other resources to protect against and respond to any attempted or existing cybersecurity incidents. In addition, our remediation efforts may not be successful.

Changes in laws, rules or regulations relating to data privacy and security, or any actual or perceived failure by us to comply with such laws, rules, regulations and standards, or contractual or other obligations relating to data privacy and security, could have a material adverse effect on our reputation, results of operations, financial condition and cash flows.

We are, and may increasingly become, subject to various laws, rules, regulations and standards, as well as contractual obligations, relating to data privacy and security in the jurisdictions in which we operate. The regulatory environment related to data privacy and security is increasingly rigorous, with new and constantly changing requirements applicable to our business, and enforcement practices are likely to remain uncertain for the foreseeable future. These laws, rules, regulations and standards may be interpreted and applied differently over time and from jurisdiction to jurisdiction in a manner that could have a material adverse effect on our results of operations, financial condition and cash flows. New laws, amendments to or reinterpretations of existing laws, rules, regulations, standards and other obligations may require us to incur additional costs and restrict our business operations, and may require us to change how we use, collect, store, transfer or otherwise process certain types of personal information and to implement new processes to comply with those laws.

Evolving compliance and operational requirements impose significant costs, which are likely to increase over time. In addition, such requirements may require us to modify our data-processing practices and policies, distract management or divert resources from other initiatives and projects. For instance, the European Union Court of Justice and the Swiss Data Protection Authority have declared the U.S. Privacy Shield to be inadequate for transfers of personal data out of the EU and Switzerland, which could increase our compliance burden. If we are unable to properly protect the privacy and security of personal information, including protected health information, we could be found to have breached our contracts. In addition, any failure or perceived failure by us to comply with any applicable federal, state or similar foreign laws and regulations relating to data privacy and security could result in damage to our reputation and our relationship with our customers, as well as proceedings or litigation by governmental agencies, customers, partners, collaborators and/or study subjects, including class action privacy litigation in certain jurisdictions, which would subject us to significant fines, sanctions, awards, penalties or judgments, all of which could have a material adverse effect on our business, results of operations, financial condition and prospects.

Business disruptions could seriously harm our future revenue and financial condition and increase our costs.

Our operations and those of our third-party collaborators and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, medical epidemics, and other natural or man-made disasters or business interruptions, for which we are partly uninsured. In addition, we rely on our third-party research institution collaborators for conducting research and development of our product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third-party manufacturers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man-made or natural disaster or by other business interruption.

Our operations are conducted internationally with employees, consultants and strategic vendors located in the U.S. and in Europe, including Switzerland where the Company is headquartered. Damage or extended periods of interruption to our corporate, development or research facilities due to fire, natural disaster, power loss, communications failure, unauthorized entry or other events could cause us to cease or delay development of some or all of our product candidates. Although we maintain property damage and business interruption insurance coverage on these facilities, our insurance might not cover all losses under such circumstances and our business may be seriously harmed by such delays and interruption.

We have little history of commercializing pharmaceutical products, which may make it difficult to evaluate our future viability.

Our operations to date have been limited to financing and staffing our company and developing our technology and developing our product candidates, and until our acquisition of APR we had not generated any revenue from product sales. While since our acquisition of APR we have begun marketing commercial products, our history of operating in the commercial market is short. Consequently, predictions about our future success or viability may not be as accurate as they could be if we had a longer history of successfully developing and commercializing pharmaceutical products. Factors that may affect our ability to commercialize our product candidates on our own include recruiting and retaining adequate numbers of effective sales and marketing personnel, obtaining access to or persuading adequate numbers of physicians to prescribe our drug candidates, and other unforeseen costs associated with creating an independent sales and marketing organization. Developing a sales and marketing organization requires significant investment, is time-consuming and could delay the launch of our product candidates. We may not be able to build an effective sales and marketing organization. In addition, successful commercialization also requires an enhanced regulatory organization which we currently do not have. If we are unable to build our own distribution and marketing capabilities, are unable to find suitable partners for the commercialization of our product candidates or do not successfully obtain the necessary regulatory capabilities, we may not generate revenues from them or be able to reach or sustain profitability.

We may not be able to formulate or manufacture RLF-100 to the standards needed for sustained commercial supply.

RLF-100 has not been formulated or manufactured under chemistry, manufacturing and controls required for successful commercialization of drugs. A long-term stable IV or Inhaled formulation of RLF-100 has not yet been produced, and while NRx has stated in its filings with the SEC that they have developed such a formulation, we has not been provided with information allowing us to validate their findings. Further, while we assert that NeuroRx' s formulation is available to us under the Collaboration Agreement, NeuroRx contests this position in the lawsuit. The failure to produce such a formulation would have a significant negative impact on the medical application and commercial opportunity of RLF-100.

Risks related to our Relationships with Third Parties

We are in litigation with NeuroRx, and there can be no assurance as to the result of that litigation.

On October 7, 2021, we filed a lawsuit against NeuroRx and its now former Chief Executive Officer, Dr. Jonathan Javitt, for multiple breaches of the Collaboration Agreement. The complaint was filed in the Supreme Court in the State of New York in Manhattan.

The complaint alleges that defendants are in breach of numerous provisions of the Collaboration Agreement, including without limitation:

- by failing to provide Relief with the full data set from NeuroRx' s phase 2b/3 clinical trial evaluating IV RLF-100 (aviptadil) for the treatment of acute respiratory failure due to COVID-19, and the FDA correspondence relating to their trial and the failure to obtain EUA for the product, which data and information are required to be provided to Relief by NeuroRx under the Collaboration Agreement and which data and information are required for Relief to seek approval to commercialize the product in Europe;
- by failing to allow Relief, despite multiple requests, to conduct a forensic audit of NeuroRx' s books and records to determine how the funds that Relief provided to NeuroRx were actually used in order to help determine the amount, if any, that may be owed by us to NeuroRx under the Collaboration Agreement;
- by entering into multiple agreements relating to the development of the product subject to the collaboration without Relief' s consent, as required under the Collaboration Agreement;
- by engaging in commercialization efforts in territories outside the purview of NeuroRx' s territory under the Collaboration Agreement; and
- by developing additional COVID-19 treatments in violation of the exclusivity provisions of the Collaboration Agreement.

The suit also alleges, among other matters, breaches of the covenant of good faith and fair dealing and tortious interference with prospective economic advantage.

The Complaint, among other remedies, seeks damages, an order compelling NeuroRx to comply with multiple provisions of the Collaboration Agreement, and a declaration directing NeuroRx to deliver the entire data set from the Phase 2b/3 clinical trial of intravenously-administering aviptadil to Relief.

Further, on January 10, 2022, NeuroRx, filed a complaint against Relief. Among other claims, NeuroRx' s complaint makes the following allegations:

- NeuroRx claims that Relief has breached the Collaboration Agreement by refusing to make required payments thereunder. NeuroRx currently appears to claim that we have failed to pay them approximately $13.8 million. We believe we have paid all amounts required to be paid under the Collaboration Agreement.
- NeuroRx claims that by failing to pay what they allege is due, Relief has repudiated the Collaboration Agreement and that NeuroRx is no longer bound thereby. We dispute this allegation and believe that the Collaboration Agreement remains in full force and effect.
- NeuroRx claims that Relief has defamed NeuroRx through its statements regarding NeuroRx' s breaches of the Collaboration Agreement and other matters, claiming that Relief knew that such statements were recklessly made and/or knowingly false. Relief denies that any such statements were untrue or defamatory.

In the complaint, NeuroRx is claiming damages in excess of $185 million, as well as seeking a ruling that the Collaboration Agreement is void. We have yet to be served with the complaint filed by NeuroRx, which we expect will ultimately be consolidated with our complaint. We are also considering filing additional claims against NeuroRx and Dr. Javitt, including for defamation, as a result recent public statements made about Relief by NeuroRx. We believe that NeuroRx' s claims are without merit and that we will prevail before the court. However, there can be no assurance as to the result of the litigation, and an adverse ruling in the litigation could have a material adverse effect on our business, financial position, and results of operations.

On March 8, 2022, NeuroRx announced the retirement of Dr. Javitt as its Chief Executive Officer. Dr. Javitt continues to serve on NRx' s Board of Directors and as its Chief Scientist and Dr. Javitt' s retirement as CEO does not affect the status of Relief' s lawsuit against Dr. Javitt. Further, the parties have begun to mediate their disputes, and these mediation efforts remain ongoing. On April 5, 2022, we issued a press release announcing that we had entered into a stipulation to stay the litigation for 90 days in order to allow the parties to focus on mediation. There can be no assurance that efforts to mediate the dispute will be successful.

If we fail to maintain our strategic relationships with any of our current or future strategic partners, our business, commercialization prospects and financial condition may be materially adversely affected.

We rely on our strategic partners, NeuroRx, which is developing RLF-100 in the United States, and Acer, from which we license ACER-001. Good relationships with our strategic partners are important for our business prospects and while we have a very positive relationship with Acer, we are in litigation with NeuroRx. Further, if our relationships with our current or future strategic partners were to challenge our use of their intellectual property or our calculations of the payments we are owed under our agreements, our business, financial condition, commercialization prospects and results of operations could be materially adversely affected.

We may seek to form additional strategic alliances in the future with respect to our product candidates, and if we do not realize the benefits of such alliances, our business, financial condition, commercialization prospects and results of operations may be materially adversely affected.

We face significant competition in seeking appropriate collaborators. Collaborations are complex and time-consuming to negotiate, document and manage. Any delays in entering into new strategic partnership agreements related to our product candidates could delay the development and commercialization of our product candidates and reduce their competitiveness even if they reach the market. We may also be restricted under existing and future collaboration agreements from entering into strategic partnerships or collaboration agreements on certain terms with other potential collaborators. We may not be able to negotiate collaborations on acceptable terms, or at all, for any of our existing or future product candidates and programs because the potential partner may consider that our research and development pipeline is insufficiently developed to justify a collaborative effort, or that our product candidates and programs do not have the requisite potential to demonstrate safety and efficacy in the target population. If we are unsuccessful in establishing and maintaining a collaboration with respect to a particular product candidate, we may have to curtail the development of that product candidate, reduce the scope of or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense, for which we have not budgeted. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue. Even if we are successful in establishing a new strategic partnership or entering into a collaboration agreement, we cannot be certain that, following such a strategic transaction or license, we will be able to progress the development and commercialization of the applicable product candidates as envisaged, or that we will achieve the revenues that would justify such transaction, and we could be subject to the following risks, each of which may materially harm our business, commercialization prospects and financial condition:

- we may not be able to control the amount and timing of resources that the collaboration partner devotes to the product development program;
- the collaboration partner may experience financial difficulties;
- we may be required to grant or otherwise relinquish important rights such as marketing, distribution and intellectual property rights; or
- business combinations or significant changes in a collaboration partner' s business strategy may adversely affect our willingness to continue any arrangement.

We rely on third parties to conduct our nonclinical and clinical studies and perform other tasks for us. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or comply with regulatory requirements, we may not be able to obtain regulatory approval for or commercialize our product candidates, and our business could be substantially harmed.

We have relied upon and plan to continue to rely upon third-party clinical research organizations or contract research organizations ("CROs"), to monitor and manage data for our ongoing nonclinical and clinical programs, including the clinical studies of our product candidates. We rely on these parties for execution of our nonclinical and clinical studies and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the clinical CROs does not relieve us of our regulatory responsibilities. We and our clinical CROs and other vendors are required to comply with current Good Manufacturing Practice ("cGMP"), current Good Clinical Practice ("cGCP"), and current Good Laboratory Practice ("cGLP"), which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the EU and comparable foreign regulatory authorities for our product candidates in nonclinical and clinical development (where applicable). Regulatory authorities enforce these regulations through periodic inspections of study sponsors, principal investigators, study sites and other contractors. If we or any of our clinical CROs or vendors fail to comply with applicable regulations, the data generated in our nonclinical and clinical studies may be deemed unreliable and the EMA, FDA, other regulatory authorities may require us to perform additional nonclinical and clinical studies before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that all of our clinical studies comply with cGCP regulations. In addition, our clinical studies must be conducted with products produced under cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical studies, which would delay the regulatory approval process.

If any of our relationships with these third-party clinical CROs terminates, we may not be able to enter into arrangements with alternative clinical CROs or do so on commercially reasonable terms. In addition, our clinical CROs are not our employees, and except for remedies available to us under our agreements with such clinical CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing nonclinical and clinical programs. If clinical CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our protocols, regulatory requirements, or for other reasons, our clinical studies may be extended, delayed, or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Clinical CROs may also generate higher costs than anticipated. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase, and our ability to generate revenue could be delayed.

Switching or adding additional clinical CROs involves additional cost and requires management time and focus. In addition, there is a natural transition period when a new clinical CROs commences work. As a result, delays occur, which could materially impact our ability to meet our desired clinical development timelines. Though we carefully manage our relationships with our clinical CROs, there can be no assurance that we will not encounter similar challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

We currently rely on third-party suppliers and other third parties for production of our product candidates and our dependence on these third parties may impair the advancement of our research and development programs and the development of our product candidates.

We currently rely on and expect to continue to rely, on third parties for the manufacturing and supply of chemical and biological compounds and formulations for the clinical studies of our current and future product candidates. For the foreseeable future, we expect to continue to rely on such third parties for the manufacture of any of our product candidates on a clinical or commercial scale, if any of our product candidates receives regulatory approval. Reliance on third-party providers may expose us to different risks than if we were to manufacture product candidates ourselves. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or other regulatory authorities, pursuant to inspections that will be conducted after we submit our New Drug Application ("NDA") or comparable marketing application to the FDA or other regulatory authority. We do not have control over a supplier' s or manufacturer' s compliance with these laws, regulations and applicable cGMP standards and other laws and regulations, such as those related to environmental health and safety matters. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control ("QC"), quality assurance ("QA") and qualified personnel. If we are compelled or we wish to find alternative manufacturing facilities, this could significantly impact our ability to develop, obtain regulatory approval for or market our product candidates. Any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of our product candidates or that obtained approvals could be revoked, which would adversely affect our business and reputation.

Third-party providers may breach agreements they have with us because of factors beyond our control. Contract manufacturers often encounter difficulties involving production yields, QC and QA, as well as shortages of qualified personnel. They may also terminate or refuse to renew their agreements because of their own financial difficulties or business priorities, potentially at a time that is costly or otherwise inconvenient for us. If we are unable to find adequate replacement or another acceptable solution in time, our clinical studies could be delayed, or our commercial activities could be harmed.

In addition, the fact that we are dependent on our suppliers and other third parties for the manufacture, storage and distribution of our product candidates means that we are subject to the risk that our product candidates and, if approved, commercial products may have manufacturing defects that we have limited ability to prevent or control. The sale of products containing such defects could result in recalls or regulatory enforcement action that could adversely affect our business, financial condition and results of operations.

Growth in the costs and expenses of components or raw materials may also adversely influence our business, financial condition and results of operations. Supply sources could be interrupted from time to time and, if interrupted, we cannot be certain that supplies could be resumed (whether in part or in whole) within a reasonable timeframe and at an acceptable cost or at all. Our current and anticipated future dependence upon others for the manufacturing of our current and future product candidates may adversely affect our future profit margins and our, or our collaboration partners' , ability to commercialize any products that receive marketing approval on a timely and competitive basis.

Risks related to Intellectual Property

We may not have sufficient patent terms to protect our products and business effectively.

Patents have a limited lifespan. In the U.S. and Europe, the natural expiration of a patent is generally 20 years after it is filed. Although various extensions or adjustments may be available, such as adjustments based on certain delays caused by the U.S. Patent and Trademark Office (the "USPTO") or the European Patent Office ("EPO") to the life of a patent, and the protection it affords, is limited. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned, co-owned and licensed patent portfolios may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage. Even if patents covering our product candidates are obtained and unchallenged, once the patent life has expired for a product, we may be open to competition from generic medications.

Although patent term extensions under the Hatch-Waxman Act in the U.S. and under supplementary protection certificates ("SPCs") in Europe may be available to extend the patent exclusivity term for our products, we cannot provide any assurances that any such patent term extension will be obtained and, if so, for how long. The Hatch-Waxman Act permits a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended, and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. However, we may not be granted any extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. It is not possible to base an SPC in Europe on a patent in a European Member State if that patent expires before the market approval of the clinical product, protected by the patent, is obtained. As the "product" (active ingredient(s)) must be "protected by a basic patent in force", only a granted patent that is in force, and remains in force until it reaches the end of its full term, can serve as a "basic patent" upon which an SPC can be based. Therefore, expired patents and pending patent applications cannot serve as the basis for an SPC. Given the relatively long clinical development timelines of biologicals and new chemical entities for therapeutic purpose, we may not be granted any patent extensions as we might fail to apply for the extensions prior to expiration of relevant patents. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or if the term of any such extension is less than we request, such result could have a material adverse effect on our business.

We or our licensing or collaboration partners may become subject to intellectual property-related litigation or other proceedings to protect or enforce our patents or the patents of our licensors or licensees and collaborators, any of which could be expensive, time-consuming, and unsuccessful, and may ultimately result in our loss of ownership of intellectual property.

Competitors may infringe our patents or the patents of our licensors or collaborators. To counter such infringement, we may be required to file infringement claims against those competitors, which can be expensive and time-consuming. If we or one of our licensing or collaboration partners were to initiate legal proceedings against a third party to enforce a patent covering one of our product candidates, the defendant could counterclaim that the patent covering our product candidate is invalid or unenforceable or that the defendant' s products do not infringe our or our licensing collaborators' patents or that we or our licensing collaborators infringe the defendant' s patents. In patent litigation in the U.S., defendant counterclaims alleging invalidity, unenforceability and non-infringement are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, obviousness-type double patenting, lack of written description, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or the EPO, or made a misleading statement, during prosecution. In addition, third parties may raise similar claims before administrative bodies in the U.S., in Europe or elsewhere, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, inter partes review, interference and derivation proceedings as well as equivalent proceedings in foreign jurisdictions, such as opposition proceedings in Europe. The outcome following legal assertions of invalidity and unenforceability is unpredictable. Such proceedings or patent litigations could result in the revocation or cancellation of or amendment to our patents in such a way that they no longer cover our product candidates or otherwise provide any competitive advantage. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which the patent examiner and we or our licensing or collaboration partners were unaware during prosecution. A court may also refuse to stop a third party from using the technology in question on the grounds that our patents do not cover that technology. An adverse result in any proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly, which could have a material adverse effect on our business and financial condition.

Interference proceedings provoked by third parties or brought by us or declared by the USPTO or the EPO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors, licensees or collaborators. An unfavorable outcome could require us or our licensing or collaboration partners to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be materially harmed if the prevailing party does not offer us or our licensing or collaboration partners a license on commercially reasonable terms or at all. If we or our licensing or collaboration partners are unsuccessful in any interference proceedings, we may lose our ownership of intellectual property or our patents may be narrowed or invalidated. There can be no assurance as to the outcome of the interference and opposition proceedings, and any of the foregoing could result in a material adverse effect on our business, financial condition, results of operations or prospects.

Our defense of litigation, interference proceedings or other intellectual property-related proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees from their normal responsibilities. Such litigation or proceedings could substantially increase our operating losses and could substantially reduce the funds necessary to continue our clinical studies and research programs or force us to license necessary technology from third parties or enter into development partnerships that would help us bring our product candidates to market. We may not be able to prevent, alone or with our licensing or collaboration partners, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the U.S.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. There could also be public announcements of the results of hearings, motions, decisions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our Shares.

If we or our licensing or collaboration partners are unable to obtain and maintain effective patent rights for our technologies, product candidates or any future product candidates, or if the scope of the patent rights obtained is not sufficiently broad, our competitors could develop and commercialize products and technology similar or identical to ours, and our, or our collaboration partners' ability to successfully commercialize our products and technology may be adversely affected.

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies and product candidates. Our success depends in large part on our and our licensing or collaboration partners' ability to obtain and maintain patent and other intellectual property protection in the U.S., the EU and other countries with respect to our proprietary technologies and product candidates. If such license is not granted or terminated, our licensing or collaboration partners may be required to cease development and commercialization of our product candidates, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

We have sought to protect our proprietary position by filing patent applications in the U.S. and other countries related to any of our novel technologies and products that are important to our business. This process is expensive, time-consuming, and complex, and we may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost, in a timely manner or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our or our licensing or collaboration partners' research and development output before it is too late to obtain patent protection. Moreover, in some circumstances, we do not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents, covering technology that we license to or from third parties. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business.

The patent position of pharmaceutical and biopharmaceutical companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unsolved. As a result, the inventorship, issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. The pending or future patent applications that we own, co-own or in-license may fail to issue, fail to result in issued patents with claims that cover our product candidates in the U.S. or in other countries, or fail to effectively prevent others from commercializing competitive technologies and product candidates. Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection.

We may not be aware of all third-party intellectual property rights potentially relating to our technologies or product candidates. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U.S. and other jurisdictions remain confidential for a period of time after filing, and some remain so until issued. Therefore, we cannot be certain that we were the first to file any patent application related to our product candidates or technologies, or whether we were the first to make the inventions claimed in our owned or co-owned patents or pending patent applications, nor can we know whether those from whom we license patents were the first to make the inventions claimed or were the first to file.

There is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can invalidate a patent or prevent a patent from issuing from a pending patent application. Even if patents do successfully issue, and even if such patents cover our product candidates, third parties may challenge their validity, enforceability, or scope, which may result in such patents being narrowed, found unenforceable or invalidated, which could allow third parties to commercialize our technology or products and compete directly with us, without payment to us, or result in our or our collaboration partners' inability to manufacture or commercialize products without infringing third-party patent rights. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property, provide exclusivity for our product candidates, prevent others from designing around our claims or provide us with a competitive advantage. Any of these outcomes could impair our ability to prevent competition from third parties, which may have a material adverse effect on our business.

We may be subject to claims challenging the inventorship of our patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest or title in our patents or other intellectual property as an inventor or co-inventor. For example, we may have inventorship disputes arise from conflicting obligations of consultants, CROs, contract manufacturing organizations ("CMOs"), academic institutions or others who are involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or our ownership of our patents or other intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or the right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Patent policy and rule changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, thereby impairing our ability to protect our technologies and products.

Changes in either the patent laws or interpretation of the patent laws in the U.S., EU or elsewhere could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming the other requirements for patentability are met, in the U.S. prior to March 15, 2013, the first to make the claimed invention is entitled to the patent, whereas outside the U.S., the first to file a patent application was entitled to the patent. After March 15, 2013, under the Leahy-Smith America Invents Act (the "Leahy-Smith Act"), which was enacted on September 16, 2011, the U.S. moved to a first-to-file system. Under a first-to-file system, assuming the other requirements for patentability are met, the first inventor to file a patent application generally will be entitled to the patent on an invention regardless of whether a third party was the first to invent the invention. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications are prosecuted and may also affect patent litigation. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by the USPTO administered during post grant proceedings, including re-examination proceedings, inter partes review, post-grant review and derivation proceedings. Therefore, the Leahy-Smith Act and its implementation increases the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations and prospects. In addition, future actions by the U.S. Congress, the federal courts and the USPTO could cause the laws and regulations governing patents to change in unpredictable ways. Any of the foregoing could harm our business, financial condition and results of operations.

In addition, the patent positions of companies in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. Depending on future actions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future in the U.S.

If we are unable to maintain effective proprietary rights for our technologies, product candidates or any future product candidates, we may not be able to compete effectively in our markets.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable or that we elect not to patent, processes for which patents are difficult to enforce, and any other elements of our product candidate discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. However, trade secrets can be difficult to protect and some courts inside and outside the U.S. are less willing or unwilling to protect trade secrets. For instance, the EU has introduced a new Directive on trade secrets increasing the standards for protection. Because we rely on our advisors, employees and third-party contractors and consultants to research and develop and to manufacture our product candidates, we must, at times, share our intellectual property with them. We seek to protect our intellectual property and other proprietary technology in part by entering into confidentiality agreements and master service agreements, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, contractors, consultants, licensing and collaboration partners, and other third parties with confidentiality provisions. These agreements typically limit the rights of these third parties to use or disclose our confidential information, including our intellectual property and trade secrets. These agreements also typically restrict the ability of third parties to publish data potentially relating to our intellectual property, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with in the future may expect to be granted rights to publish data arising out of such collaboration, provided that we may have the right to be notified in advance and given the opportunity to delay publication for a limited time period in order for us to secure patent protection of intellectual property rights arising from the collaboration, in addition to the opportunity to remove confidential or trade secret information from any such publication. We also conduct joint research and development programs that may require us to share intellectual property under the terms of our research and development or similar agreements. However, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or other confidential information or proprietary technology and processes, or that such agreements will not be breached or that our trade secrets or other confidential information will not otherwise be disclosed. Despite the contractual provisions employed when working with these advisors, employees and third-party contractors and consultants, the need to share intellectual property and other confidential information increases the risk that such confidential information becomes known by our competitors, is inadvertently incorporated into the product development of others or is disclosed or used in violation of these agreements. Additionally, our grant agreements typically provide for dissemination of results to academic institutions and to the general public. As a result, our information may be disseminated with the loss of protection status.

We also seek to preserve the integrity and confidentiality of our data and trade secrets by maintaining the physical security of our premises and the physical and electronic security of our information technology systems. Despite our efforts to protect our intellectual property, our competitors may discover our trade secrets through breach of our agreements by third parties, for which we may not have adequate remedies for any breach, or publication of information by any of our CROs, academic partners, funding organizations or our licensing or collaboration partners. Additionally, if the steps taken to maintain our trade secrets are deemed inadequate by law, we may have insufficient recourse against third parties for misappropriating such trade secrets. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business. Moreover, if any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent such competitor or other third party from using that technology or information to compete with us. A competitor' s or other third party' s discovery of our intellectual property would impair our competitive position and have a material adverse effect on our business.

Further, the laws of different countries protect proprietary rights to a different extent or in a different manner. As a result, we may encounter significant problems in protecting and defending our intellectual property in different countries both in the U.S. and abroad. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition and results of operations.

Despite confidentiality clauses within our employment agreements, we cannot ensure that departing employees will not breach any post-termination commitments in such agreements by allowing others to access our trade secrets.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document-submission, fee-payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on a patent and patent application are due to be paid to the USPTO and other national patent agencies in several stages over the lifetime of the patent and patent application. The USPTO, the EPO and various other governmental patent agencies require compliance with a number of procedural, documentary, fee-payment and other similar provisions during the patent application process. We employ reputable law firms and other professionals to help us comply with these requirements and we are also dependent on our licensors or collaboration partners to take the necessary action to comply with these requirements with respect to certain of our intellectual property. Although an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, nonpayment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

The patent protection and patent prosecution for some of our product candidates could be dependent on third parties.

Although we normally seek to obtain the right to control prosecution, maintenance and enforcement of the patents relating to our product candidates, there may be times when the filing and prosecution activities for patents relating to our product candidates are controlled by our licensors or collaboration partners. If any of our current or future licensing or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidates, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our or our collaboration partners' ability to develop and commercialize those product candidates may be adversely affected and we may not be able to prevent competitors from making, using, and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed to and from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Additionally, we may be adversely affected or prejudiced by actions or inactions of our external and internal patent counsels working solely on our projects or our joint patent counsels representing us and our collaboration partners.

Third-party claims of intellectual property infringement may expose us to substantial liability or may prevent or delay our or our collaboration partners' development and commercialization efforts.

Numerous EU- and foreign-issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. For example, we are aware of third-party patents or patent applications that may be construed to cover one or more of our product candidates. If these patents are asserted against us or our licensing or collaboration partners and either we or our licensing or collaboration partners are found to infringe any of these patents, and are unsuccessful in demonstrating that such patents are invalid or unenforceable, then we and our licensing or collaboration partners could be required to pay substantial monetary damages or cease further development or commercialization of one or more of our product candidates or be compelled to enter into onerous licenses with such third parties. There may also be other third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods of treatment related to the use or manufacture of our product candidates and technology. Although we generally conduct a freedom-to-operate search and review with respect to our product candidates, we cannot guarantee that our search and review is complete and thorough, nor can we be sure that we have identified each and every patent and pending application in the U.S. and abroad that is relevant or necessary to the manufacturing or commercialization of our product candidates or use of our technology. Because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that our product candidates may infringe. In addition, third parties may file and obtain additional patents in the future and claim that use of our technologies infringes upon these patents.

Third parties may assert infringement claims against us based on existing patents or on patents that may be granted in the future, regardless of merit. Even if we believe such claims are without merit, a court of competent jurisdiction could hold that these third-party patents are valid, enforceable and infringed, which could materially and adversely affect our or our collaboration partners' ability to commercialize our product candidates or technologies covered by the asserted third-party patents.

Parties making claims against us may also obtain injunctive or other equitable relief, which could effectively block our or our collaboration partners' ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. Any of the foregoing could have a material and adverse effect on our business, financial conditions, results of operations and prospects.

In addition, claims that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business, financial condition, results of operations and prospects.

There could also be public announcements of the results of hearings, motions, decisions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our Shares.

Some of our competitors may have substantially greater resources and more mature and developed intellectual property portfolios than we do and may be able to sustain the costs of complex intellectual property litigation to a greater degree and for longer periods of time than we could. In addition, patent-holding companies that focus solely on extracting royalties and settlements by enforcing patent rights may target us. As the pharmaceutical and biopharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. The uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties or that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

We employ and utilize the services of individuals who were previously employed or provided services to universities or other pharmaceutical or biopharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants, and independent contractors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of any of our employees' , consultants' or independent contractors' former employers or of other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel, which could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

In addition, although it is our policy to require our employees, consultants and independent contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries may be less extensive than those in the U.S. or Europe. In addition, the laws of different countries do not protect intellectual property rights to the same extent as the laws in the U.S. or Europe. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U.S. or Europe, or from selling or importing products made using our inventions in and into the U.S., Europe or other jurisdictions. In the ordinary course of prosecution and maintenance activities, we determine whether to seek patent protection outside the U.S. and Europe and in which countries. This also applies to patents we have acquired or in-licensed from third parties. In some cases, we, or our predecessors in interest or licensors of patents within our portfolio, have sought patent protection in a limited number of countries for patents covering our product candidates. Competitors may use our technologies and products in jurisdictions where we have not obtained or are unable to adequately enforce patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection but enforcement is not as strong as that in the U.S. or Europe. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing, which would have a material adverse effect on our business and financial positions.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology products, which could make it difficult for us to stop the infringement, misappropriation or other violations of our intellectual property and proprietary rights. Proceedings to enforce our patent rights in foreign jurisdictions, whether or not successful, could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We may be unable to protect our trade secrets, know-how and technologies.

We also rely on trade secrets and non-patentable know-how and technologies it seeks to protect, in part, by confidentiality agreements with our employees, consultants, suppliers, licensees and other contractual parties. Trade secrets and non-patentable know-how and technologies are difficult to protect. There can be no assurance that these agreements represent effective protection or that they will not be breached, that we would have adequate remedies for any breach, or that our trade secrets or non-patentable know-how and technologies will not otherwise become known or be independently developed by competitors and other third parties.

These and other factors, alone or together, may have a material adverse effect on our business, financial condition, results of operations and growth prospects as well as the price of our shares.

Risks related to our Financial Condition and Results of Operations

We are a commercial-stage biopharmaceutical company with a history of operating losses. While we currently believe that we have sufficient funds for our planned operations well into 2023, there can be no assurance that we will be able to obtain the funds necessary to continue our operations beyond that point.

We incurred a net loss (defined as net loss attributable to owners of the Company) of approximately CHF 34.3 million for the year ended December 31, 2021 and had accumulated losses at consolidation level of approximately CHF 69.8 million as of December 31, 2021. We may continue to incur losses in the foreseeable future as development expenses and other operating expenses may exceed future revenue.

Our losses have resulted principally from research and development expenses and from general business and administrative expenses. We expect to continue to incur significant operating losses in the future as we continue our research and development efforts for our current and future product candidates and seek to obtain regulatory approval and commercialization of such product candidates.

To date, we have financed our liquidity requirements primarily from equity financings and loans from our main shareholder. Biopharmaceutical and pharmaceutical product development are highly speculative undertakings and involve a substantial degree of risk. While we currently believe that we have sufficient funds for our planned operations well into 2023, there can be no assurance that we can obtain the additional funds necessary to continue our planned operations beyond that point. Our inability to obtain the required funds may make it impossible for us to continue as a going concern.

If we fail to obtain additional funding required for our planned activities, we may not have sufficient funds to continue our operations and may have to delay, reduce or eliminate one or more of our product development programs or commercialization efforts.

We are currently advancing our product candidates through clinical development, either together with a collaboration partner or independently. We expect our research and development expenses to continue to increase in connection with our ongoing activities, particularly as we and/or our collaboration partners continue our ongoing studies and initiate new studies and initiate preclinical and clinical development of our product candidates.

As of December 31, 2021, we had cash and cash equivalents of approximately CHF 44.8 million, As of June 28, 2022, we have cash and cash equivalents of approximately CHF 30.0 million.

Based on current financial current projections and available cash, we expect that we have sufficient resources to fund operations well into 2023. We also expect that with a successful launch of ACER-001 and the potential expansion of our Golike franchise into the United States, of which there can be no assurance, we could reach operating cash flow-positive operations during 2024. There can be no assurance whether our estimates will be accurate or whether we will ever achieve cash flow-positive operations.

Accelerated growth strategy, potential milestone payments, and acquisitions will require significant additional funding. We may also need to raise additional funds due to various factors such as the scope and rate of progress of our development activities, regulatory approval outcomes and emergence of competing technologies, among others. There can be no assurance that our commercialization efforts will be successful or if we need additional funding in the future, whether such funding will be available to us.

We expect that we will require additional capital to develop and commercialize certain of our product candidates. If we receive regulatory approval for our current and future product candidates, and if we have not already licensed such product candidate to a collaboration partner and choose to commercialize such product candidate independently, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing, distribution and establishing a regulatory structure, depending on where we choose to commercialize. Additional funds may not be available on a timely basis, on favorable terms, or at all, and such funds, if raised, may not be sufficient to enable us to continue to implement our long-term business strategy. Additionally, we may be dependent on the status of the capital markets at the time such capital is sought. If we are not able to raise capital when needed, we could be forced to delay, reduce or eliminate our product development programs or commercialization efforts.

Raising additional capital may cause dilution to our shareholders, restrict our operations or require us to relinquish rights to our intellectual property or future revenue streams.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our liquidity needs through a combination of equity offerings, debt financings, grants, and license and development agreements in connection with collaborations. We do not have any material committed external source of funds. In the event we need to seek additional funds, we may raise additional capital through the sale of equity, convertible debt or other securities, and through drawdowns from our Share Subscription Facility in place with GEM Global Yield LLC SCS (“GEM”). In such an event, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our Shares. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or proposing dividends to our shareholders.

If we raise additional funds through collaborations, strategic alliances, or marketing, distribution or licensing arrangements with third parties, we may have to grant or otherwise relinquish valuable rights to our intellectual property or future revenue streams.

Our ability to use tax loss carry-forwards may be limited.

As of December 31, 2021, we had consolidated tax loss carry-forwards for purposes of Swiss corporate income tax in the aggregate amount of approximately CHF 136.4 million, which could be available to offset future taxable income. If not used, these tax losses will expire seven years after the year in which they were incurred. Due to our limited income, there is a high risk that the tax loss carryforwards will expire partly or entirely and we will not be able to use them to offset future taxable income thereafter for corporate income tax purposes. Further, taxable income generated by an entity of the group may only be offset against carried forward losses incurred by the same entity, hence reducing the overall likelihood of benefiting from these losses.

Exchange rate fluctuations may materially affect our results of operations and financial condition.

As our reporting currency is the Swiss franc, transactions and balance sheet items denominated in foreign currencies are converted into Swiss francs at the applicable exchange rates. Our current expenses are denominated in Swiss francs, U.S. Dollars and Euros. In the future, we expect that the majority of our revenue and expenses will be in U.S. Dollars and Euros. Therefore, unfavorable developments in the value of the Swiss franc as compared to the U.S. Dollar and Euro could have a material adverse effect on our business, financial condition and results of operations.

Risks related to regulation of our business

The SIX Exchange Regulation AG has launched an investigation into Relief, the results of which are uncertain.

We have recently been notified by SIX Exchange Regulation AG – the self-regulatory supervisory body for issuers listed on the SIX Swiss Exchange – of a formal investigation due to potential violations of the rules on ad-hoc publicity. While we do not believe that this investigation will have a material adverse effect on our business, there can be no assurance of that conclusion.

We cannot give any assurance that any of our product candidates in development will receive regulatory approval, which is necessary before they can be commercialized.

We cannot be certain that any of our product candidates in development will be successful in clinical studies or receive regulatory approval. Applications for our product candidates could fail to receive regulatory approval for many reasons, including but not limited to the following:

- the FDA, EMA, Swissmedic or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical studies;
- the population studied in the clinical program may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- the FDA, EMA, Swissmedic or comparable foreign regulatory authorities may disagree with our interpretation of data from nonclinical or clinical studies;
- the data collected from clinical studies of our product candidates may not be sufficient to support the submission of an NDA or other submission or to obtain regulatory approval in the U.S., Switzerland or elsewhere;
- we may be unable to demonstrate to the FDA, EMA, Swissmedic or comparable foreign regulatory authorities that a product candidate' s benefit-risk ratio for its proposed indication is acceptable;
- the FDA, EMA, Swissmedic or other regulatory authorities may fail to approve the manufacturing processes, test procedures and specifications, or facilities of third-party manufacturers with which we contract for clinical and commercial supplies; and
- the approval policies or regulations of the FDA, EMA, Swissmedic or comparable foreign regulatory authorities may change significantly in a manner rendering our clinical data insufficient for approval.

We generally plan to seek regulatory approval to commercialize our product candidates in the U.S., the EU, Switzerland and in additional foreign countries where we have commercial and typically IP rights. To obtain regulatory approval in other countries, we must comply with numerous and varying regulatory requirements of such other countries regarding safety, efficacy, chemistry, manufacturing and controls, clinical studies, commercial sales, pricing, marketing and distribution of our product candidates. Even if we are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. Failure to obtain marketing authorization for our product candidates will result in our being unable to market and sell such products, which would materially adversely affect our business, financial condition and results of operations. If we fail to obtain approval in any jurisdiction, the geographic market for our product candidates could be limited.

Similarly, regulatory agencies may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates.

Clinical drug development involves a lengthy and expensive process with uncertain timelines and uncertain outcomes. If clinical studies of our product candidates are prolonged or delayed, we may be unable to obtain required regulatory approvals, and therefore be unable to commercialize our product candidates on a timely basis or at all.

In order to commercialize any of our product candidates, we or our partners must obtain the necessary regulatory approvals to market and sell such product. To obtain that approval, we must demonstrate through extensive preclinical and clinical studies that our products are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical study process. The results of preclinical and early clinical studies of our product candidates may not be predictive of the results of later-stage clinical studies. For example, the positive results generated to date in clinical studies for our product candidates do not ensure that later clinical studies will demonstrate similar results. Product candidates in later stages of clinical studies may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical studies. A number of companies in the pharmaceutical or biopharmaceutical industry, including us, have suffered significant setbacks in advanced clinical studies due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier studies. Our future clinical study results may not be successful.

Clinical studies must be conducted in accordance with the legal requirements, regulations or guidelines of the FDA, EMA, Swissmedic and comparable regulatory authorities, and are subject to oversight by these governmental agencies and Institutional Review Boards ("IRBs") at the medical institutions where the clinical studies are conducted. In addition, clinical studies must be conducted with supplies of our product candidates produced under cGMP and other requirements. We depend on medical institutions and CROs to conduct our clinical studies in compliance with cGCP standards. To the extent the CROs fail to enroll participants for our clinical studies, fail to conduct the study to cGCP standards or are delayed for a significant time in the execution of studies, including achieving full enrollment, we may be affected by increased costs, program delays or both, which may harm our business.

The completion of clinical studies for our clinical product candidates may be delayed, suspended or terminated as a result of many factors, including but not limited to:

- the delay or refusal of regulators or IRBs to authorize us to commence or amend a clinical study at a prospective study site or changes in regulatory requirements, policies and guidelines;
- delays or failure to reach agreement on acceptable terms with prospective CROs and clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and study sites;

delays in patient enrollment and variability in the number and types of patients available for clinical studies;

the inability to enroll a sufficient number of patients in studies to ensure adequate statistical power to detect statistically significant treatment effects;

negative or inconclusive results, which may require us to conduct additional preclinical or clinical studies or to abandon projects that we expected to be promising;

safety or tolerability concerns, which could cause us to suspend or terminate a study if we find that the participants are being exposed to unacceptable health risks;

regulators or IRBs requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements or safety concerns, among others;

lower than anticipated retention rates of patients and volunteers in clinical studies;

our CROs or clinical study sites failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, deviating from the protocol or dropping out of a study;

delays relating to adding new clinical study sites;

difficulty in maintaining contact with patients after treatment, resulting in incomplete data;

delays in establishing the appropriate dosage levels;

the quality or stability of the product candidate falling below acceptable standards;

the inability to produce or obtain sufficient quantities of the product candidate to complete clinical studies; and

exceeding budgeted costs due to difficulty in accurately predicting costs associated with clinical studies.

Any delays in completing our clinical studies will increase our costs, slow our product candidate development and approval process, and jeopardize our ability to commence product sales and generate sales revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical studies may also ultimately lead to the denial of regulatory approval of certain of our product candidates.

Even if we obtain and maintain approval for certain of our drug candidates from one jurisdiction, we may never obtain approval for our drug candidates in other jurisdictions, which would limit our market opportunities and adversely affect our business.

Sales of our approved drugs will be subject to U.S. and non-U.S. regulatory requirements governing clinical studies and regulatory approval, and we plan to seek regulatory approval to commercialize our drug candidates in the U.S., the European Economic Area ("EEA"), Switzerland and other countries. Clinical studies conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not ensure approval in any other country, while a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. For example, approval in the U.S. by the FDA does not ensure approval by the regulatory authorities in other countries or jurisdictions, and similarly, approval by a non-U.S. regulatory authority, such as the EMA, does not ensure approval by regulatory authorities in other countries, including by the FDA. However, the failure to obtain approval in one jurisdiction may have a negative impact on our ability to obtain approval elsewhere. Approval processes and regulatory requirements vary among countries and can involve additional drug testing and validation and additional administrative review periods. Even if a drug is approved, the FDA or EMA, as the case may be, may limit the indications for which the drug may be marketed, require extensive warnings on the drug labeling, or require expensive and time-consuming clinical studies or reporting as conditions of approval. In many countries outside the U.S., a drug candidate must be approved for reimbursement before it can be approved for sale in that country. In some cases, the price that would be charged for a drug is also subject to approval. Regulatory authorities in other countries also have their own requirements for approval of drug candidates with which we must comply prior to marketing in those countries. Obtaining non-U.S. regulatory approvals and compliance with such non-U.S. regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our current and any future drugs, in certain countries. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of our drug candidates will be unrealized.

Even if certain of our product candidates obtain regulatory approval, we will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expenses. Additionally, our additional product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal and we may be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our products.

If marketing authorization is obtained for certain of our product candidates, the products will remain subject to continual regulatory review and therefore authorization could be subsequently withdrawn or restricted. Any regulatory approvals that we receive for certain of our product candidates may also be subject to limitations on the approved indicated uses for which the products may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including phase 4 clinical studies, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA or a comparable regulatory authority approves any of our product candidates in development, we will be subject to ongoing regulatory obligations and oversight by regulatory authorities, including with respect to the manufacturing processes, labeling, packing, distribution, adverse event reporting, storage, advertising and marketing restrictions, and record-keeping and, potentially, other post-marketing obligations, all of which may result in significant expense and limit our or our collaboration partners' ability to commercialize such products. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP and cGCP requirements for any clinical studies that we conduct post-approval. Later discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on clinical studies;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product license approvals;
- regulatory constraints in promotion and distribution of drug products in various markets;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

If any of these events occurs, our ability to sell such product may be impaired, and we may incur substantial additional expense to comply with regulatory requirements, which could materially adversely affect our business, financial condition and results of operations. Regulatory policies may be enacted that could prevent, limit or delay regulatory approval of our product candidates. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, which would adversely affect our business, prospects and ability to achieve or sustain profitability.

We have conducted and may in the future conduct clinical studies for our drug candidates outside the U.S., Europe and Switzerland, and the FDA, EMA and Swissmedic and applicable foreign regulatory authorities may not accept data from such studies.

We, or our collaboration partners, have conducted and may in the future choose to conduct one or more of our clinical studies outside the U.S., Europe and Switzerland. The acceptance of study data from clinical studies conducted outside the U.S., Europe and Switzerland or another jurisdiction by the FDA, EMA and Swissmedic or applicable foreign regulatory authority may be subject to certain conditions. In cases where data from foreign clinical studies are intended to serve as the basis for marketing approval, for instance in the U.S., the FDA will not approve the application on the basis of foreign data alone unless the following are true: the data are applicable to the U.S. population and U.S. medical practice; the studies were performed by clinical investigators of recognized competence; and the data are considered valid without the need for an on-site inspection by the FDA or, if the FDA considers such an inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. Additionally, the FDA' s clinical study requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar requirements. In addition, such foreign studies would be subject to the applicable local laws of the foreign jurisdictions in which the studies are conducted. There can be no assurance that the FDA, EMA, Swissmedic or any applicable foreign regulatory authority will accept data from studies conducted outside of the U.S. or the applicable jurisdiction. If the FDA, EMA, Swissmedic or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional studies, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our drugs or drug candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

Our business is subject to complex and evolving U.S. and international laws and regulations regarding clinical trials reimbursement and privacy and data protection. Many of these laws and regulations are subject to change and uncertain interpretation and could result in claims, changes to our business practices, penalties, increased cost of operations, or declines in user growth or engagement, or otherwise harm our business.

Regulatory authorities around the world have adopted laws and regulations, and are continuing to consider a number of legislative and regulatory proposals, concerning privacy and data protection, including measures to ensure that encryption of users' data does not hinder access of law enforcement agencies to that data. In addition, the interpretation and application of consumer and data protection laws in the U.S., Europe, Switzerland and elsewhere are often uncertain and in flux. It is possible that these laws may be interpreted and applied in a manner that is inconsistent with our data practices. These laws and regulations, and legislative and regulatory proposals, if adopted, and such interpretations could, in addition to the possibility of fines, result in an order requiring that we change our data practices, which could have an adverse effect on our business and results of operations. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices in a manner adverse to our business.

In the EU, new clinical trial regulations came into force on January 31, 2022. This new legislation enforces the centralization of clinical trial applications and approvals, New clinical trial sponsors must begin using the new system by January 31, 2023, and any previously approved trial sponsors must comply from January 31, 2025, but in some cases, this may extend timelines for clinical study approvals, due to potentially longer wait times enabling sponsors to apply for trial authorization in up to 30 European countries with a single online application. The General Data Protection Regulation ("GDPR"), which became effective in May 2018 in all EU member states, created a range of new compliance obligations for companies that process the personal data of EU residents. Although it is expected that the GDPR will provide consistency across the territory of the EU, it imposes more onerous requirements concerning consent and the obligations of sponsors of clinical trials (acting as data controllers), among other measures, which may increase the costs and extend the timelines of our product development efforts. Austerity measures in certain European nations may also affect the prices we are able to seek if our products are approved, as discussed below. Furthermore, the Brexit vote and the impact of the withdrawal of the UK may adversely affect business activity, political stability and economic conditions in the UK, the Eurozone, the EU and elsewhere. Specifically, Brexit and ongoing developments in the UK have created uncertainty with regard to data protection regulation in the UK. We may be required to comply with both the GDPR and the UK GDPR, exposing us to two parallel regimes with potentially divergent interpretations and enforcement actions for certain violations. The relationship between the UK and the EU in relation to certain aspects of data protection law remains unclear, for example, how data transfers between EU member states and the UK will be treated and the role of the UK' s Information Commissioner' s Office with respect to the EU following the end of the transitional period. Although we do not have material operations in the UK, we cannot rule out potential disruptions in relation to the clinical regulatory framework applicable to our clinical studies in the UK, and to data privacy and security rules with respect to personal data sharing with vendors and clinical investigators in the UK, and we cannot predict future implications.

Both in the U.S. and in the EU, legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for pharmaceutical and biopharmaceutical products. We do not know whether additional legislative changes will be enacted, whether the regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals of our product candidates, if any, may be.

We could be subject to liabilities under environmental, health and safety laws or regulations, or fines, penalties or other sanctions, if we fail to comply with such laws or regulations or otherwise incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws, regulations, and permitting requirements, including those governing laboratory procedures, decontamination activities, and the handling, transportation, use, remediation, storage, treatment and disposal of hazardous materials, human substances and wastes. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials that produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials or wastes either at our sites or at third-party disposal sites. In the event of such contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, human substances or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws, regulations or permitting requirements. Such laws, regulations and requirements are becoming increasingly more stringent and may impair our research, development or production efforts. Failure to comply with these laws, regulations and permitting requirements also may result in substantial fines, penalties or other sanctions.

Our relationships with clinical centers, customers and payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which, if violated, could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs, contractual damages, reputational harm and diminished profits and future earnings.

for instance, the U.S. healthcare Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under U.S. government healthcare programs such as Medicare and Medicaid;

for instance, the U.S. False Claims Act imposes criminal and civil penalties, including civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the U.S. government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

for instance, the Health Insurance Portability and Accountability Act ("HIPAA"), imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

for instance, the transparency requirements under the Health Care Reform Law require manufacturers of drugs, devices, biologics and medical supplies to report to the U.S. Department of Health and Human Services information related to payments and other transfers of value made by such manufacturers to physicians and teaching hospitals, and ownership and investment interests held by physicians or their immediate family members; and

in various other jurisdictions, analogous laws and regulations, such as state anti-kickback and false claims laws, will apply to sales or marketing arrangements, consultancy and service agreements, and claims involving healthcare items or services reimbursed by nongovernmental third-party payors, including private insurers, and some state laws require pharmaceutical and biopharmaceutical companies to comply with the pharmaceutical and biopharmaceutical industries' voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, in addition to requiring manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under the U.S. federal Anti-Kickback Statute, it is possible that some of our future business activities could be subject to challenge under one or more of such laws. In addition, recent healthcare-reform legislation has strengthened these laws. For example, the Health Care Reform Law, among other things, amends the intent requirement of the federal anti-kickback and criminal healthcare fraud statutes. A person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it. Moreover, the Health Care Reform Law provides that the government may assert that a claim including items or services resulting from a violation of the federal anti-kickback statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from U.S. government-funded healthcare programs, such as Medicare and Medicaid, other foreign healthcare reimbursement and procurement programs, and the curtailment or restructuring of our operations. If any of the physicians or other providers or entities with whom we expect to do business with is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government-funded healthcare programs.

Risks from the improper conduct of employees, agents, contractors, or collaborators could adversely affect our reputation and our business, prospects, operating results, and financial condition.

We cannot ensure that our compliance controls, policies, and procedures will in every instance protect us from acts committed by our employees, agents, contractors, or collaborators, which would violate the laws or regulations of the jurisdictions in which we operate, including, without limitation, healthcare, employment, foreign corrupt practices, environmental, competition, and patient privacy and other privacy laws and regulations. Such improper actions could subject us to civil or criminal investigations, and monetary and injunctive penalties, and could adversely impact our operating results, our ability to conduct business and our reputation.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA or EMA regulations, to provide accurate information to the FDA or the EMA, or intentional failures to report financial information or data accurately or to disclose unauthorized activities to us. Employee misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and serious harm to our reputation. While we take precautions to detect and prevent this activity, it may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Our business activities may be subject to the Foreign Corrupt Practices Act (FCPA) and similar anti-bribery and anti-corruption laws.

Our business activities may be subject to the FCPA and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including the UK Bribery Act. The FCPA generally prohibits offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation, and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials. including officials of non-U.S. governments. Additionally, in many other countries, the healthcare providers who prescribe pharmaceuticals or biopharmaceuticals and the investigators who perform our studies are employed by their government, and the purchasers of pharmaceuticals are government entities; therefore, our dealings with these prescribers and purchasers are subject to regulation under the FCPA. The Securities and Exchange Commission (“SEC”) and the Department of Justice have increased their FCPA enforcement activities with respect to pharmaceutical companies. There is no certainty that all of our employees, agents, contractors or collaborators, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results and financial condition.

Risks related to our common shares and our ADRs

We do not know whether an active, liquid and ordinary trading market will develop for our ADRs or what the market price of our ADRs will be. As a result, it may be difficult for you to sell your ADRs.

While our ordinary shares have traded on the SIX Swiss Exchange since 2009, our recently enacted ADR program constitutes the first opportunity to purchase our ADRs in the United States. Our ADRs recently began trading over-the-counter, and we intend to apply to list our ADRs on the NASDAQ Stock Market in the future. Until our ADRs are listed on NASDAQ, they will continue to be traded on the over-the-counter market. Until our ADRs are listed on NASDAQ, it may be more difficult for holders to sell the ADRs. There can be no assurance that an active trading market for the ADRs will develop or be sustained after this registration is completed or that we will be successful in listing our ADRs on NASDAQ.

The market price of our common shares is volatile and may fluctuate due to factors beyond our control, and the market for our ADRs is likely to be similarly volatile

The market price of our common shares is volatile and the market for our ADRs is likely to be similarly volatile. The stock market in general, and the market for biopharmaceutical companies in particular, has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, you may not be able to sell your ordinary shares or your ADRs at or above the purchase price. The market price for our common shares is, and the market for our ADRs is likely to be, influenced by many factors, including:

- positive or negative results of testing and clinical studies by us, strategic partners, or competitors;
- delays in entering into strategic relationships with respect to development and/or commercialization of our product candidates or entry into strategic relationships on terms that are not deemed to be favorable to us;
- technological innovations or commercial product introductions by us or competitors;
- changes in government regulations;
- developments concerning proprietary rights, including patents and litigation matters;
- public concern relating to the commercial value or safety of any of our product candidates;
- financing or other corporate transactions;
- publication of research reports or comments by securities or industry analysts;
- general market conditions in the pharmaceutical or biopharmaceutical industry or in the economy as a whole; or
- other events and factors beyond our control.

Broad market and industry factors may materially affect the market price of companies' stock, including ours, regardless of actual operating performance. Furthermore, issuers such as ourselves, whose securities have historically had limited trading volumes and/or have been susceptible to relatively high volatility levels, can be particularly vulnerable to short-seller attacks and trading in our common shares by non-fundamental investors such as hedge funds and others who may enter and exit positions in our common shares frequently and suddenly, causing increased volatility of our share price. Short selling is the practice of selling securities that the seller does not own but rather has borrowed or intends to borrow from a third party with the intention of buying identical securities at a later date to return to the lender, and profit from a decline in the value of the securities in the process. The publication of any commentary by short sellers with the intent of creating negative market momentum may bring about a temporary, or possibly long-term, decline in the market price of our common stock.

Future sales, or the possibility of future sales, of a substantial number of our common shares could adversely affect the price of our common shares.

Future sales of a substantial number of our ADRs, or the perception that such sales will occur, could cause a decline in the market price of our ADRs. If certain of our shareholders sell substantial amounts of common shares in the public market, or the market perceives that such sales may occur, the market price of our common shares and our ability to raise capital through an issue of equity securities in the future could be adversely affected. If a large number of our ADRs are sold in the public market after they become eligible for sale, the sales could reduce the trading price of our common shares and impede our ability to raise future capital.

Holders of ADRs are not treated as holders of our ordinary shares.

After purchasing an ADR, you will become a holder of ADRs with underlying ordinary shares in a company incorporated under Swiss law. Holders of ADRs are not treated as holders of our ordinary shares, unless they withdraw the ordinary shares underlying their ADRs in accordance with the deposit agreement and applicable laws and regulations. The depositary is the holder of the ordinary shares underlying the ADRs. Holders of ADRs therefore do not have any rights as holders of our ordinary shares, other than the rights that they have pursuant to the deposit agreement. See "Description of American Depositary Shares."

You will not have the same voting rights as holders of our ordinary shares and may not receive voting materials in time to exercise your right to vote.

Except as described in this registration statement and the deposit agreement, holders of the ADRs will not be able to exercise voting rights attaching to the ordinary shares represented by the ADRs. Under the terms of the deposit agreement, holders of the ADRs may instruct the depositary to vote the ordinary shares underlying their ADRs. Otherwise, holders of ADRs will not be able to exercise their right to vote unless they withdraw the ordinary shares underlying their ADRs to vote them in person or by proxy in accordance with applicable laws and regulations and our Articles of Association. Even so, ADR holders may not know about a meeting far enough in advance to withdraw those ordinary shares. If we ask for the instructions of holders of the ADRs, the depositary, upon timely notice from us, will notify ADR holders of the upcoming vote and arrange to deliver our voting materials to them. Upon our request, the depositary will mail to holders a shareholder meeting notice that contains, among other things, a statement as to the manner in which voting instructions may be given. We cannot guarantee that ADR holders will receive the voting materials in time to ensure that they can instruct the depositary to vote the ordinary shares underlying their ADRs. A shareholder is only entitled to participate in, and vote at, the meeting of shareholders, provided that it holds our ordinary shares as of the record date set for such meeting and otherwise complies with our Articles of Association. In addition, the depositary' s liability to ADR holders for failing to execute voting instructions or for the manner of executing voting instructions is limited by the deposit agreement. As a result, holders of ADRs may not be able to exercise their right to give voting instructions or to vote in person or by proxy and they may not have any recourse against the depositary or us if their ordinary shares are not voted as they have requested or if their shares cannot be voted.

You may not receive distributions on our ordinary shares represented by ADRs or any value for them if it is illegal or impractical to make them available to holders of ADRs.

The depositary for the ADRs has agreed to pay to you any cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities after deducting its fees and expenses. You will receive these distributions in proportion to the number of our ordinary shares your ADRs represent. However, in accordance with the limitations set forth in the deposit agreement, it may be unlawful or impractical to make a distribution available to holders of ADRs. We have no obligation to take any other action to permit distribution on the ADRs, ordinary shares, rights or anything else to holders of the ADRs. This means that you may not receive the distributions we make on our ordinary shares or any value from them if it is unlawful or impractical to make them available to you. These restrictions may have an adverse effect on the value of your ADRs.

We are a foreign private issuer and, as a result, we are not subject to U.S. proxy rules and are subject to Exchange Act reporting obligations that, to some extent, are more lenient and less frequent than those of a U.S. domestic public company.

We are reporting under the Exchange Act as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act and although we are subject to Swiss laws and regulations with regard to such matters, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; (ii) the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and their liability for insiders who profit from trades made in a short period of time; and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or of current reports on Form 8-K, upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their annual report on Form 20-F until four months after the end of each financial year, whereas U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers are also exempt from the Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

We are an "emerging growth company," and there are reduced disclosure requirements applicable to emerging growth companies, above and beyond the reduced disclosure requirements we have as a Foreign Private Issuer.

We are an "emerging growth company" as defined in the SEC' s rules and regulations and we will remain an emerging growth company until the earlier to occur of (1) the last day of 2025, (2) the last day of the fiscal year in which we have total annual gross revenues of at least $1.07 billion, (3) the last day of the fiscal year 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 equity securities that is held by non-affiliates exceeds $700 million as of the prior June 30th, or (4) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, or Section 404;
- not being required to comply with any requirement that has or may be adopted by the Public Company Accounting Oversight Board, or PCAOB, regarding mandatory audit firm rotation or a supplement to the auditor' s report providing additional information about the audit and the financial statements;
- being permitted to provide only two years of audited financial statements in this initial registration statement, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management' s Discussion and Analysis of Financial Condition and Results of Operations" disclosure;

reduced disclosure obligations regarding executive compensation; and

an exemption from the requirement to seek nonbinding advisory votes on executive compensation or golden parachute arrangements.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens in this registration statement. In particular, we have not included all of the executive compensation information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our ADRs less attractive if we rely on certain or all of these exemptions. If some investors find our ADRs less attractive as a result, there may be a less active trading market for our ADRs and our ADR price may be more volatile.

In addition, the Jumpstart Our Business Startups Act of 2012 provides that an emerging growth company may take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We are considering whether we will take advantage of the extended transition period for complying with new or revised accounting standards. Since IFRS makes no distinction between public and private companies for purposes of compliance with new or revised accounting standards, the requirements for our compliance as a private company and as a public company are the same.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" if the market value of our ordinary shares held by non-affiliates is below $250 million (or $700 million if our annual revenue is less than $100 million) as of June 30 in any given year, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements.

One of our principal shareholders has a significant holding in the company which may give them influence in certain matters requiring approval by shareholders, including approval of significant corporate transactions in certain circumstances.

As reported to the SIX Swiss Exchange, GEM Global Yield LLC SCS, Luxembourg, Luxembourg (26.24% of the registered share capital of the Company) is the only shareholder that holds more than 3% of the registered share capital of the Company. This shareholding percentage excludes derivatives holdings and is reported as published in the SIX database as of the date of this Registration Statement.

GEM or other major shareholders, alone or acting in concert with third parties, would be able to exert significant influence over, or in some cases to decide or block, certain matters that must be decided by a vote of the shareholders, including the election of members to the Board of Directors of the Company or the declaration of dividends or other distributions. To the extent that the interests of these shareholders may differ from the interests of the Company' s other shareholders, the Company' s other shareholders may be disadvantaged by any actions that these shareholders may seek to pursue.

We have broad discretion in the use of our cash and cash equivalents and short-term financial assets and may not use them effectively.

Our management has broad discretion in the application of our cash and cash equivalents and short-term financial assets. Our or our collaboration partners' decisions concerning the allocation of research, development, collaboration, management and financial resources toward particular product candidates or therapeutic areas may not lead to the development of any viable commercial product and may divert resources away from better opportunities. If we make incorrect determinations regarding the viability or market potential of any of our programs or product candidates or misread trends in the pharmaceutical or biopharmaceutical industry, in particular for neurodegenerative diseases, our business, financial condition and results of operations could be materially adversely affected. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other product candidates or other diseases and disease pathways that may later prove to have greater commercial potential than those we choose to pursue, or relinquish valuable rights to such product candidates through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to invest additional resources to retain sole development and commercialization rights.

We have not in the past paid dividends and we do not expect to pay dividends in the foreseeable future.

We have not paid any dividends since our incorporation. Even if future operations lead to significant levels of distributable profits, we currently intend that any earnings will be reinvested in our business and that dividends will not be paid until we have an established revenue stream to support continuing dividends. Under our articles of association, the declaration of dividends requires a resolution passed by a simple majority of the votes cast at a shareholders' meeting regardless of abstentions and empty or invalid votes. The proposal to pay future dividends to shareholders will in addition effectively be at the discretion of our board of directors after considering various factors including our business prospects, liquidity requirements, financial performance and new product development. In addition, payment of future dividends is subject to certain limitation pursuant to Swiss law or by our articles of association. Accordingly, investors cannot rely on dividend income from our common shares and any returns on an investment in our common shares will likely depend entirely upon any future appreciation in the price of our common shares.

We are a Swiss corporation. The rights of our shareholders may be different from the rights of shareholders in companies governed by the laws of U.S. jurisdictions.

We are a Swiss corporation. Our corporate affairs are governed by our articles of association and by the laws governing companies, including listed companies, incorporated in Switzerland. The rights of our shareholders and the responsibilities of members of our board of directors may be different from the rights and obligations of shareholders and directors of companies governed by the laws of U.S. jurisdictions. In the performance of its duties, our board of directors is required by Swiss law to consider the interests of our Company, our shareholders, our employees and other stakeholders in all cases, with due observation of the principles of reasonableness and fairness. It is possible that some of these parties will have interests that are different from, or in addition to, your interests as a shareholder. Swiss corporate law limits the ability of our shareholders to challenge resolutions made or other actions taken by our board of directors in court. Our shareholders generally are not permitted to file a suit to reverse a decision or an action taken by our board of directors but are instead only permitted to seek damages for breaches of fiduciary duty. As a matter of Swiss law, shareholder claims against a member of our board of directors for breach of fiduciary duty would have to be brought in Geneva, Switzerland, or the country in which the relevant member of our board of directors is domiciled. In addition, under Swiss law, any claims by our shareholders against us must be brought exclusively in Geneva, Switzerland (except for certain U.S. securities and other claims that may be brought in U.S. federal court).

Our status as a Swiss corporation may limit our flexibility with respect to certain aspects of capital management and may cause us to be unable to make distributions without subjecting our shareholders to Swiss withholding tax.

Swiss law allows our shareholders to authorize share capital that can be issued by the board of directors without additional shareholder approval. This authorization is limited to 50% of the existing registered share capital and must be renewed by the shareholders every 2 years. Further, our articles of association provide for conditional share capital (up to a maximum of 50% of the ordinary share capital) for the purpose of issuing shares in connection with, among other things, (i) conversion or option rights, or (ii) to our employees, members of our board of directors, consultants, our subsidiaries or other persons. Additionally, as a principle, Swiss law grants pre-emptive subscription rights to existing shareholders to subscribe to any new issuance of shares. Any common share capital increase resolution preserving pre-emptive subscription rights expires after 3 months and requires a simple majority of the votes cast at the shareholder' s meeting regardless of abstentions and empty or invalid votes. Swiss law also does not provide as much flexibility in the various terms that can attach to different classes of shares as do the laws of some other jurisdictions. Swiss law also reserves for approval by shareholders certain corporate actions over which a board of directors would have authority in some other jurisdictions. For example, dividends must be approved by shareholders. These Swiss law requirements relating to our capital management may limit our flexibility, and situations may arise in which greater flexibility would have provided substantial benefits to our shareholders.

Under Swiss law, a Swiss corporation may pay dividends only if the corporation has sufficient distributable profits from previous fiscal years, or if the corporation has distributable reserves, each as evidenced by its audited statutory balance sheet. Freely distributable reserves are generally booked either as "free reserves" or as "capital contributions" (*apports de capital*, contributions received from shareholders) in the "reserve from capital contributions." Distributions may be made out of issued share capital only by way of a capital reduction. As of December 31, 2021, the Company had CHF 304.9 million of reserves from capital contributions and approximately CHF 44.1 million of issued share capital (consisting of 4,413,334,617 common shares each with a par value of CHF 0.01 and no preferred shares) on its statutory balance sheet. Of the total issued shares and issued share capital, the Company held 299,867,357 fully paid-in treasury shares representing CHF 2.9 million of issued share capital at nominal value.

We expect the aggregate of these amounts (less the lowest legally possible issued share capital and legal reserve of together CHF 150,000) to represent the amount available for future dividends or capital reductions on a Swiss withholding tax-free basis. We will not be able to pay dividends or make other distributions to shareholders on a Swiss withholding tax-free basis in excess of that amount unless the Company increases its share capital or its reserves from capital contributions. We would also be able to pay dividends out of distributable profits or freely distributable reserves but such dividends would be subject to Swiss withholding taxes. There can be no assurance that we will have sufficient distributable profits, free reserves, reserves from capital contributions or registered share capital to pay a dividend or effect a capital reduction, that our shareholders will approve dividends or capital reductions proposed by us, or that we will be able to meet the other legal requirements for dividend payments or distributions as a result of capital reductions.

Generally, Swiss withholding tax of 35% is due on dividends and similar distributions to our shareholders, regardless of the place of residency of the shareholder, unless the distribution is made to shareholders out of (i) a reduction of nominal value or (ii) assuming certain conditions are met, reserves from capital contributions accumulated on or after January 1, 1997. A U.S. Holder who qualifies for benefits under the Convention Between the United States of America and the Swiss Confederation for the Avoidance of Double Taxation with Respect to Taxes on Income, which we refer to as the "U.S.-Swiss Treaty," may apply for a refund of the tax withheld in excess of the 15% treaty rate (or in excess of the 5% reduced treaty rate for qualifying corporate shareholders with at least 10% participation in our voting stock, or for a full refund in the case of qualified pension funds). There can be no assurance that we will have sufficient reserves from capital contributions to pay dividends free from Swiss withholding tax, or that Swiss withholding tax rules will not be changed in the future. In addition, we cannot provide assurance that the current Swiss law with respect to distributions out of reserves from capital contributions will not be changed or that a change in Swiss law will not adversely affect us or our shareholders, in particular as a result of distributions out of reserves from capital contributions becoming subject to additional corporate law or other restrictions. In addition, over the long term, the amount of par value available to us for nominal value reductions or reserves from capital contributions available to us to pay out as distributions is limited. If we are unable to make a distribution through a reduction in nominal value or out of reserves from capital contributions, we may not be able to make distributions without subjecting our shareholders to Swiss withholding taxes.

U.S. shareholders may not be able to obtain judgments or enforce civil liabilities against us or our executive officers or members of our board of directors.

We are organized under the laws of Switzerland and our registered office and domicile is located in Geneva, Switzerland. Moreover, a number of our directors and executive officers are not residents of the U.S., and all or a substantial portion of the assets of such persons are located outside the U.S. As a result, it may not be possible for investors to effect service of process within the U.S. upon us or upon such persons or to enforce against them judgments obtained in U.S. courts, including judgments in actions predicated upon the civil liability provisions of the federal securities laws of the U.S.. We have been advised by our Swiss counsel that there is doubt as to the enforceability in Switzerland of original actions, or of actions for enforcement of judgments of U.S. courts, for civil liabilities to the extent solely predicated upon the federal and state securities laws of the U.S. Original actions against persons in Switzerland based solely upon the U.S. federal or state securities laws are governed, among other things, by the principles set forth in the Swiss Federal Act on Private International Law. This statute provides that the application of provisions of non-Swiss law by the courts in Switzerland shall be precluded if the result is incompatible with Swiss public policy. Additionally, certain mandatory provisions of Swiss law may be applicable regardless of any other law that would otherwise apply.

Switzerland and the U.S. do not have a treaty providing for reciprocal recognition and enforcement of judgments in civil and commercial matters. The recognition and enforcement of a judgment of the courts of the U.S. in Switzerland is governed by the principles set forth in the Swiss Federal Act on Private International Law. This statute provides in principle that a judgment rendered by a non-Swiss court may be enforced in Switzerland only if:

- the non-Swiss court had jurisdiction pursuant to the Swiss Federal Act on Private International Law;
- the judgment of such non-Swiss court has become final and non-appealable;
- the judgment does not contravene Swiss public policy;
- the court procedures and the service of documents leading to the judgment were in accordance with the due process of law; and
- no proceeding involving the same parties and the same subject matter was first brought in Switzerland, or adjudicated in Switzerland, or was earlier adjudicated in a third state for which the decision is recognizable in Switzerland.

Our status as a Swiss corporation means that our shareholders enjoy certain rights that may limit our flexibility to raise capital, issue dividends and otherwise manage ongoing capital needs.

Swiss law reserves for approval by shareholders certain corporate actions over which a board of directors would have authority in some other jurisdictions. For example, the payment of dividends and cancellation of treasury shares must be approved by shareholders. Swiss law also requires that our shareholders themselves resolve, or authorize our board of directors, to increase our share capital. Although our shareholders may authorize share capital that can be issued by our board of directors without additional shareholder approval, Swiss law limits this authorization to 50% of the issued share capital at the time of the authorization. The authorization, furthermore, has a limited duration of up to two years and must be renewed by the shareholders from time to time thereafter in order to be available for raising capital. Additionally, subject to specified exceptions, including exceptions explicitly described in our articles of association, Swiss law grants pre-emptive subscription rights to existing shareholders to subscribe for new issuances of shares. Swiss law also does not provide as much flexibility in the various rights and regulations that can attach to different categories of shares as do the laws of some other jurisdictions. These Swiss law requirements relating to our capital management may limit our flexibility, and situations may arise where greater flexibility would have provided benefits to our shareholders.

Swiss law restricts our ability to pay dividends.

The proposal to pay future dividends to shareholders will effectively be at the discretion of our board of directors and subject to approval by, at their discretion, our shareholders after considering various factors including our business prospects, liquidity requirements, financial performance and new product development.

In addition, payment of future dividends is subject to certain limitations pursuant to Swiss law or our articles of association. Investors cannot rely on dividend income from our common shares and any returns on an investment in our common shares will likely depend entirely upon any future appreciation in the price of our common shares. Dividends paid on our common shares are subject to Swiss Federal withholding tax, except if paid out of reserves from capital contributions (*apports de capital*).

See "Item 10. Additional information- E. Taxation−Swiss tax considerations" for a summary of certain Swiss tax consequences regarding dividends distributed to holders of our common shares.

Shareholders in countries with a currency other than Swiss Francs face additional investment risks from currency exchange rate fluctuations in connection with their holding of our common shares.

Any future payments of dividends, if any, will likely be denominated in Swiss Francs. The foreign currency equivalent of any dividend, if any, paid on our common shares or received in connection with any sale of our common shares could be adversely affected by the depreciation of the Swiss Franc against such other currency.

As a foreign private issuer and as permitted by the listing requirements of Nasdaq, we rely on certain home country governance practices rather than the corporate governance requirements of Nasdaq.

We are a foreign private issuer. If we are successful in listing our ADRs on the Nasdaq Stock Market, as a result, in accordance with Nasdaq Listing Rule 5615(a)(3), we will comply with Swiss governance requirements and certain exemptions thereunder rather than complying with certain of the corporate governance requirements of Nasdaq. Swiss law does not require that a majority of our board of directors consist of independent directors. Our board of directors therefore may include fewer independent directors than would be required if we were subject to Nasdaq Listing Rule 5605(b)(1). In addition, we are not subject to Nasdaq Listing Rule 5605(b)(2), which requires that independent directors regularly have scheduled meetings at which only independent directors are present.

Although Swiss law also requires that we adopt a compensation committee, we follow home country requirements with respect to such committee and our compensation, nomination and corporate governance committee is tasked with certain director nomination and governance responsibilities as described under "Item 6. Directors, senior management and employees." As a result, our practice varies from the requirements of Nasdaq Listing Rule 5605(d), which sets forth certain requirements as to the responsibilities, composition and independence of compensation committees, and from the independent director oversight of director nominations requirements of Nasdaq Listing Rule 5605(e).

Furthermore, in accordance with Swiss law and generally accepted business practices, our articles of association do not provide quorum requirements generally applicable to general meetings of shareholders. Our practice thus varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock. Our articles of association provide for an independent proxy holder elected by our shareholders, who may represent our shareholders at a general meeting of shareholders, and we must provide shareholders with an agenda and other relevant documents for the general meeting of shareholders. Our practice varies from the requirement of Nasdaq Listing Rule 5620(b), which sets forth certain requirements regarding the solicitation of proxies. In addition, we have opted out of shareholder approval requirements for the issuance of securities in connection with certain events such as the acquisition of stock or assets of another company, the establishment of or amendments to equity-based compensation plans for employees, a change of control of us, and certain private placements. To this extent, our practice varies from the requirements of Nasdaq Listing Rule 5635, which generally requires an issuer to obtain shareholder approval for the issuance of securities in connection with such events.

For an overview of our corporate governance principles, see "Item 6. Directors, Senior Management and Employees." As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

We may lose our foreign private issuer status, which would then require us to comply with the Exchange Act's domestic reporting regime and cause us to incur significant legal, accounting and other expenses.

We are a foreign private issuer and therefore we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. In order to maintain our current status as a foreign private issuer, either (a) a majority of our common shares must be either directly or indirectly owned of record by non-residents of the U.S. or (b) (i) a majority of our executive officers or directors may not be U.S. citizens or residents, (ii) more than 50 percent of our assets cannot be located in the U.S. and (iii) our business must be administered principally outside the U.S. If we lost this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and stock exchange rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time-consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors.

If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common shares.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, are designed to prevent fraud, among other objectives. Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes-Oxley Act of 2002, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting, which are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also subject us to regulatory scrutiny and sanctions, impair our ability to raise revenue and cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common shares.

In March 2020, the SEC approved amendments to exempt from the requirements of Section 404(b) any companies with less than USD 100 million of revenue and less than USD 700 million of public float. These amendments provide that such companies are no longer required to obtain an attestation of their internal controls over financial reporting from an independent outside auditor, even if such companies are no longer "emerging growth companies."

For as long as we are exempt from the requirement of Section 404(b) per the aforementioned SEC amendments adopted in March 2020, we may not be able to detect problems that an independent assessment of the effectiveness of our internal controls could. Undetected material weaknesses in our internal controls could lead to financial statement restatements and require us to incur the expense of remediation.

If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, the price of our common shares and our trading volume could decline.

The trading market for our common shares will depend in part on the research and reports that securities or industry analysts publish about us or our business. If no or too few securities or industry analysts cover our company, the trading price for our common shares would likely be negatively affected. In addition, if one or more of the analysts who cover us downgrade our common shares or publish inaccurate or unfavorable research about our business, the price of our common shares would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our common shares could decrease, which might cause the price of our common shares and trading volume to decline.

ITEM 4. INFORMATION ON THE COMPANY

A. HISTORY AND DEVELOPMENT OF THE COMPANY

We were formed in 2007 under the company name i-Mondo AG, which later in 2007 was changed to mondoRPHAN AG and in 2008 to mondoBIOTECH holding AG. In 2013, we changed our company name to THERAMETRICS holding AG and in 2016 to Relief. We have been listed on the SIX Swiss Exchange since 2009.

Our legal seat is located in Geneva, Switzerland. Our registered office is located at Avenue de Sécheron 15, 1202 Genève, Switzerland, and our telephone number is +41 22 545 11 16. Our website address is http://www.relieftherapeutics.com. The reference to our website is for textual reference only and information contained in, or that can be accessed through, our website or any other website cited in this registration statement is not a part thereof.

B. BUSINESS OVERVIEW

We are a commercial-stage biopharmaceutical company developing drug products for therapeutic use.

Historically, our development has focused primarily on clinical-stage projects with molecules of natural origin (peptides and proteins) that have a history of clinical testing and use in human patients and/or a strong scientific rationale. We announced in August 2019 our intention to divest one of our subsidiaries, Relief Therapeutics SA, to Sonnet BioTherapeutics, Inc., which divestiture closed in March 2020.

We are led by a proven and seasoned management team of business leaders with significant experience in discovering, developing and commercializing important new medicines, delivering them to market and maximizing shareholder value. Collectively, the members of our management team have overseen research and development of products supporting regulatory approvals as well as commercial launches of marketed products.

We are actively pursuing a strategy to diversify our portfolio and are continuously evaluating additional potential in-licensing and partnering opportunities. To bring assets as quickly as possible to the market, we are seeking partnerships with, or acquisitions of, companies that have late-stage clinical molecules, with a strong safety profile allowing for relatively short, capital-effective, clinical trials with objective endpoints. Our focus is on rare diseases with significant unmet medical need with an objective to maintain a lean organization, building a strong core of experienced, high performance experts that drive growth by effectively managing partnerships and efficiently allocating capital across the portfolio.

Aviptadil is a vasoactive intestinal peptide with predominant biological activity in the lungs. The clinical development program of RLF-100 is focused on various lung indications including; (i) COVID-19 induced acute respiratory distress syndrome (“ARDS”), (ii) COVID-19 non-acute lung injury (“NALI”); (iii) non-COVID-19 related ARDS; (iv) pulmonary sarcoidosis; (v) Berylliosis; and (vi) Checkpoint Inhibitor-induced Pneumonitis.

In March 2020, at the beginning of the first wave of the pandemic in the United States, our U.S. partner NeuroRx, Inc. (“NeuroRx”) submitted an Investigational New Drug (“IND”) application with the U.S. Food and Drug Administration (the “FDA”) for a phase 2b/3 trial of RLF-100 for the intravenous (“IV”) 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 subsequently treated in April 2020 at Thomas Jefferson University Hospital in Philadelphia. In June 2020, RLF-100 was awarded Fast Track designation by the FDA for the treatment of acute lung injury (“ALI”) / ARDS associated with COVID-19. In July 2020, the FDA granted Expanded Access Protocol (“EAP”) designation for treatment of respiratory failure induced by COVID-19 with RLF-100 IV. Treatment was available to patients who had exhausted standard therapies and were not eligible for the phase 2b/3 trial due to concomitant medical conditions.

In September 2020, we entered into a binding collaboration agreement with NeuroRx (the "Collaboration Agreement"). The Collaboration Agreement establishes the terms under which we and NeuroRx will collaborate and assist each other to maximize the revenues in their respective territories from the sale of aviptadil for intravenous and inhale use primarily for the treatment of COVID-19 related conditions. The collaboration agreement provides that NeuroRx will be responsible for developing and commercializing the product in the United States, Canada and Israel and that we will be responsible for developing and commercializing the product in the European Union, Switzerland, Iceland, Norway, the United Kingdom, the Channel Islands, Lichtenstein, Monaco, Andorra, San Marino and Vatican City. The collaboration agreement also provides that it will be conducted on an exclusive basis and that neither party may develop or commercialize any product that would be competitive with RLF-100.

The collaboration agreement includes profit sharing splits between the parties as follows: (i) net profits from sales of the product in NeuroRx' s territories will be split 50%/50% between Relief and NeuroRx, respectively; (ii) net profits from sales of the product in Relief' s territories will be split 85%/15% between Relief and NeuroRx, respectively; and (iii) net profits from sales of the product in the rest of the world will be split 80%/20% between Relief and NeuroRx, respectively.

In late 2020 and into early 2021, NeuroRx conducted a phase 2b/3 trial of intravenous aviptadil to evaluate its use in the treatment of respiratory failure due to COVID-19. In March 2021, NeuroRx reported the results of that trial. In its press release reporting those results, NeuroRx reported that across all patients and sites RLF-100 IV met the primary endpoint for successful recovery from respiratory failure at days 28 (p=0.14) and 60 (p=0.13) and also demonstrated a meaningful benefit in survival after controlling for ventilation status and treatment 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. On the basis of these findings, NeuroRx announced on June 1, 2021 that it had applied to the FDA for Emergency Use Authorization ("EUA").

Also in March 2021, NeuroRx announced that RLF-100 had been selected for inclusion in "TESICO" (Therapeutics for Severely Ill Inpatients with COVID-19), a phase 3 multicenter clinical trial that included sites in the United States and multiple foreign countries, that was being sponsored by the U.S. National Institutes of Health ("NIH"). On May 26, 2022, NRx (as defined below) reported that the Data and Safety Monitoring Board for the TESICO trial had determined that the evaluation of aviptadil in that trial should cease due to futility.

On June 16, 2021, NeuroRx' s parent corporation, NRx Pharmaceutical, Inc. ("NRx"), issued a press release reporting additional results from the aviptadil U.S. Expanded Access Protocol ("EAP"). The EAP included 240 patients in the intensive care unit (ICU) with critical COVID-19 respiratory failure requiring either invasive or non-invasive mechanical ventilation, or high flow rate oxygen by nasal cannula, and not eligible to participate in its phase 2b/3 clinical trial with IV aviptadil. According to NRx' s press release, these EAP data are being submitted by NeuroRx to the FDA as "real world" evidence in support of the findings from the phase 2b/3 trial.

On July 28, 2021, NRx issued a press release reporting that the Nation of Georgia' s Prime Minister and Minister of Health had issued an Emergency Use Authorization for intravenous aviptadil for the treatment of critical COVID-19, with the first doses being administered shortly thereafter. On March 9, 2022, NRx reported in a Form 8-K that in light of their strategic focus and the ongoing hostilities in Eastern Europe, it would not pursue opportunities in Georgia (which neighbors Russia and Ukraine), elsewhere in the Caucasus region or Europe. Further, NRx stated that its board of directors could not confirm the current status or effectiveness of the authorization for emergency use of ZYESAMI (aviptadil) in Georgia. NRx stated that although it engaged in an initial training of physicians, it has not sold any doses, and at this time, it has ceased efforts to pursue further regulatory drug interactions in Georgia or to conduct clinical trials there.

On November 5, 2021, NRx announced that the FDA had declined NeuroRx' s application for EUA of IV aviptadil for the treatment of acute respiratory failure due to critical COVID-19. In its press release, NRx stated that in the letter from the FDA denying EUA, the FDA noted that it has only reviewed safety data on 131 patients treated with aviptadil. NRx further announced in its press release that it will attempt to coordinate a review by the FDA of 150 or more additional patients treated with aviptadil through other trials. Additionally, NRx stated in its press release that the study' s Data Safety and Monitoring Board reviewing the trial found no safety issues. Further, on November 24, 2021, NRx reported that it was denied breakthrough therapy designation for the product. On June 10, 2022, NRx reported that its second application for breakthrough therapy designation was also denied.

On January 5, 2022, NRx reported in a press release that it has submitted an additional application to the FDA seeking EUA for the use of aviptadil to treat patients with critical COVID-19 who are at immediate risk for death from respiratory failure despite treatment with approved therapy, including Remdesivir. Additionally, on January 26, 2022, NRx issued a press release reporting, NeuroRx' s receipt of a first safety report from a southwestern hospital where physicians have administered aviptadil to patients with COVID-19 respiratory failure. According to NRx' s press release, the patients were treated under the United States' Right to Try Act, which gives access to investigational medicines for patients who have been diagnosed with life-threatening diseases or conditions, who have tried all approved treatment options, and who are unable to participate in a clinical trial to access certain unapproved treatments. The press release stated that of the first 19 patients treated by December 31, 2021, three had died and sixteen (84%) were reported to be alive as of January 22, 2022. Further, according to the press release, 14 of these 16 patients had been discharged to a rehabilitation facility or to home. By way of comparison, according to "Clinical characteristics, risk factors and outcomes in patients with severe COVID-19 registered in the ISARIC WHO clinical characterisation protocol: a prospective, multinational, multicentre, observational study", published in the journal ERJ Open Research in January 2021, the overall 28-day fatality rate for COVID-19 patients admitted to the ICU was approximately 30.7%. The press release also indicated that this use of aviptadil had occurred during the then-current COVID-19 surge caused by the omicron variant, although patients were not necessarily tested for the specific COVID variant that caused their ICU admission. Finally, NRx reported in its press release that no serious adverse events were reported. There can be no assurance that NeuroRx' s reapplication seeking EUA for aviptadil for the treatment of acute lung disease caused by COVID-19 will be successful.

On March 3, 2022, two U.S. Senators and two members of the House of Representatives sent a letter to Dr. Robert Califf, Commissioner of the FDA, and Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Disease regarding the results of the right-to-try administration of ZYESAMI. The letter discusses the results and seeks comment on the FDA review of the ZYESAMI EUA application and the FDA' s stance that the EUA will not be reviewed until the completion of clinical trials later this year. There can be no assurance as to what effect the letter will have on the review and consideration of the EUA application.

While we have received a phase 2b/3 Study Report summary from NeuroRx and are reviewing the contents of the report to decide on the best path forward for the development of RLF-100 IV in Europe and other territories, NeuroRx has refused to share the full clinical trial data with us, which has prevented us from moving forward to seek approval for the product in its territories. They have also reported publicly their intent to file their own applications in Europe and the U.K. We believe that all of these actions, along with many others, constitutes breaches of the Collaboration Agreement.

To that end, on October 7, 2021, we filed a lawsuit against NeuroRx and its then - CEO, Dr. Jonathan Javitt, for multiple breaches of the Collaboration Agreement between Relief and NeuroRx relating to the development and commercialization of RLF-100. The complaint was filed in the Supreme Court of the State of New York in Manhattan. The complaint alleges that the defendants are in breach of numerous provisions of the Collaboration Agreement. The complaint, among other remedies, seeks damages, an order compelling defendants to comply with multiple provisions of the Collaboration Agreement, and a declaration directing NeuroRx to deliver the entire data set from the Phase 2b/3 clinical trial of intravenously-administering aviptadil to Relief. On January 10, 2022, NeuroRx filed a complaint against Relief alleging that we are in breach of the Collaboration Agreement and have thus repudiated and cancelled the Collaboration Agreement. Additionally, NeuroRx claims that we, through our press releases and statements to investors, have defamed NeuroRx and Dr. Javitt. We believe that such claims are without merit. There can be no assurance as to the result of this litigation.

In March 2021, we signed a Collaboration and License Agreement with Acer Therapeutics, Inc. ("Acer") for the worldwide development and commercialization of ACER-001 for the treatment of Urea Cycle Disorders ("UCDs") and Maple Syrup Urine Disease ("MSUD"). ACER-001 is a proprietary powder formulation of sodium phenylbutyrate (NaPB) designed to be both taste-masked and immediate release.

In August 2021, Acer submitted an NDA for ACER-001 to the FDA for use as a treatment of UCD, which submission was accepted for filing in November 2021 with a PDUFA decision date of June 5, 2022. On June 7, 2022, Acer announced that it has not yet received a decision from the FDA on its NDA. Further, in accordance with our collaboration agreement with Acer, we are planning to submit an application for marketing authorization for this product to European and U.K. regulatory authorities assuming ACER-001 is approved by the FDA.

On June 28, 2021, we signed and closed a definitive agreement to acquire all outstanding shares of APR Applied Pharma Research SA ("APR"), a privately held Swiss pharmaceutical company with over 25 years' experience in identifying, developing and commercializing known molecules engineered with drug delivery systems in niche and rare diseases on a global basis.

APR is applying advanced patented pharma technologies, as well as proprietary delivery systems and novel dosage forms, to optimize the therapeutic potential of pharmaceuticals and improve patient outcomes. Its products are commercialized in about 50 countries worldwide. APR' s pipeline and portfolio include products for the treatment of rare or debilitating diseases. APR is, for example, commercializing Golike to improve metabolic control in patients suffering from phenylketonuria, a rare genetic metabolic disorder. A direct sales and marketing team is in place in selected European countries to support Golike, as well as established distribution partnerships for other countries in Europe and beyond. APR also has a strong pipeline of programs in development, including two orphan drug designations. Additionally, Sentinox, an intranasal spray to help block the transmission of the SARS-CoV-2 virus, just recently received clearance as a Class III medical device in the EU.

On March 15, 2022, we announced that APR has signed a binding term sheet with Meta Healthcare Ltd. ("Meta"), our United Kingdom distribution partner for Golike, to acquire the worldwide commercialization rights, except in the United Kingdom and Ireland, for a novel dosage form of a prescription drug already approved by the FDA and intended for the treatment of patients with PKU. At this time, we plan to file an IND for the novel dosage form in the U.S. as soon as possible and to file for FDA regulatory approval sometime in the first half of 2023. Additionally, Meta has submitted a patent application in the United Kingdom and APR intends to seek a patent extension in all major territories including the U.S. and Europe.

Further, in July 2021, we acquired all of the shares of AdVita Lifescience GmbH ("AdVita"), a Germany-based privately held pharmaceutical company developing effective products and strategies to improve the treatment and diagnosis of rare lung diseases. We believe that AdVita' s activities should help us further the development of RLF-100 for a range of lung diseases.

On November 24, 2021, we announced that we had 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 biopharma and other industries, in order to identify promising drug candidates to treat rare and specialty diseases (the "InveniAI Collaboration Agreement").

Under the terms of the InveniAI Collaboration Agreement, InveniAI will use its proprietary platform for the identification of potential pharmaceutical product opportunities using its Pharma Big Innovation Data Lab, consisting of (i) its proprietary AlphaMeld platform, a cloud-based artificial intelligence 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.

Capital Resources

As of December 31, 2021, we had cash and cash equivalents of approximately CHF 44.8 million, As of June 28, 2022, we have cash and cash equivalents of approximately CHF 30.0 million.

Based on current financial current projections and available cash, we expect that we have sufficient resources to fund operations well into 2023. We also believe that with a successful launch of ACER-001 (assuming it is approved by the FDA, of which there can be no assurance) and the potential expansion of our Golike franchise into the United States, we could reach operating cash flow-positive operations during 2024, of which there can be no assurance. These forecasts of available cash assume no revenue from sales of RLF-100 (aviptadil). Accelerated growth strategy, potential milestone payments, and acquisitions will require significant additional funding. There can be no assurance that our commercialization efforts will be successful or if we need additional funding in the future, whether such funding will be available to us. Our inability to obtain required funding could cause us to have to delay one or more of our planned activities and might make it difficult or impossible to continue our operations as a going concern.

Our Strategy

Our goal is to focus on clinical stage projects with a history of clinical testing and use in human patients or a strong scientific rationale. We are dedicated to developing these drugs to make a positive difference in the lives of patients suffering from severe conditions such as ARDS. Specifically, we intend to:

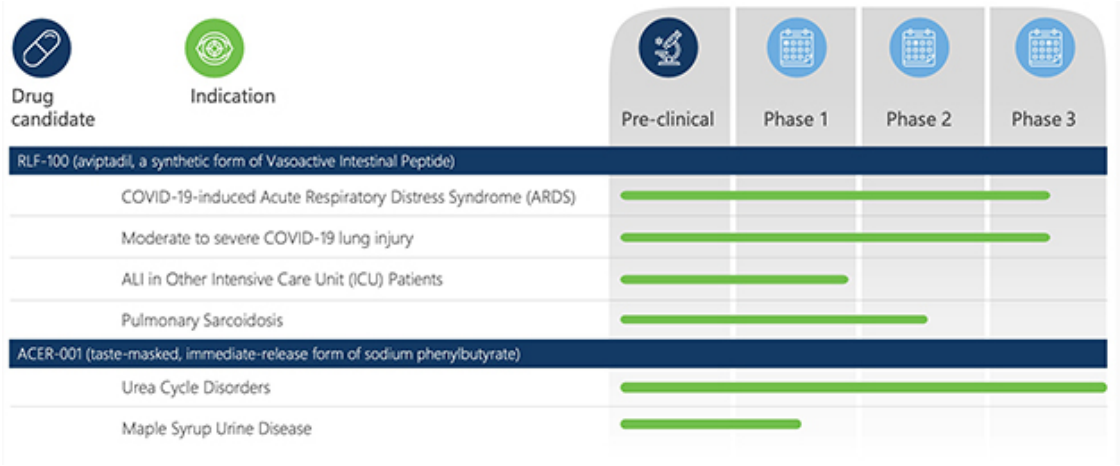
Develop RLF-100 for the treatment of COVID-19 related ARDS and other lung conditions. We intend to focus on developing RLF-100 for the treatment of, among other indications, COVID-19 lung injury, non-COVID-19 related ARDS, Checkpoint Inhibitor-induced Pneumonitis, Berylliosis, and pulmonary sarcoidosis. We also believe that the work of our recently acquired AdVita subsidiary, will also help us develop this product for these other lung diseases.

Develop ACER-001. Together with our collaboration partner Acer Therapeutics, we are currently pursuing approvals for use of ACER-001 for the treatment of UCD. We also intend in the near future to commence a clinical trial evaluating ACER-001 for the treatment of Maple Syrup Urine Disease ("MSUD").

Maximize the value of the development and commercial pipeline of APR.

Seek to acquire additional products. We have in the past sought out late-stage products that fit our profile and we plan to continue to seek such products in the future.

The following chart sets forth the status of each of our product candidates:



RLF-100

Aviptadil (branded RLF-100 by Relief and ZYESAMI by NeuroRx) 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. Here VIP has shown a multimodal mechanism of action: anti-inflammatory / Immunomodulatory, vasodilating effect, lung anti-proliferative and protective activity, bronchodilating effect and promotion of surfactant production. 70% of the VIP in the body is bound to a specific type of cell in the lung: the Alveolar Type II ("ATII") cell, which is critical to the transmission of oxygen to the body.VIP may be attractive from a global health perspective to combat the worst public health crisis since the 1918-1920 influenza pandemic: the COVID-19 pandemic. VIP has been granted Fast Track Designation by FDA for the treatment of critical COVID-19 patients with respiratory failure.

In 1970, Nature published a short report entitled "Potent peripheral and splanchnic vasodilator peptide from normal gut," published by two young scientists working at the Karolinska Institute (Said, Mutt, 1970). Five decades of subsequent research documented VIP' s role as a potent natural anti-cytokine that has unique capability to block pathways of cell death in ATII cells – the cell targeted by the SARS-CoV-2 virus.

Acute respiratory failure is the primary cause of death in COVID-19. In some cases, the injury is attributed to cytokine storm – i.e. a massive release of inflammatory cytokines and then cause destruction of pulmonary epithelium cells. However, the cytokine storm is only produced after the SARS-CoV2 virus enters the ATII cell through binding of its spike protein to Angiotensin Converting Enzyme 2 ("ACE2") surface receptors (Mason 2020). ACE2 is not present on Type I alveolar cells, which comprise 95% of the pulmonary epithelium and those cells are not infected by the coronavirus. Similarly, only the ATII cell expresses the VPAC1 receptor to which VIP binds. VIP is shown to prevent their apoptosis in models of lung injury (Ao 2011, Pakbaz 1993). Hence, VIP represents a highly specific approach to rescuing the lung from the overwhelming failure of oxygenation seen in COVID-19.

Pulmonary drugs are notoriously difficult to develop, given regulatory requirements for long-term toxicology studies in multiple species, including primates (Tepper 2016). FDA has asserted that these preclinical toxicology requirements must be observed in the case of candidate drugs to treat COVID-19. VIP, on the other hand, completed four species toxicology and safety pharmacology studies in both intravenous and inhaled dosage. Phase 2 trials in sarcoidosis (Prasse 2010), pulmonary hypertension (Petkov 2003, Leuchte 2008), pulmonary fibrosis (unpublished data), and asthma (Bundgaard 1983, Morice 1983 and 1986, Altiere 1984, Barnes 1984, Crimi 1988, Morice 1986) document that VIP has no major toxicities when inhaled at doses of 300µg/day or infused at dose of 6 pmol/kg/min.

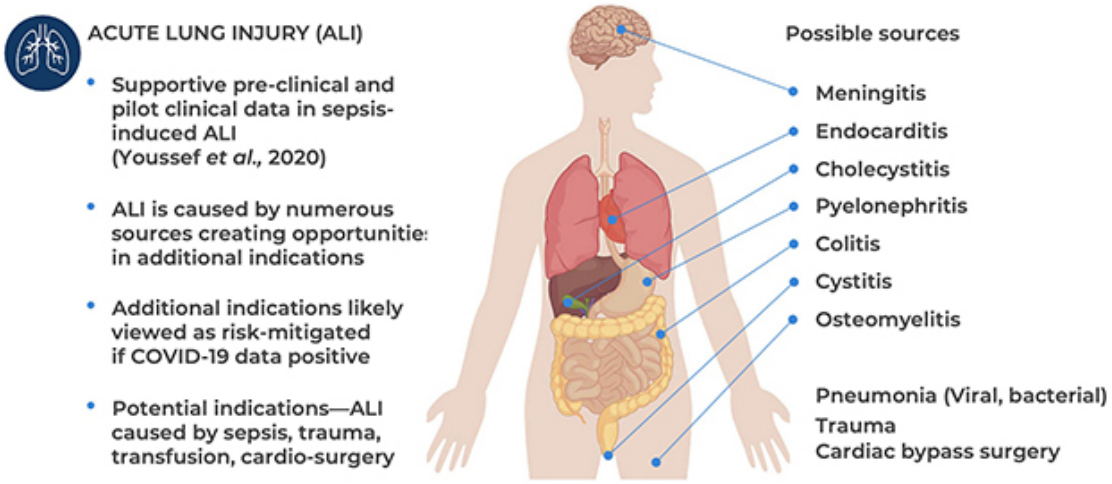
VIP was first proposed as a modulator of lung inflammation by Said (Said 1988, 1991). It has demonstrated positive effects in clinical trials of sepsis-related ARDS (Youssef 2020 preprint) and Sarcoidosis (Prasse 2010).

Although named (or mis-named) for the intestinal tissue in which it was first isolated, VIP is produced by neuroendocrine cells throughout the body and by T-lymphocytes, B-lymphocytes, and macrophages. VIP is highly localized in the lung (Leys 1986, Virgolini 1995) but is a widely distributed that showed, in various models, effects in hemodynamics and coronary circulation (Feliciano 1998, Frase 1987, Henning 2001), kidney (Dimaline 1983, Calam 1983 and 1988), immune system (Gonzales-Rey 2007, Ganea 2015, Li 2013), intestinal tract (Iwasaki 2019) and reproduction (Fredericks 1983, Fraccaroli 2012).

Early COVID-19 lung injury is characterized by a remarkable degree of hypoxia in the absence of overwhelming pneumonia, suggesting a primary injury to the pulmonary gas-exchange mechanism. Loss of surfactant and alveolar gas exchange is an hallmark of COVID-19 (Catel 2021, Mason 2020). Unlike synthetic anticytokines, such as anti-IL6 drugs, VIP is shown to have a specific role in preserving surfactant production in the lung (Li 2004, Li 2010) and in protecting type 2 alveolar cells (Ao 2011). Accordingly, VIP and longer acting modifications of VIP have been proposed in the past as respiratory therapeutics (Mathioudakis 2013).

RLF-100 in COVID-19

When the COVID-19 pandemic began, we devised a plan of action to respond to one of the largest healthcare disasters of our time by rapidly advancing RLF-100 towards approval in COVID-19-induced acute lung injury. Through its multimodal mechanism of action, RLF-100 may uniquely target the pathways attacked by COVID-19, preventing acute lung injury ("ALI").



1. Anti-inflammatory / Immunomodulatory activities of VIP

VIP belongs to the VIP/secretin/glucagon family of peptides. VIP is present and released from both innervation and immune cells, particularly Th2 cells, and exerts a wide spectrum of immunological functions controlling the homeostasis of immune system through different receptors expressed in various immunocompetent cells VIP has a general anti-inflammatory effect (Leceta 2000), both in innate and adaptive immunity (for review Ganea et al., 2015). In innate immunity, VIP inhibits the production of pro-inflammatory cytokines, including TNF-α (Delgado et al., 1998, 1999, Dewitt 1998) and chemokines from macrophages, microglia and dendritic cells. Furthermore, VIP reduces the expression of co-stimulatory molecules (particularly CD80 and CD86) on antigen-presenting cells, and therefore reduces stimulation of antigen-specific CD4+ T cells.

VIP exerts a favorable effect on chemokine receptors (Grimm 2003) and on immune tolerance (Gonzalez-Rey 2007) and has a positive role in lung inflammation (Lilly 1994, Said 2000) and on TGF-ß1 production (Sun 2000). In terms of adaptive immunity, VIP promotes Th2-type responses, and reduces the pro-inflammatory Th1-type responses. The molecular mechanisms involved result in the inhibition of cytokine and chemokine expression, and in the preferential development and/or survival of Th2 effectors. VIP inhibits production of pro-inflammatory and promotes production of anti-inflammatory factors in activated innate immune cells (Ganea 2015).

Addition of VIP during Dendritic Cells (DCs) maturation dose-dependently decreases CD83, MHC-I and MHC-II expression. VIP acts as a pacifier on DCs. The VIP effects on DCs induce an anergic response as demonstrated by in vivo administration of VIP together with specific antigens to T-cell receptors that results in the expansion of CD4+/CD25+ regulatory T (Treg) cells (Delgado 2005).

In the lung, VIP acts as an endogenous homeostatic factor regulating the composition of T-cell subsets, DCs and monocytes activities. VIP knock-out mice display airway hyper-responsiveness to cholinergic agonist, as well as peribronchial and perivascular inflammation, which is partially reversible by exogenous Aviptadil (Szema 2006). In the opposite way, VIP-receptor antagonists resulted in enhanced antiviral immunity with increased levels of type-I cytokines such as IFN-γ and TNF-α (Li 2013).

VIP inhalation also improves clinical respiratory outcome in ovalbumin-induced asthma in mice. This benefit is accompanied by a decrease of IL-17 and IL-10 levels in the bronchoalveolar lavage fluid (BALF), suggesting that VIP can improve airway inflammation by regulating the Th17/Treg imbalance in asthmatic mice (Ke et al., 2017). This modulation of IL-17 expression by macrophages leading to Th17 switch has already been reported in BALF from acute lung injury (ALI) murine model (Ran 2015).

These set of data comfort those obtained on VIP deficient mice, unravelling the role of VIP not only on inflammatory cells but also on Treg (Szema 2011).

2. Vasodilating activity of VIP

Globally VIP has a direct vasodilating effect (Ynwin 1987, Thom 1987, Frase 1987, Eriksson 1989, Nese 2000), at the heart level it increases coronary blood flow with an inotropic and chronotropic effect (Feliciano 1998, Henning 2001). In the lung, VIP is found in perivascular nerves and VIP receptors were predominately found in smooth muscles of pulmonary arteries and lung membranes. Acute inhalation of VIP in idiopathic pulmonary arterial hypertension (IPAH) patients lead to a small and temporary but significant selective pulmonary vasodilation, an improved stroke volume and mixed venous oxygen saturation (Leuchte et al., 2008). VIP causes both bronchial and pulmonary artery vasodilation and mice lacking VIP gene spontaneously develop moderately severe pulmonary arterial hypertension (PAH). This phenotype is associated with right ventricle hypertension and hypertrophy, with enlarged, thickened pulmonary arteries and smaller branches, presenting increased vessels muscularization and narrowed lumen. Both the vascular and right ventricular remodeling were attenuated following 4-week treatment with VIP (Said 2007). Lung sections also showed perivascular inflammatory cell infiltrates that could not be explained by arterial hypoxemia. Overall, VIP deficiency was associated with PAH, lower body weight, hypothermia, and pro-inflammatory milieu resulting in increased mortality (Szema & Hamidi, 2014). VIP plays a positive role in the regulation of pulmonary circulation and ventilation/perfusion distribution (Keith 2000, Söderman 1993, Yin 2013). Benefit of VIP administration alone or in combination with endothelin (ET) receptor antagonist has been demonstrated in models of PAH induced by monocrotaline in rats (Hamidi 2011).

3. Lung Anti-proliferative and protective activity of VIP

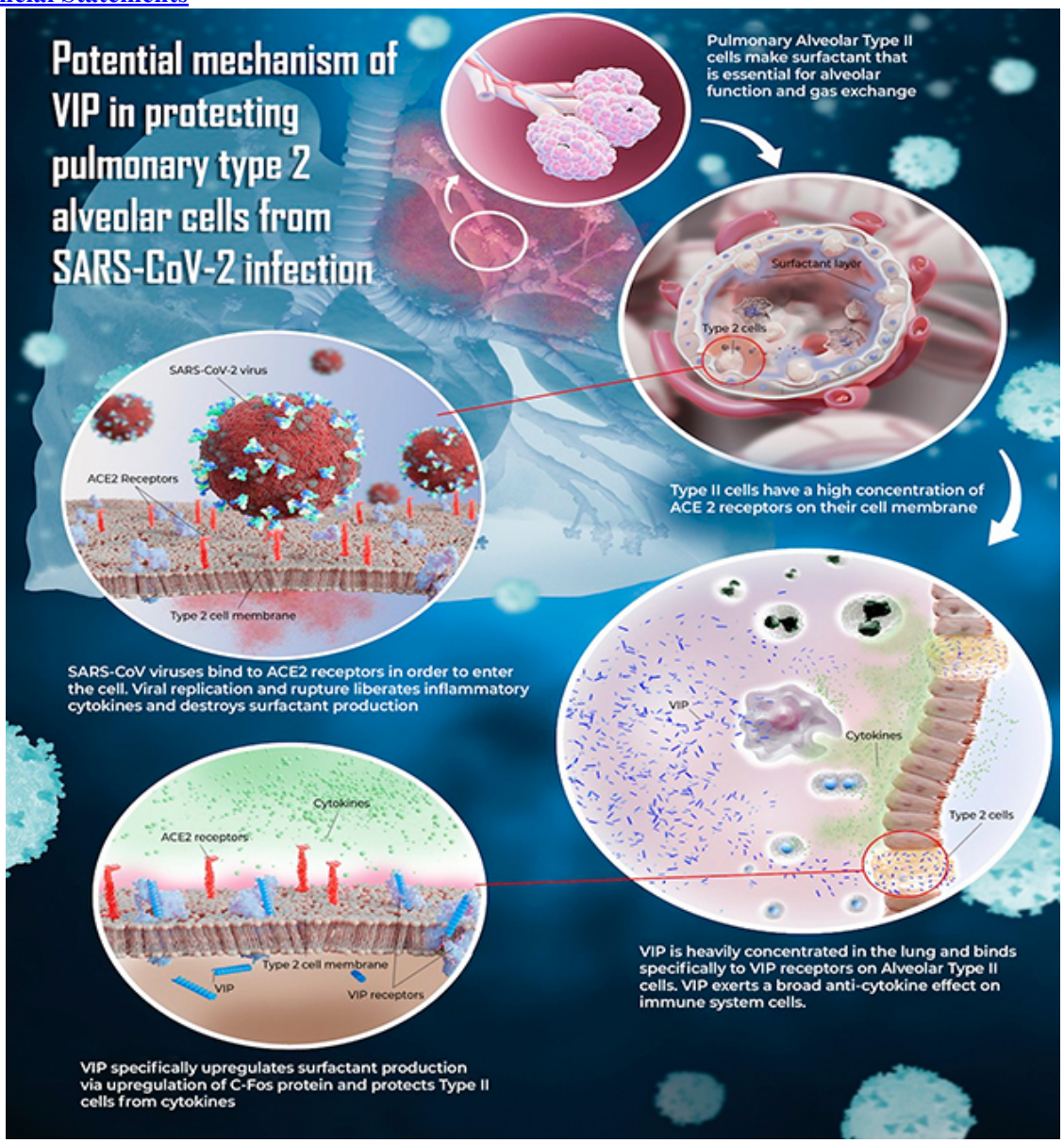
Beside a direct effect on pulmonary arterial pressure as illustrated in ex-vivo experiments (Leuchte 2015), VIP could also exert an anti-proliferative activity on smooth muscle cells. Indeed, VIP dose-dependently inhibited basal proliferation of pulmonary arterial smooth muscle cells from PAH patients (Petkov 2003). Further studies suggested that VIP suppresses vascular smooth muscle cell proliferation primarily by reducing intracellular Ca2+ via activation of the cAMP/protein kinase A (PKA) pathway (St.Hilaire 2009) and by inhibiting NFATc3, a transcription factor linked to pulmonary arterial smooth muscle hyperplasia and hypertrophy in chronic hypoxia-induced PH (Szema 2017). Furthermore, VIP does not affect the baseline TGF-ß1 production by unstimulated macrophages but reduces dramatically transforming growth factor-ß1 (TGF-ß1) production by lipopolysaccharide-stimulated murine peritoneal macrophages and Raw 264.7 cells (Sun 2000).

Endothelin is a major player in inducing contraction of pulmonary artery and promoting smooth muscle cells proliferation and both events could be attenuated by VIP, suggesting that VIP directly inhibits endothelin-signaling pathways (Szema 2017).

In addition, VIP could have antioxidant and anti-apoptosis property on lung ATII epithelial cells (Ao 2011, Pakbaz 1993), or a protective activity on cell injury in a rat lung experimental model (Berisha 1990).

4. Bronchodilating effect of VIP and effect on surfactant

VIP showed a protective effect against propranolol-induced bronchoconstriction (Crimi 1988), mice lacking the VIP gene show airway hyperresponsiveness partially reversible by VIP (Szema 2006) and inhalation of a synthetic selective VIP PACAP type 2 (VPAC2) receptor agonist has been shown to induce bronchodilation in patients with asthma (Linden 2003) although a direct bronchodilating effect is challenged by other authors (Palmer 1986). In addition, VIP promotes the surfactant secretion in ATII cells (LI 2004, 2007, 2010).



Phase 2b/3 clinical trial in COVID-19

The following information is based on the public reporting by NeuroRx and its parent company, NRx Pharmaceuticals, Inc., since NeuroRx has not provided the trial results from these clinical trials to Relief.

On March 29, 2021, NeuroRx reported in a press release results of the phase 2b/3 double-blind, multicenter trial of intravenously administered ZYESAMI (aviptadil, RLF-100) for the treatment of respiratory failure in critically ill patients with COVID-19. According to NeuroRx, across all patients and sites, RLF-100 met the primary endpoint for successful recovery from respiratory failure at days 28 (P = .014) and 60 (P = .013) and also demonstrated a meaningful benefit in survival (P = < .001) after controlling for ventilation status and treatment site. However, they also reported that the study did not demonstrate a statistically-significant difference on the study' s primary endpoint without statistical adjustment for these pre-specified covariates.

According to NeuroRx, in addition to the robust overall significance across all 196 treated patients at all 10 clinical sites, the prespecified analysis of recovery from respiratory failure is clinically and statistically significant in the 127 patients treated by High Flow Nasal Cannula (HFNC) (P = .02), compared to those treated with mechanical or non-invasive ventilation at tertiary care hospitals. In this subgroup, ZYESAMI patients had a 71% chance of successful recovery by day 28 vs. 48% in the placebo group (P = .017) and a 75% rate of successful recovery by day 60 vs. 55% in the placebo group (P = .036). 84% of HFNC patients treated at tertiary medical centers with RLF-100™ survived to day 60 compared with 60% of those treated with placebo (P = .007).

Recovery from respiratory failure (without relapse) with discharge from acute care and survival through the observation period was, still according to NeuroRx, the prespecified primary endpoint specified by FDA for the study, originally intended to be assessed at 28 days and then extended to 60 days based on recently-published FDA guidance. The above analysis were from a sample size of 196 participants who were randomized and treated in the placebo-controlled, double-blind clinical trial (www.clinicaltrials.gov, NCT04311697) conducted at ten U.S. hospitals. Treatment with ZYESAMI or placebo was in addition to standard of care treatment that included steroids, convalescent plasma, antiviral therapy, anticoagulants, and various anti-cytokine drugs.

On June 1, 2021, NRx, which became NeuroRx' s parent corporation in May 2021 upon the completion of NeuroRx' s merger with Big Rock Partners Acquisition Corp., announced that NeuroRx had filed an application with the U.S. Food and Drug Administration ("FDA") requesting Emergency Use Authorization ("EUA") for ZYESAMI (Aviptadil-acetate), its version of aviptadil, to treat critically ill COVID-19 patients suffering with respiratory failure. Further, on or about August 31, 2021, NRx issued a press release announcing an additional finding in its Phase 2b/3 clinical trial investigating ZYESAMI for the treatment of patients with ARDS due to critical COVID-19. According to the press release, the new analysis shows that patients treated with ZYESAMI demonstrated improvement in blood oxygen, indicative of improved lung function, within a day of starting treatment.

On November 5, 2021, NRx announced that the FDA had declined EUA for the use of aviptadil for the treatment of acute respiratory failure due to critical COVID-19. In its press release, NRx stated that in the letter from the FDA denying EUA, the FDA noted that it has only reviewed safety data on 131 patients treated with aviptadil. NRx further announced in its press release that it will attempt to coordinate a review by the FDA of 150 or more additional patients treated with aviptadil through other trials. Additionally, NRx stated in its press release that the study' s Data Safety and Monitoring Board reviewing the trial found no safety issues. Further, on November 24, 2021, NRx reported that it was denied breakthrough therapy designation for the product.

On January 5, 2022, NRx issued a press release reporting that it has submitted an additional application to the FDA seeking EUA for the use of aviptadil to treat patients with critical COVID-19 who are at immediate risk for death from respiratory failure despite treatment with approved therapy, including Remdesivir. Additionally, on January 26, 2022, NRx issued a press release announcing, NeuroRx' s receipt of a first safety report from a southwestern hospital where physicians have administered aviptadil to patients with COVID-19 respiratory failure. According to NRx, the patients were treated under the United States' Right to Try Act, which gives access to investigational medicines for patients who have been diagnosed with life-threatening diseases or conditions, who have tried all approved treatment options, and who are unable to participate in a clinical trial to access certain unapproved treatments. NRx' s press release stated that of the first 19 patients treated by December 31, 2021, three had died and sixteen (84%) were reported to be alive as of January 22, 2022. Further, according to the press release, 14 of these 16 patients had been discharged to a rehabilitation facility or to home. By way of comparison, according to "Clinical characteristics, risk factors and outcomes in patients with severe COVID-19 registered in the ISARIC WHO clinical characterisation protocol: a prospective, multinational, multicentre, observational study", published in the journal ERJ Open Research in January 2021, the overall 28-day fatality rate for COVID-19 patients admitted to the ICU was approximately 30.7%. The press release also indicated that this use of aviptadil had occurred during the then-current COVID-19 surge caused by the omicron variant, although patients were not necessarily tested for the specific COVID variant that caused their ICU admission. Finally, NRx reported in its press release that no serious adverse events were reported. There can be no assurance that NeuroRx' s reapplication seeking EUA for aviptadil for the treatment of acute lung disease caused by COVID-19 will be successful.

On November 29, 2021, NRx issued a press release announcing the results of a subsequent statistical analysis it commissioned from Dr. David Schoenfeld, a statistician with expertise in life-threatening diseases of the lung. According to the press release, Dr. Schoenfeld analyzed the subgroup of patients in the Phase 2b/3 trial that remained in respiratory failure despite treatment with remdesivir and stated that the analysis identified a statistically significant (p=0.03) 2.5-fold increased odds of a patient having survived and being free of respiratory failure at 60 days (the primary endpoint) and a statistically significant (p=0.006) four-fold higher odds of 60-day survival among patients treated with ZYESAMI compared to those treated with placebo.

On March 3, 2022, two U.S. Senators and two members of the House of Representatives sent a letter to Dr. Robert Califf, Commissioner of the FDA, and Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Disease regarding the results of the right-to-try administration of ZYESAMI. The letter discusses the results and seeks comment on the FDA review of the ZYESAMI EUA application and the FDA' s stance that the EUA will not be reviewed until the completion of clinical trials later this year. There can be no assurance as to what effect the letter will have on the review and consideration of the EUA application.

The NCT04311697 trial is completed by an Expanded Access Protocol (SAMICARE NCT04453839), currently ongoing, aiming to include patient that were ineligible in the phase 2b/3 NCT04311697 trial in an open label study. On June 15, 2021, NRx announced in a press release positive data about the 240 patients (including those receiving palliative care) included in this protocol. Among the 196 patients receiving maximal intensive non-palliative care, 76% of those treated with HFNC were discharged from the hospital or were alive and in the hospital at day 28, compared to 54% of those treated with mechanical ventilation.

NeuroRx has also reported that it has initiated a trial with an inhaled formulation of aviptadil for the Treatment of Severe COVID-19 (AVICOVID-2 NCT04360096) aiming to prevent the progression to respiratory failure. NRx has reported that this trial should be completed during the first half of 2022.

Other indications for RLF-100

Beyond COVID-19, our objective is to evaluate RLF-100 as a treatment for respiratory failure and its complications in Intensive Care Units ("ICUs").

Since RLF-100' s mechanism of action ("MoA") is not restricted to the protection of ATII cells, beneficial effects could extend to other types of ALI where involvement of ATII cells is not the leading cause. Preclinical and pilot clinical data in sepsis-induced ALI support this view. Other forms of ALI where treatment with RLF-100 may hold promise include ALI due to other infectious agents. These other programs are likely to be viewed as risk-mitigated if the FDA determines that RLF-100 is safe and effective in treating COVID-19-induced ALI.

Pulmonary sarcoidosis

An open label proof of concept trial (Avisarco, EudraCT 2004-003759-38) in 20 patients with pulmonary sarcoidosis demonstrated a reduction of inflammatory processes in the lung, as well as amelioration of cough and dyspnea spontaneously reported by patients (Prasse 2010). It was found that RLF-100 reduced the production of TNF-α by cells isolated from bronchoalveolar lavage fluids of these patients and also increase the $CD4^+$, $CD127^-$ and $CD25^+$ T cells showing regulatory activities on conventional effector T cells. No SAEs were reported. On August 3, 2021, Relief announced that the FDA had granted Orphan Drug Designation for RLF-100 for the treatment of pulmonary sarcoidosis.

On September 2, 2021, we reported that our recently acquired German subsidiary, AdVita, has received regulatory clearance by the German Federal Institute for Drugs and Medical Devices, Bundesinstitut für Arzneimittel und Medizinprodukte ("BfArM") to conduct a randomized, double-blind, multicenter clinical trial in sarcoidosis patients.

We intend to conduct a Phase 2b dose ranging study in 72 patients with pulmonary sarcoidosis using inhaled aviptadil administered over a 12 week period, following which patients will have the option to participate in the extension phase. A pre-IND FDA meeting is planned to confirm the efficacy and safety endpoints as well as the proposed dosing regimen.

Berylliosis

Chronic beryllium disease (CBD) is a clinical phenocopy of sarcoidosis with the important difference, that it is caused by inhalation of beryllium. CBD is considered an occupational disease and often causes a chronic, long-lasting disease with shortness of breath and cough and can be diagnosed by a beryllium-lymphocyte proliferation test (Be-LPT). Patients with chronic beryllium disease may benefit from inhalation of aviptadil. Presently the ex-vivo effect of aviptadil on mononuclear cells in the setting of chronic beryllium disease is being evaluated. Together with the results from the phase 2b sarcoidosis trial, these results would justify the therapeutic use of inhaled aviptadil in CBD and provide a rationale for the clinical trial design in this indication.

Checkpoint Inhibitor-induced Pneumonitis

Checkpoint inhibitor-induced pneumonitis (CIP), an indication in which Relief' s wholly owned subsidiary AdVita obtained method of use patent protection for aviptadil earlier this year. This indication will be further evaluated in due course.

Non-COVID-19 related ARDS

Testing of RLF-100 in treatment of non-COVID-19 related acute respiratory distress syndrome (ARDS) with a particular focus on infectious ARDS is part of the future clinical development plans for aviptadil.

NeuroRx Collaboration Agreement

On September 18, 2020, we entered into a binding collaboration agreement (the "Collaboration Agreement") with NeuroRx.

The Collaboration Agreement establishes the terms under which we agreed to collaborate and work with NeuroRx in order to maximize revenues in our respective territories from the sale of RLF-100 for intravenous and inhaled use primarily in the treatment of COVID-19 related conditions. The NeuroRx territory includes the United States, Canada, and Israel. The Relief territory comprised the rest of the world and includes the European Union, Switzerland, Iceland, Norway, the United Kingdom, the Channel Islands, Liechtenstein, Monaco, Andorra, San Marino and Vatican City. The collaboration agreement provides that the collaboration is to be conducted on an exclusive basis and the parties have agreed not to develop or commercialize any drug product that may be competitive with RLF-100.

The Collaboration Agreement provides that we shall fund certain associated with the clinical trials and development of RLF-100 in the United States, which development will be conducted and managed by NeuroRx. NeuroRx is responsible for ensuring that the costs of the clinical trials and development activities for RLF-100 IV do not exceed the budget contemplated by the parties by more than 30%.

The Collaboration Agreement also provides options for the parties to treat health conditions outside COVID-19 and for the commercialization of RLF-100 outside of the above-described territories.

The Collaboration Agreement includes a non-exclusive list of assets that each party brought to the collaboration, including, but are not limited to:

Relief	NeuroRx
Funding for clinical trials, formulation and stability of RLF-100, and purchasing supplies for manufacture;	U.S. regulatory information;
U.S. Patent No. 8,178,489, and related patents and corresponding foreign patents;	Authorized application, and information included in, or pursuant to, United States IND 149,152 or United States IND 151,070 and related documents;
U.S. and European Union Orphan Drug Designations related to ARDS, sarcoidosis, and pulmonary hypertension;	GCP clinical trial structures with multiple qualified data sites, data monitoring, institutional review boards, active protocols, and ongoing data collection;
EU-compliant toxicity file and preclinical data; and	Manufacturing and cGMP formulation and stability data for RLF-100; and
Clinical phase 2 data from prior human trials conducted in the EU.	Qualification through SAMS and teaming agreements with BARDA-preferred partners.

Under the Collaboration Agreement, Relief initially committed $8.3 million to fund a Phase 2b/3 clinical trial of the aviptadil IV product. Relief also agreed that it would fund an additional amount equal to 30% of the initial budget (aggregating with the initial budget a total of $10.9 million). Relief also loaned $500,000 to NeuroRx in March 2020, a loan that would not have to be repaid for two years – well after the then-anticipated commercialization date of the proposed aviptadil product, so that it had funds to operate. In total, Relief funded to the collaboration approximately $15.4 million (either to NeuroRx directly or to third-party vendors on NeuroRx' s behalf), plus the loan (which was made on very favorable terms). This loan was repaid in April 2022 pursuant to its terms.

Relief also was willing to consider funding more towards the aviptadil project, but NeuroRx was obligated to provide reasonable information to support why the additional funds were required. Dr. Javitt and NeuroRx demanded additional funds, but refused to provide the reasonable information requested by Relief to determine why the additional funds were required, despite repeated requests by Relief for documentation to support proposed additional charges. Relief also sought backup for the use of the funds already provided (to assess whether the funds delivered to NeuroRx had been used for the purposes for which they were provided), but NeuroRx refused to provide such information. When Relief sought to audit NeuroRx' s books and records to obtain the necessary information, as permitted under the Collaboration Agreement, NeuroRx and Dr. Javitt refused to allow Relief' s outside accountants to conduct the audit, despite repeated requests.

Dispute and Litigation with NeuroRx

Relief believes that NeuroRx has breached the Collaboration Agreement in many ways. In that regard, NRx has made certain statements regarding these pending disputes, including the following:

In its September 2021 registration statement, NRx made numerous statements of purported fact setting forth NeuroRx' s version of the history of the relationship between the companies that led to the signing of the Collaboration Agreement. Many of these allegations were false or misleading (and the lawsuit that Relief has filed against NeuroRx and its CEO lays out the facts that actually occurred). Further, the Collaboration Agreement expressly states that it "supersedes any and all prior understandings or agreements, whether written or oral, and there are no promises, agreements, condition, undertakings, warranties or representations (whether oral or written, express or implied) between them other than as [herein set forth]." Therefore, the history of what discussions led up to the parties' entry into the Collaboration Agreement has no application to the parties' rights and responsibilities presently in force and effect.

In its September 2021 registration statement, NRx accuses Relief of misleading them and Relief' s public shareholders about the stability of the formulation of aviptadil that Relief brought to the parties' collaboration. We believe that there is no truth to these allegations, and that NeuroRx was expressly tasked with developing a stable formulation of aviptadil under the Collaboration Agreement. Further, we have stated on numerous occasions that we never guaranteed that we already had an 18-month shelf stable product, and no such statements are made in the Collaboration Agreement, which contains the entire agreement between the parties. Finally, NRx asserts that its version of aviptadil is not covered by the Collaboration Agreement and, as set forth in our compliant, we do not believe that to be true.

In its September 2021 registration statement and in its more recent filings with the SEC, NRx has continued to state that Relief has not paid certain amounts due to NeuroRx relating to the collaboration. While the amount allegedly owed by Relief to NeuroRx according to NRx' s filings with the SEC has grown exponentially when compared to the amounts stated in NRx' s earlier public filings (and currently is claimed to be approximately $13.8 million), we assert in the complaint that we have met all of our financial obligations to NeuroRx under the Collaboration Agreement. Further, we have demanded the right to perform a forensic audit on NeuroRx' s books and records to determine whether the funds provided were used for the purposes for which they were provided (which NeuroRx has, to date, refused to allow).

In its SEC filings, NRx has stated that Relief has "declined" to fund certain expenses relating to the development of the formulation of aviptadil and NeuroRx' s clinical trial evaluating inhaled aviptadil for the treatment of patients with moderate COVID-19. In fact, for some months, Relief repeatedly requested information that it believed was reasonably necessary to make a decision on whether or not to fund these expenses. Until sufficient information is provided so that Relief can make the decision whether or not to fund these expenses, Relief asserts that the Collaboration Agreement does not allow NeuroRx to bring in another source to directly fund these expenses.

NeuroRx continues to refuse, despite repeated demands by Relief requesting this information, to share with Relief the full clinical trial data set, including details on the statistical analysis performed, from its recently completed phase 2b/3 trial, which data and information is required to be provided to Relief by NeuroRx under the Collaboration Agreement. To date, Relief has only received a high-level summary of the clinical study report and has not been provided with, among other information, access to the 53,909 individual case reports, the raw data from the clinical trial, or the data on the multiple statistical analyses performed. NeuroRx has likewise refused to share with Relief any of the correspondence between NeuroRx and the FDA relating to the development of aviptadil. Further, NeuroRx has refused to allow NeuroRx' s contract partners dealing with issues relating to the development of aviptadil to share information with Relief that it requires to develop RLF-100™ (aviptadil) in its territories (including the European Union and the United Kingdom). The failure of NeuroRx to provide this information is seriously impairing Relief' s ability to develop and execute a clinical and regulatory strategy for RLF-100™ (aviptadil) in its territories.

Under Section 5.1 of the Collaboration Agreement, neither party may engage in any development activities for any drug or related product or treatment intended to be used to treat, combat, ameliorate, prevent or mitigate the effects of COVID-19 that can or may reasonably be expected to compete against or reduce sales (or other monetization) of aviptadil.

Relief believes that it has satisfied all of its obligations under the Collaboration Agreement and that as a result, all revenue/profit splits set forth in the Collaboration Agreement remain in full force and effect.

On October 7, 2021, because of the many breaches of the Collaboration Agreement by NeuroRx, we filed a lawsuit against NeuroRx and its Chief Executive Officer, Dr. Jonathan Javitt, for multiple breaches of the Collaboration Agreement (the "Complaint"). The Complaint was filed in the Supreme Court in the State of New York in Manhattan. Among the many alleged breaches of the Collaboration Agreement that are enumerated in the complaint are the following:

failing to provide Relief with the full data set from NeuroRx' s recently completed phase 2b/3 clinical trial evaluating IV RLF-100 (aviptadil) for the treatment of acute respiratory failure due to COVID-19, which data and information are required to be provided to Relief by NeuroRx under the Collaboration Agreement and which data and information are required for Relief to seek approval to commercialize the product in Europe and by failing to collaborate with Relief so that Relief was provided meaningful input into NeuroRx' s U.S. development program;

failing to allow Relief, despite multiple requests, to conduct a forensic audit of NeuroRx' s books and records to determine how the funds that Relief provided to NeuroRx were actually used;

entering into multiple agreements relating to the development of the product subject to the collaboration without Relief' s consent, as required under the Collaboration Agreement;

engaging in commercialization efforts in territories outside the purview of NeuroRx' s territory under the Collaboration Agreement; and

developing additional COVID-19 treatments in violation of the exclusivity provisions of the Collaboration Agreement.

The suit also alleges, among other matters, breaches of the covenant of good faith and fair dealing and tortious interference with prospective economic advantage.

The Complaint, among other remedies, seeks damages, an order compelling NeuroRx to comply with multiple provisions of the Collaboration Agreement, and a declaration directing NeuroRx to deliver the entire data set from the Phase 2b/3 clinical trial of intravenously-administering aviptadil to Relief. There can be no assurance as to the outcome of this litigation.

On January 10, 2022, NeuroRx, filed a complaint against Relief in the Supreme Court of the State of New York in Manhattan. In its complaint, NeuroRx makes numerous allegations, including the following:

NeuroRx claims that Relief has breached the Collaboration Agreement by refusing to make required payments thereunder. NeuroRx currently appears to claim that we have failed to pay them approximately $13.8 million. We believe we have paid all amounts required to be paid under the Collaboration Agreement.

NeuroRx claims that by failing to pay what they allege is due , Relief has repudiated the Collaboration Agreement and NeuroRx is no longer bound thereby. We disagree with their allegations and assert that the Collaboration Agreement remains in full force and effect.

NeuroRx claims that Relief has defamed NeuroRx through its statements regarding NeuroRx' s breaches of the Collaboration Agreement and other matters, claiming that Relief knew that such statements were recklessly made and/or knowingly false. Relief denies that any such statments were untrue or defamatory.

In the complaint, NeuroRx is claiming damages in excess of $185 million as well as seeking a ruling that the Collaboration Agreement is void. We have yet to be served with the complaint filed by NeuroRx, which we expect will be consolidated with our complaint. We are also considering filing additional claims, including for defamation, as a result of recent public statements claims made about Relief by NeuroRx. We believe that NeuroRx' s claims are without merit and that we will prevail before the court. However, there can be no assurance as to the result of the litigation, and an adverse ruling in the litigation could have a material adverse effect on our business, financial position, and results of operations.

On January 12, 2022, NRx issued a press release about NeuroRx' s complaint. In the press release, NRx made several additional claims about Relief, which we responded to in a press release on January 14, 2022:

While NeuroRx claims in its press release that the Collaboration Agreement has been cancelled, we have started that we continue to believe that the Collaboration Agreement remains in full force and effect, and that NeuroRx, not Relief, is in breach of that agreement.

NeuroRx' s press release included numerous statements that we believe to be false and materially inaccurate. Among others, these include statements made in the press release regarding the formulation of aviptadil that is the subject of the Collaboration Agreement. We assert that the statements in the NRx press release to the effect that we are misleading the public and our shareholders in our public statements and regulatory filings are false and defamatory.

The press release discusses a damages calculation that we believe to be completely illogical and unsupported and makes claims, which we believe to be inaccurate and misleading, to the effect that our conduct was so egregious as to warrant the imposition of punitive damages. It is our belief that, to the contrary, it is NeuroRx' s conduct that warrants the imposition of punitive damages.

The press release also makes allegations regarding our Chairman, Ram Selvaraju, that are false and defamatory. Contrary to the claims made in the press release, no members of Relief' s board of directors are criminals or have been incarcerated, and we believe that the statements made in the press release, and Jonathan Javitt' s statements in multiple posts on investor message boards regarding this topic, are false and defamatory as to Relief and its board and management.

The claims by NeuroRx will be responded to in an appropriate filing with the court once Relief is served with the complaint. Further, in light of these claims and statements made in the above-described press release, we are considering whether to file additional claims against NeuroRx and Jonathan Javitt. NeuroRx claims damages in excess of $185 million in addition to its claim that Relief has repudiated the Collaboration Agreement. We believe that these claims are without merit, but there can be no assurance of the outcome of the litigation, and an adverse result could have a material adverse effect on our business, financial position, and results of operations.

On March 8, 2022, NRx announced the retirement of Dr. Javitt as its Chief Executive Officer. According to NRx' s press release, Dr. Javitt continues to serve on NRx' s Board of Directors and as its Chief Scientist. Dr. Javitt' s retirement as CEO does not affect the status of Relief' s lawsuit against Dr. Javitt. Further, the parties have begun to mediate their disputes, and these mediation efforts remain ongoing. On April 5, 2022, we issued a press release announcing that we had entered into a stipulation to stay the litigation for 90 days in order to allow the parties to focus on mediation. There can be no assurance that efforts to mediate the dispute will be successful.

ACER-001

Sodium phenylbutyrate (NaPB) is currently approved in the U.S. and the European Union to treat patients with Urea Cycle Disorders ("UCDs"). In collaboration with Acer Therapeutics, we are developing ACER-001 (proposed trade name Olpruva), a proprietary immediate release multi-particulate powder formulation of NaPB with a taste-masked coating designed potentially to treat UCDs and MSUD.

ACER-001 for the Treatment of Urea Cycle Disorders

The urea cycle is a series of biochemical reactions that occur primarily in the liver, which converts toxic ammonia produced by the breakdown of protein and other nitrogen-containing molecules in the human body into urea for excretion. UCDs are a group of disorders caused by genetic mutations that result in a deficiency in 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, while 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.

Diagnosis and Incidence

The diagnosis of UCDs is based on clinical observations, confirmed by biochemical and molecular genetic testing. A plasma ammonia concentration of 150 µmol/L or higher associated with a normal anion gap and a normal plasma glucose concentration is an indication for the presence of UCDs. Plasma quantitative amino acid analysis and measurement of urinary orotic acid can distinguish between the various types of UCDs. A definitive diagnosis of UCDs depends on either molecular genetic testing or measurement of enzyme activity. Molecular genetic testing is possible for all urea cycle defects. Studies suggest that the incidence of UCDs in the U.S. is 1 in 35,000 live births. Approximately 2,000 patients suffer from UCDs in the U.S.

Current treatment options for UCDs

The current treatment of UCDs consists of dietary management to limit ammonia production in conjunction with medications that provide alternative pathways for the removal of ammonia from the bloodstream. Dietary protein must be carefully monitored, and some restriction is necessary; too much dietary protein causes excessive ammonia production. However, if protein intake is too restrictive or insufficient calories are consumed, the body will break down lean muscle mass to obtain the amino acids or energy it requires, which can also lead to excessive ammonia in the bloodstream. Dietary management may also include supplementation with special amino acid formulas developed specifically for UCDs, which can be prescribed to provide approximately 50% of the daily dietary protein allowance. Some patients may also require individual branched-chain amino acid supplementation.

Medications for UCDs primarily comprise nitrogen scavenger drugs, which are substances that provide alternative metabolic excretion pathways for nitrogen, thereby bypassing the urea cycle. The use of these alternative pathways for nitrogen removal is important for the management of acute episodes of hyperammonemia and are also included as part of a long-term treatment regime for UCD patients. Current nitrogen scavenger treatments for UCDs are based on sodium benzoate or phenylbutyrate, which conjugate with glycine and glutamine, respectively, allowing for urinary excretion of nitrogen as hippurate and phenylacetylglutamine, respectively.

According to a 2016 study by Shchelochkov et al., published in Molecular Genetics and Metabolism Reports, while nitrogen scavenging medications are effective in helping to manage UCD, non-compliance with treatment is common. Reasons given for non-compliance include the unpleasant taste associated with available medications, the frequency with which medication must be taken and the high cost of the medication.

Phenylbutyrate is available as NaPB, which is marketed as BUPHENYL (sodium phenylbutyrate), and RAVICTI (glycerol phenylbutyrate). While a study provided by Horizon Therapeutics, Inc. in the RAVICTI package insert involving 46 adults with UCD demonstrated that BUPHENYL and RAVICTI were similarly effective in controlling the blood level of ammonia over a 24-hour period, many patients who take their medicine orally prefer RAVICTI, as it is significantly more palatable than BUPHENYL. However, the very high annual treatment cost of RAVICTI, based on patient weight, is often prohibitive. Phenylburate is also marketed in Europe, Australia and New Zealand under the trade name Pheburane. Ammonaps, another formulation of NaPB that claims to be tasteless and odor free is approved and marketed in Europe.

In cases where dietary management or medication is not effective, patients with UCD may require a liver transplant.

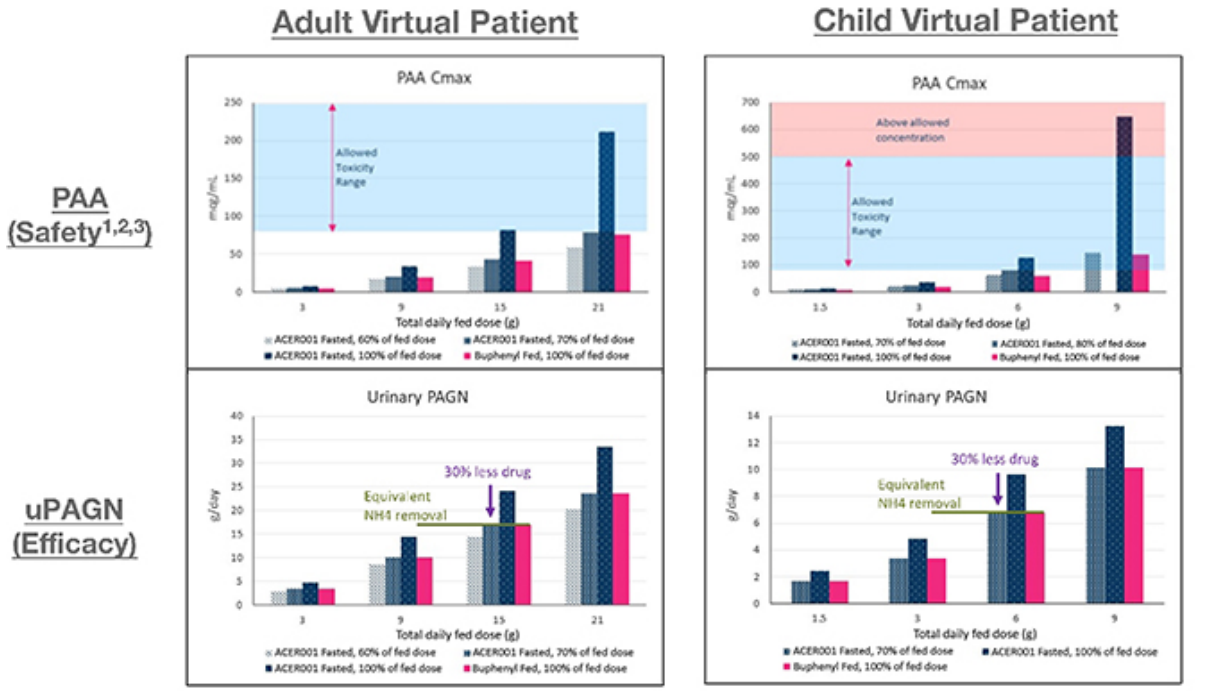
Rationale for ACER-001 treatment in UCDs

In February 2020, Acer reported the completion and acquisition of the final data from the clinical trial evaluating the bioavailability and bioequivalence of ACER-001 to BUPHENYL (sodium phenylbutyrate) both under fasted conditions. The trial was a single-center, single-blind, randomized, single-dose crossover study designed to show bioequivalence of ACER-001 compared to BUPHENYL in 36 healthy adult subjects under fasted conditions. Data showed ACER-001 to have similar pharmacokinetic (“PK”) profiles for both phenylbutyrate (“PBA”) and phenylacetate (“PAA”) compared to BUPHENYL under fasted conditions.

This trial also included an arm of ACER-001 administered under fed conditions. When the fed and fasted arms of the study were compared, it was shown that administration of ACER-001 in a fasted state achieved more than two times the maximum concentration (“Cmax”) of PBA compared to administration of the same dose of ACER-001 in a fed state. These results are consistent with previously published data by Nakano, et al that evaluated PK of NaPB in patients with progressive familial intrahepatic cholestasis, also demonstrating that administration of NaPB in a fasted state significantly increased PBA peak plasma concentration compared to administration of NaPB in a fed state.

Currently approved therapies for UCDs, including BUPHENYL and RAVICTI, are required to be administered with food. BUPHENYL is required to be administered in a fed state due to its aversive odor and taste, with side effects including nausea, vomiting and headaches, which can lead to discontinuation of treatment. Additionally, prescribing information states that the BUPHENYL food effect is unknown. RAVICTI PK and pharmacodynamic (“PD”) properties were determined to be indistinguishable in fed or fasted states. ACER-001 is uniquely formulated with its multi-particulate, taste-masked coating to allow for administration in a fasted state, while still allowing for rapid systemic release.

Based on the results from the food effect study within the first ACER-001 BE trial, Acer commissioned Rosa & Co. LLC to create a PhysioPD PK model to evaluate the potential food effect on exposure, tolerability, and efficacy of ACER-001 in UCDs patients. Results from this in silico model suggested that administration of ACER-001 in a fasted state required approximately 30% less PBA to achieve comparable therapeutic benefit to that in a fed state. In addition, the model predicted that administration of ACER-001 in a fasted state compared to administration of BUPHENYL or RAVICTI (same amounts of PBA) in their required fed states would be expected to result in higher peak blood PBA, PAA and PAGN concentrations, which should achieve a 43% increase in urinary PAGN levels (a negative correlation between blood ammonia area under the curve and 24-hour urinary PAGN amount has been demonstrated).



- ACER-001 in a fasted state required ~30% less PBA to achieve comparable therapeutic benefit in a fed state
- Model predicted 43% increase in urinary PAGN levels (negative correlation with blood ammonia AUC)

1. Mol. Genet Metab. 2013 Dec.; 110(4); 446-453
2. Pediatr Res. 1986 Nov; 20(11); 1117-21
3. Cancer. 1995 Jun 15; 75(12); 2932-8

In February 2021, Acer announced topline results from its bioequivalence trial in which ACER-001 showed similar relative bioavailability to BUPHENYL (sodium phenylbutyrate) under fed conditions. The single-center, single-blind, randomized, single-dose crossover trial evaluated BE of ACER-001 compared to BUPHENYL when administered under fed conditions in 36 healthy adults. The topline data from this trial showed ACER-001 to have similar PK profiles for both PBA and PAA compared to BUPHENYL under fed conditions.

Registration Plan for UCDs

In August 2021, Acer submitted an application in the U.S. to market ACER-001 for administration initially under fed conditions for the treatment of UCDs using a regulatory pathway established under section 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("FDCA") that allows applicants to rely at least in part on third party data for approval, which may expedite the preparation, submission, and approval of a marketing application. We also intend to seek EMA approval in the European Union and potentially other territories outside the U.S., after the 505(b)(2) NDA for treatment of UCDs is filed. Because the FDA has approved an NDA for BUPHENYL, which is referred to as the reference listed drug ("RLD"), we intend to rely on the RLD' s preclinical and clinical safety and efficacy data, while supplementing the data with a bridging study that shows similar relative bioavailability of ACER-001 to BUPHENYL.

On May 25, 2021, Acer and Relief announced the outcome of Acer' s pre-NDA meeting with the FDA for ACER-001 for the treatment of UCDs. The purpose of the pre-NDA meeting was to discuss the content of Acer' s planned NDA submission. Based on FDA feedback, the companies believe the proposed data package will be sufficient to support an NDA submission under the Section 505(b)(2) regulatory pathway for ACER-001. As a result, Acer submitted its NDA application on August 5, 2021. The submission was accepted for review by the FDA with a Prescription Drug User Fee Act ("PDUFA") approval decision action date of June 5, 2022. On June 7, 2022, ACER announced that it has not yet received a decision from the FDA on its NDA. We are also preparing to submit a marketing authorization application ("MAA") for ACER-001 to the European and U.K. regulatory agencies subject to positive conclusion of a commercial assessment in those countries and approval of ACER-001 by the FDA.

In parallel or after initial potential FDA approval for administration under fed conditions, and subject to additional capital, we also plan to evaluate potential development of ACER-001 for administration under fasted (pre-meal) conditions, which will likely require additional nonclinical and clinical studies to provide the necessary evidence of safety and efficacy of ACER-001 to be considered for FDA approval for administration under fasted (pre-meal) conditions.

ACER-001 for the treatment of MSUD

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. The most severe presentation of MSUD, known as "classic" MSUD, accounts for 80% of cases and can result in neonatal onset with encephalopathy and coma. Although metabolic management of the disease is possible via a highly restrictive diet, the outcome is unpredictable, and a significant portion of affected individuals are mentally impaired or experience neurological complications.

Diagnosis and incidence of MSUD

MSUD is typically diagnosed at birth via newborn screening. Studies indicate that MSUD affects an estimated 1 in 185,000 infants worldwide. The disorder occurs more frequently in the Old Order Mennonite population, with an estimated incidence of about 1 in 380 newborns, and the Ashkenazi Jewish population, with an estimated incidence of 1 in 26,000. Approximately 3,000 patients suffer from MSUD worldwide, of whom approximately 1,000 are located in the U.S.

Current treatment options in MSUD

There are currently no approved pharmacologic therapies in the U.S. or the European Union 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.

Rationale for ACER-001 Treatment in MSUD

Therapy with NaPB in UCD patients has been associated with a selective reduction in BCAA despite adequate dietary protein intake.

Based on this clinical observation, investigators at Baylor College of Medicine ("BCM") explored the potential of NaPB treatment to lower BCAA and their corresponding BCKA in patients with MSUD. The investigators found that BCAA and BCKA were both significantly reduced following NaPB therapy in control subjects and in patients with MSUD, although there was no simple correlation between the patients' levels of residual enzymatic activity with the response of plasma BCAA and their BCKA to NaPB. NaPB showed a statistically significant reduction of BCAA leucine, in all three healthy subjects and in three out of the five MSUD patients who participated in the trial. The reduction in leucine, the most toxic of the BCAAs, in the three responsive MSUD patients ranged between 28-34%, which is considered by clinicians to be a clinically meaningful response.

Investigators at BCM further explored the mechanistic rationale for NaPB lowering BCAA/BCKA levels. NaPB was found to be an allosteric inhibitor of the branched-chain keto acid dehydrogenase complex kinase ("BCKD-kinase"), and enzyme that regulates the activity of the branched-chain keto acid dehydrogenase complex ("BCKDC") enzyme that is responsible for the normal metabolism of BCKAs. By inhibiting the BCKD-kinase, the BCKDC is constitutively activated, thus the increased activity results in a reduction in the plasma levels of BCAA and BCKA in all people, including those with MSUD, suggesting that NaPB may be an effective treatment for people with MSUD, who experience elevated BCAA levels.

In November 2020, study results evaluating the effect of NaPB in the management of acute MSUD attacks in pediatric patients (n=10) were published in the Journal of Pediatric Endocrinology and Metabolism showing a significant reduction in leucine levels in MSUD patients experiencing an acute attack. The results suggested that NaPB can be safely administered in combination as part of an emergency protocol and may provide additional clinical benefit beyond emergency protocol alone. However, verifying this outcome would require additional validation in a controlled trial. If ACER-001 is approved for the treatment of chronic MSUD, we believe patients will not be required to interrupt their therapy in the event of an acute crisis.

Registration Plan for MSUD

We anticipate initiation of clinical studies evaluating ACER-001 in MSUD to occur sometime in 2022. Given its regulatory status with regard to UCDs, there is no requirement for phase 1 studies in healthy volunteers. The timing of a phase 2 clinical trial, if such a trial occurs, would be subject to completion of a commercial assessment of the opportunity, including, but not limited to, a possible pre-IND meeting with the FDA and/or the EMA, with an objective of validation and agreement on the primary and secondary clinical trial end-points, which remain important given that there are presently no approved treatment options for this disease nor are there guidelines to assess efficacy and safety of an investigational drug in this disease. If a successful clinical trial for ACER-001 in MSUD is completed, along with our partner Acer, we plan to seek FDA approval to market ACER-001 for the treatment of MSUD as an added indication in the U.S. by submitting a supplemental NDA (sNDA) incorporating the efficacy and safety data from the MSUD population, assuming ACER-001 is approved for the treatment of UCDs prior to sNDA submission. We also intend to seek approval in the European Union and other territories outside the U.S. after the sNDA for treatment of MSUD is filed, or simultaneously with the U.S. filing.

Acquisition of APR Applied Pharma Research SA

On April 30, 2021, we entered into a binding term sheet with the then current shareholders of APR Applied Pharma Research SA, a privately held Swiss company with over 25 years of experience in identifying developing and commercializing known molecules engineered with drug delivery systems in niche and rare diseases, to acquire all of the outstanding shares of APR. Under the term sheet, APR shareholders were to receive CHF 22 million in cash (plus or minus APR' s working capital adjustment), plus CHF 50 million payable in Shares. APR' s shareholders would also be eligible to receive contingent payments in the form of a combination of cash and Relief registered ordinary shares upon achievement of pre-arranged contingent milestones. Further, APR had the right to designate an individual to stand for election as APR' s designee at Relief' s Annual General Meeting of Shareholders of June 18, 2021, and, it designated its CEO Paolo Galfetti for that purpose, who was appointed to the Board of Directors of Relief on June 18, 2021.

On June 28, 2021, the former shareholders of APR and Relief signed and closed a definitive agreement for Relief to acquire all outstanding shares of APR. Under the terms of the agreement APR' s shareholders have received from Relief CHF 21.5 million in cash and 206,786,784 Consideration Shares at a value of CHF 45 million when the Consideration Shares were issued and listed. The APR shareholders are also eligible to receive possible future contingent milestone payments in the aggregate maximum amount of up to CHF 35 million, upon achievement of pre-agreed objectives involving (i) the execution of a definitive agreement for the commercialization of Sentinox (as such product is defined below), (ii) the launch of Sentinox in the first of France, Germany, Spain, Italy, and the United Kingdom, (iii) the launch of Golike in the U.S., and (iv) the launch of APR-TD011 (as such product is described below) in the first of France, Germany, Spain, Italy and the United Kingdom.

APR programs and pipeline in a snapshot

The APR acquisition brings to Relief a pipeline of product candidates at various stages of development. Relief is carefully evaluating all of the APR programs and will focus on advancing the development of those that offer the optimal strategic fit combined with differentiation that can offer strong growth potential.

Relief plans to optimize APR' s product portfolio and out-licensing programs. Furthermore, the combined Relief–APR management teams will work closely to leverage opportunities to drive revenue growth, accelerate clinical development programs and capture synergies.

PKU Golike

Phenylketonuria

Phenylketonuria is a rare metabolic disorder that hinders the body' s ability to break down the amino acid phenylalanine, resulting in a dangerous build-up of phenylalanine when patients eat foods containing protein or aspartame. According to a study published in August 2020 in the American Journal of Human Genetics, approximately 450,000 people suffer from PKU worldwide. If diet is not controlled in patients with PKU, these high levels of the amino acid can lead to severe symptoms, including:

a musty odor in the breath, skin or urine, caused by too much phenylalanine in the body;

neurological problems, which may include seizures;

skin rashes (eczema);

fair skin and blue eyes, because phenylalanine can' t transform into melanin, the pigment responsible for hair and skin tone;

abnormally small head (microcephaly);

hyperactivity;

cognitive disorders and intellectual disability;

delays in development;

behavioral, emotional and social problems; and

psychiatric disorders.

In classic PKU, the enzyme needed to convert phenylalanine (PHE) is missing or severely reduced, which can result in high build-up of phenylalanine and severe systemic damages mainly in the brain. These patients have a diet composed by 75% of PHE-free AA supplementation and only 25% of natural proteins. In more mild or moderate forms, the enzyme retains some function, but a reduced intake of PHE is still recommended to reduce the risk of significant symptoms.

A further reduction of PHE levels is important before conception: pregnant women with PKU, including those with less severe forms of the disease, may place their unborn children at risk by not following the PKU diet. Children of woman with untreated PKU may have an unusually small head (microcephaly), congenital heart disease, developmental abnormalities, or facial abnormalities. There is a strong relationship between the severity of these symptoms and high PHE levels in the mother.

Current treatment options for PKU

While PKU is not curable, if diagnosed early enough, an affected newborn can grow up with normal brain development by managing and controlling PHE levels through diet, or a combination of diet and medication. Diet is composed by few amounts of natural food (based on severity of the disease) supplemented with AA mix with absence or low PHE content plus low protein foods. Diet is recommended for the entire life since it has been demonstrated that high PHE levels has an impact not only during growing but also in adulthood. In 2018, the FDA approved an enzyme substitute called pegvaliase, sold by BioMarin Pharmaceuticals under the brand name Palynziq. Palynziq is a derivative of e phenylalanine ammonia-lyase that metabolizes phenylalanine to reduce its blood levels (but it is not able to produce Tyrosine as the natural enzyme, which need to be still supplemented). Tetrahydrobiopterin (BH4), a cofactor for the oxidation of phenylalanine, when taken by mouth, is also thought to reduce blood levels of phenylalanine in some people. Along with Palynziq, BioMarin Pharmaceuticals also markets Kuvan (sapropterin dihydrochloride) for the treatment of PKU. There are also other amino acid products, sold both by prescription and over-the-counter, that are marketed towards PKU patients

PKU Golike for the dietary treatment of PKU

Patients with PKU require supplementation of amino-acid based foods for special medical purposes ("FSMP" or "Medical Formula") to prevent protein deficiency and optimize metabolic control. Many of these FSMPs can result in poor dietary compliance due to their taste and odor. Further, the unpleasant odor and aftertaste of current amino acid supplements can become a barrier to social interaction for PKU patients. In addition, proteins needed for normal growth and coming from natural food sources are broken down during the digestion process and are gradually absorbed, keeping blood amino acid levels sufficient stable over time. On the opposite, free-AA mix administered to PKU patients in the form of FSMPs are not comparable to natural proteins because they do not need to be broken down before they are absorbed, resulting in a rapid peak of absorption and rapid decrease of their concentration into the bloodstream.

This rapid peak in blood amino acids following ingestion of FSMPs impairs the ability of the body to process them properly and incorporate them into the body' s own tissues (through a process known as "anabolism") resulting in a portion of unprocessed amino acids which are then oxidated and eliminated. This rapid elimination of unprocessed AAs that is associated with traditional FSMPs represents a fundamental unmet need for PKU patients especially during any prolonged fasting period.

In order to compensate for the low levels of amino acids during fasting periods, the body is forced to initiate a process called "catabolism" where the body will break down lean muscle mass to obtain the amino acids or energy it requires.

PKU Golike is the first prolonged-release amino acid mix product with taste and odor masking and the ability to mimic the absorption time and profile of natural proteins. With these characteristics, PKU Golike® is a uniquely differentiated product, offering improved metabolic management and better compliance for PKU patients of all age groups.

On September 9, 2021, Relief announced that APR has launched, through its affiliates in Germany and Italy, PKU Golike KRUNCH, a chewable tablet for the dietary management of PKU.

Relief is planning to expand the PKU Golike commercial infrastructure beyond the current countries where APR is present and aims to strengthen the commercial activities to increase and accelerate future growth. PKU Golike is currently promoted and marketed by a direct sales and marketing infrastructure in Germany, Italy, Switzerland and Austria; in addition, the product is marketed in the UK and Spain by local distributor under contract with APR. Relief also plans to commercialize PKU Golike in the U.S. as a food supplement (which does not require FDA approval), but there can be no assurance it will be successful in its commercialization efforts.

APR-OD031 for the treatment of PKU

APR-OD031 is an extended-release, PHE-free amino acids (AAs) engineered to modify their release and absorption so as to mimicking the physiological absorption of dietary proteins. A pharmaceutical process applied to AAs, patented as Physiomimic Technology™, allows the production of minute taste and odor-masked coated granules for oral administration which are gradually released and absorbed in a prolonged physiologic manner in the gut.

We believe that the benefits of extended-release APR-OD031 could include a reduction in the fluctuation of serum PHE levels over a 24 hour period, which could result in reduced neuro-cognitive deficiencies in this patient cohort whilst allowing for a more relaxed diet with a superior quality of life. If these expectations are borne out in clinical trials, we believe that such findings would likely result in the product being seen as advantageously positioned as a treatment option for PKU patients who are unresponsive to sapropterin and non-compliant with dietary restriction. APR-OD031 contains the same qualitative and quantitative formula as PKU Golike and has been granted Orphan Drug Designation by the FDA. There can be no assurance that APR-OD31 will be approved for commercialization.

Other Products in Development or on the Market

Nexodyn AOS

Nexodyn Acid-Oxidizing Solution (AOS) is a TECHLO technology based product proven to restart wound healing of stalled wounds by creating the ideal microenvironment to sustain the physiological healing process. A clinical studies and real-world experience have consistently shown accelerated closure of chronic wounds with reduced infection rates and less wound-associated pain.

Nexodyn AOS is a solution of highly pure and stabilized hypochlorous acid (HClO >95% of free chlorine species), acidic pH (2.5 – 3.0) with 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 the European Union as a Class III medical device.

The anti-microbial and anti-inflammatory properties of Nexodyn AOS, along with its tolerability, could make this an attractive treatment candidate for the treatment of wounds in Epidermolysis Bullosa and, if approved, Nexodyn AOS would be the only product approved for the control of infection in this disease. If clinical trials are successful and Nexodyn AOS is approved for marketing, we believe that it could reduce the need for long term antibiotic use in patients, while assisting wound healing and reducing wound related pain, which could significantly benefit quality of life in patients with this genetic disorder.

Setofilm / Ondissolve

SETOFILM is the first prescription-only medicine approved in Europe and Canada, developed as an orodispersible film (ODF) formulation to be registered in Europe. The product is available in 4mg and 8mg 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 post-operative induced nausea and vomiting (PONV) in both adult and children of 6 month of age or older. The product has been formulated and developed using the RapidFilm drug delivery technology 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 drug and it is marketed by Norgine B.V. and Takeda Pharmaceuticals respectively under license from APR.

SENTINOX

APR' s novel nasal spray, Sentinox, is a Class III medical device intended to offer an additional protection against airborne viruses and bacteria and their transmission, included, but not limited to, SARS-CoV-2. Positive interim clinical data showing accelerated clearance of upper airway viral infection was recently reported for Sentinox in a randomized, controlled clinical trial.

Sentinox was certified in Europe on February 16, 2021 as a Class III Medical Device (Certificate No. EPT 0477.MDD21/4200.1). The device is intended for irrigation, cleansing and moistening of the nasal cavities and is indicated for the following uses: (i) reducing the risk of infections caused by bacteria and viruses, including SARS-CoV-2, by lowering the nasal microbial load; (ii) symptomatic nasal care; and (iii) nasal care in cases of minor lesions/alterations of the nasal mucosa.

On October 27th, 2021, we reported positive interim results from our clinical trial of nasal spray Sentinox in SARS-CoV-2 infected patients, confirming its safety and tolerability. We also reported that data from the study suggest that Sentinox could potentially be effective in reducing the SARS-CoV-2 viral load at the level of the nasal mucosa. Completion of the clinical study and issuance of the final report was expected sometime in the first quarter of 2022; in the meantime, we are assessing the commercial opportunity and currently evaluating a license of the commercial rights to third parties. Relief does not intend to market this product directly because it requires substantial sale force and commercial promotion in most of the countries.

On March 17, 2022, Relief and APR reported the final data from APR' s clinical trial of nasal spray, Sentinox, in SARS-CoV-2 infected patients. The post-market, interventional, randomized, controlled clinical study (NCT04909996, clinicaltrials.gov) enrolled 57 patients who were randomized to receive Sentinox treatment 0.5 ml into each nostril, performed 3 times/day or 5 times/day for 5 days as add-on to the standard therapy, vs. no Sentinox treatment group. The study was designed to assess the efficacy and safety of Sentinox spray in terms of viral load reduction, negativization and infectivity in recently infected SARS-CoV-2 individuals. It was conducted by the Hygiene Unit of IRCCS Policlinico San Martino Hospital in Genoa, Italy, and coordinated by Prof. Giancarlo Icardi.

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 of the study suggest the potential efficacy of Sentinox, with a better response for 3 times/day, versus the control group, in the reduction of the nasal viral load, negativization and infectivity. The final analysis on the intention-to-treat ("**ITT**") population of 54 patients who completed the study showed an about 90% (over 1.0 Log10) reduction of viral load after 5 days of treatment with Sentinox 3 times/day versus the control group.

Additional analyses have been conducted in patients stratified according to baseline value of RT-PCR cycles: in the subgroup with medium (Ct 20-30) viral load, the use of Sentinox significantly reduced the viral load of 1.9761 Log10 (p=0.0178) at day 5 compared to the control group, suggesting a positive trend in the treatment effect. Further efficacy analyses on the ITT population showed that negativization in the Sentinox 3 times/day group started at day 4; at day 6 patients with negative swab were almost two-fold compared to the control group (47% in Sentinox group versus 22% in no treatment group) (p=0.0005). Similar results were obtained in the analysis conducted in the 20-30 RT PCR cycles subpopulation.

Analysis on infectivity data was also conducted in the ITT population: patients were considered "not infectious" (patient likely not be able to spread virus to others) when the cycle threshold value of >35 cycles was achieved *(Carrouel et al. 2021; Jang et al. 2021; Iwanami et al. 2021; Choudhuri et al. 2020)*. In the 3 times/day Sentinox group, 71% of patients were non-infectious versus 44% in the control group at day 6 (p<0.0001). Overall safety data monitored through clinical examination showed a good safety profile for Sentinox. This has been confirmed also by VAS and LIKERT scale results.

APR TM-011

APR TM-011 is currently approved in EU as Class III Medical Device for the treatment of skin lesions and toxicities induced by certain cancer treatments, including certain anti Epidermal Growth Factor Receptors (anti-EGFR) Monoclonal Antibodies (e.g. Cetuximab). The use of anti-EGFR inhibitors cause papulopustular manifestations due to the interference of epidermal growth factor receptor (EGFR) signaling in the skin with a high risk of secondary infections. Subject to an internal commercial assessment, the company is planning to conduct an additional controlled clinical study in order to confirm product approval in Europe as Class III Medical Device beyond 2024 when the new EU regulations on such devices shall apply (the "MDR Regulation"). In particular, the company is planning to conduct a multi-center, post-market, double blind, exploratory placebo-controlled investigation to evaluate the efficacy (reducing occurrence of acute dermatitis of grade 3 or higher -RTOG scale), safety and tolerability of APR TM-011 in the management of skin lesions /reactions due to anti-EGFR Monoclonal Antibodies and/or radiotherapy-induced treatments in oncology patients.

This study would follow a preliminary, proof of concept study completed by the company on 15 head and neck cancer patients treated for 8-12 weeks with Cetuximab and showing a mean reduction of 94% of the lesion area compared to the standard of care.

APR-TD-011

Relief is planning to evaluate APR-TD-011 as a treatment for epidermolysis bullosa ("EB"). EB is a group of rare, genetic, life-threatening connective tissue disorders characterized by skin blistering throughout the body and the risk of severely impacting internal organs. There are an estimated 250,000 patients with EB worldwide, with an estimated 30,000 patients in the European Union and 20,000 patients in the U.S.-APR TD-011 is a proprietary formulation of hypochlorous acid sprayable solution that combines strong antimicrobial action with anti-inflammatory properties. APR-TD-011 utilizes the TECHLO patented technology platform and employs an exclusive combination of three physio-chemical properties – high-purity hypochlorous acid ("HCIO"), hypotonic low pH and high oxidation-reduction potential ("ORP"), which is believed to support a faster physiological healing of EB wounds by creating a favorable wound microenvironment. In particular, HCIO is well known as a broad-spectrum, fast acting antimicrobial agent, which reinforced by low pH and high ORP contributes to prevent and treat skin infections.

APR-TD-011 is an investigational drug candidate that, subject to clinical demonstration of efficacy and safety in clinical trials, 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.

The product was granted Orphan Drug Designation in late 2019 by the U.S. FDA. Relief plans to initiate a Phase 2 proof-of-concept study in 2022 and to discuss further development steps with regulatory authorities shortly thereafter. In particular, the company is planning to conduct a single arm (12 patients with at least 24 matched wounds in total), placebo-controlled study to evaluate efficacy (wound healing in term of reduction of wound size and wound closure, change in pain and itching and reduction of wound infection), safety and tolerability of APR-TD-011 in the management of open wounds in inherited EB patients (subtypes JEB, DEB, or Kindler syndrome). There can be no assurance this trial will be successful.

CAMBIA

Diclofenac potassium is an off-patent, potent non-steroidal anti-inflammatory drug ("NSAID") widely used therapeutically for inflammatory conditions and pain management. By applying the patented dynamic buffering technology ("DBT"), APR developed the first, and still the only, NSAID ever approved by the FDA for the treatment of acute migraine attacks in adults -- currently marketed as CAMBIA by Assertio Therapeutics Inc. in the U.S. and Miravo Healthcare (formerly Nuvo Pharmaceuticals Inc.) in Canada, under an exclusive, royalty bearing license agreement with APR.

On February 28, 2022, Unimedica Laboratories Pvt. Ltd., India, sent APR a Notice of Certification under the FFDCA related to the filing of an ANDA for CAMBIA. While there can be no assurance, that it is unlikely that Unimedica will get accelerated approval, and in any case, 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 at Cambia may become available. CAMBIA is currently available in the form of a dry powder packed into a single dose sachet to be poured and dissolved in water before administration.

VOLTADOL

Using the patented matrix patch technology, APR has developed a topical patch containing and delivering Diclofenac sodium, an off-patent, potent non-steroidal anti-inflammatory drug ("NSAID") for the local treatment painful short term, acute conditions such as strains. The product is marketed in various countries as over the counter medicine by Glaxo Smith Kleine (GSK).

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 down 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.

Patents and Licenses

Our success depends significantly on our ability to develop, obtain and maintain intellectual property rights for our product candidates, technology and know-how, to operate without infringing intellectual property rights of others and to prevent others from infringing our intellectual property rights. We seek to protect our proprietary position by, among other methods, filing patent applications in Europe, the United States and other relevant jurisdictions related to our proprietary technology, inventions and improvements that are vital to the development of our business, where patent protection is available. We also rely on trade secrets, know-how and in licensing opportunities to develop and maintain our proprietary position.

Aviptadil patents

Relief holds patents covering potential formulations of aviptadil in the United States valid until at least July 2029, with extension opportunities up to five years, as well as in several countries in Europe and the rest of the World valid until at least 2026, excluding extension opportunities comparable to the U.S. The existing patent family was filed in 2006 and granted in 2011 and 2012, as follows:

Summary Description of Patent	United States or Foreign Jurisdiction	Expiration Date
Formulation for Aviptadil	United States (No. 8,178,489), China, European Patent Convention, Mexico, India, Austria, Denmark, Switzerland/Lichtenstein, Germany, Spain, United Kingdom, Ireland, Netherlands	July 3, 2029 (United States), March 7, 2026 (all other jurisdictions)

AdVita

As of June 13, 2022, AdVita has two patent families in various stages of prosecution, including PCT/EP2020/062420, which recently entered the national phase in the U.S., Europe, and other countries; PCT/EP2021/052151, which is still pending in the international phase, and at least one unpublished application. Each family of applications is directed to novel uses and/or formulations of Aviptadil for treating various conditions such as drug induced pneumonitis. Patents granting from applications claiming priority to PCT/EP2020/062420 will expire in May 2040, excluding any patent term adjustments or extensions, or any form of potential exclusivity. Patents granted from applications claiming priority to PCT/EP2021/052151 will expire in January 2041, excluding any patent term adjustments or extensions, or any form of potential exclusivity, as follows:

Summary Description of Patent Application	United States or Foreign Jurisdiction	Expiration Date
Patent Family 1		
Vasoactive Intestinal Peptide (VIP) for Use in the Treatment of Drug-Induced Pneumonitis	United States (Application No. 17/595,025), Australia, Brazil, Canada, Switzerland, China, European Patent Convention, Hong Kong, Israel, India, Japan, Republic of Korea, Mexico, New Zealand, Patent Cooperation Treaty, Russian Federation, Singapore, South Africa	Applications, if granted, will expire no earlier than May 5, 2040.
Patent Family 2		
Human Anti-Inflammatory Peptides for the Inhalatory Treatment of Inflammatory Pulmonary Diseases	Patent Cooperation Treaty	Applications claiming priority to this PCT application, if granted, will expire no earlier than Jan 29, 2041.

ACER-001 license

We in-licensed from Acer the rights to commercialize ACER-001 for the treatment of UCD and MSUD. Under the terms of our collaboration agreement, Acer received approximately $10 million cash payment (originally $14 million, offset by repayment of the $4 million outstanding balance of the prior loan, plus interest, from Relief to Acer). Relief has also paid Acer $20 million in U.S. development and commercial launch costs for the UCDs and MSUD indications. Acer will retain development and commercialization rights in the U.S., Canada, Brazil, Turkey, and Japan. The companies will split net profits from Acer' s territories 60%:40% in favor of Relief. In addition, Relief has licensed the rights for the rest of the world, where Acer will receive from Relief a 15% royalty on all revenues received in Relief' s territories. Acer may also receive a total of $6 million in development milestone payments following the first European (EU) marketing approvals for UCDs and MSUD.

If ACER-001 is approved for marketing, Acer intends to submit the patent for listing by the FDA in the Approved Drug Products with Therapeutic Equivalence Evaluations, or Orange Book.

In parallel with Acer' s actions, Relief and Acer are pursuing similar claims in the European Patent Office to cover ACER-001 as Relief continues to execute on its plan to submit a Marketing Authorization Application for ACER-001 for the treatment of patients with UCDs in Europe in the second or third quarter of 2022. There can be no assurance that Relief and Acer will be successful in those endeavors.

Acer maintains its own intellectual property portfolio. In August 2014, Acer was granted Orphan Drug Designation by the U.S. Food and Drug Administration to sodium phenylbutyrate (ACER-001) for the treatment of Maple Syrup Urine Disease.

As of June 13, 2022, Acer' s patent portfolio for ACER-001 consists of several patent families comprising two granted U.S. Patents with an expiration date of March 2036, exclusive of any patent term adjustments or extensions, or any form of potential exclusivity. The portfolio further includes several applications world-wide, and one pending U.S. applications directed to novel sodium phenylbutyrate particle formulations and methods of use. Patents granted from these applications will have expiration dates ranging from 2036 to 2042 excluding any patent term adjustments or extensions, or any form of potential exclusivity.

ACER-001' s patents and patent applications worldwide are as follows:

Summary Description of Patent	United States or Foreign Jurisdiction	Expiration Date
Palatable Compositions Including Sodium Phenylbutyrate and Uses Thereof	Granted**:** United States (Patent Nos. 11,154,521 and 11,202,767) Pending: United States (Application No. 16/746,186), Austria, Bahrain, Brazil, Canada, European Patent Convention, Israel, Japan, Republic of Korea, Kuwait, Mexico, New Zealand*, Oman, Qatar, Saudi Arabia, United Arab Emirates, Patent Cooperation Treaty * Two Patent Applications	October 17, 2036. Expiration of pending applications to be determined upon grant.

Partner patents and licenses

Tehclo Technology

As of June 13, 2022, APR' s TECHLO portfolio consists of four patent families. The first three families include 108 granted patents world-wide 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. If granted, additional patents, would expire no earlier than July 2040.

Summary Description of Patent	United States or Foreign Jurisdiction	Expiration Date
Patent Family 1		
Electrolytic Water Treatment Device Having Sintered Nanoparticle Coated Electrode and Method for Making Acid or Basic Water Therewith	United States (Patent No. 8,277,634)	August 23, 2029
Device Comprising an Electrode with Nanocoating for Preparing a Highly Stable Aqueous Solution and Method for Making this Aqueous Solution	Austria, Belgium, Bulgaria, Switzerland, Cyprus, Czechia, Germany, Denmark, Estonia, European Patent Convention, Finland, France, Greece, Hungary, Ireland, Iceland, Italy, Lithuania, Luxembourg, Latvia, Monaco, Netherlands, Poland, Portugal, Romania, Slovenia, Slovakia, Spain, Sweden, Switzerland, Turkey, United Kingdom	October 24, 2026 (Luxembourg), October 23, 2026 (all other jurisdictions)
New Highly Stable Aqueous Solution, Electrode with Nanocoating for Preparing the Solution and Method for Making this Electrode	Australia, Canada, China, Israel, Republic of Korea, Russian Federation, Singapore, South Africa	October 22, 2026 (China), October 23, 2026 (all other jurisdictions)
A Device for the Electrolytic Treatment of a Fluid	India	October 23, 2026
Patent Family 2		
Highly Stable Electrolytic Water with Reduced NMR Half Line Width	United States (Patent Nos. 8,709,495, 9,402,192, and 9,889,153), Austria, Australia, Belgium, Bulgaria, Brazil, Canada, Switzerland, Cyprus, Czechia, Germany*, Denmark, Estonia, European Patent Convention*, Spain*, Finland, France*, United Kingdom*, Greece, Croatia, Hungary, Ireland, Iceland, Italy*, Japan, Republic of Korea, Lithuania, Luxembourg, Latvia, Monaco, Malta, Mexico, Netherlands, Norway, New Zealand, Poland*, Portugal, Romania, Russian Federation, Sweden, Singapore, Slovenia, Slovakia, Turkey*, South Africa * Two patents	February 7, 2030 (United States Patent No. 8,709,495), April 24, 2028 (one United Kingdom patent), April 26, 2028 (Greece), April 25, 2028 (all other patents and jurisdictions)
Electrolytic Acid Water	India	April 25, 2028
Patent Family 3		
Methods of Treating Outer Eye Disorders Using High ORP Acid Water and Compositions Thereof	United States (Patent No. 8,691,289), Germany, European Patent Convention, Spain, France, United Kingdom, Italy, South Africa	June 15, 2030 (United Kingdom), March 13, 2032 (United States), June 16, 2030 (all other jurisdictions)
Patent Family 4		
Therapeutic Uses of Oxidising Hypotonic Acid Solutions	United States (Application No. 17/597,220), United Arab Emirates, Australia, Brazil, Canada, China, Colombia, Egypt, European Patent Convention, Israel, Japan, Korea, Kuwait, Qatar, Russian Federation	Applications, if granted, will expire no earlier than July 2040.

APR has granted worldwide licenses for TECHLO to numerous regional and national pharmaceutical firms. None of the licenses, either individually or as a whole, currently represent a material amount of the revenues of the consolidated company.

Physiomimic Technology - Golike

As of June 13, 2022, the Golike portfolio consists of two patent families including 37 pending applications and 15 granted patents world-wide. 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.

Summary Description of Patent or Patent Application	United States or Foreign Jurisdiction	Expiration Date
Patent Family 1		
Modified Release Orally Administered Amino Acid Formulations	Granted: United States (No. 10,500,180), Armenia, Azerbaijan, Belarus, China, Colombia, European Patent Convention, Kyrgyzstan, Kazakhstan, Israel, Lebanon, Malaysia*, Mexico, Russian Federation, Tajikistan, Turkmenistan, Taiwan	September 25, 2036 (Jordan), September 28, 2036 (Taiwan), September 27, 2036 (all other jurisdictions).
	Pending: United States (Application No. 15/303,121), Argentina, Australia, Brazil, Canada, Chile, China, Egypt, Gulf Cooperation Council, Hong Kong, Indonesia, Israel*, Iraq, Jordan, Philippines, Pakistan, Saudi Arabia, Uruguay, Venezuela, Vietnam, South Africa	Applications, if granted, will expire no earlier than September 27, 2036.
	* Two Patents	
Patent Family 2		
Methods of Normalizing Markers of Amino Acid Metabolism	Pending: United States (Application No. 16/543,437)	Expiration of pending applications to be determined upon grant.
Methods of Normalizing Amino Acid Metabolism	Pending: Australia, Brazil, Canada, Chile, China, Colombia, European Patent Convention, Hong Kong, Israel, Iraq, Pakistan, Saudi Arabia, Taiwan	Expiration of pending applications to be determined upon grant.

APR has granted licenses for Golike in Spain, the United Kingdom, Ireland, Brazil, Israel, Colombia, Panama, Peru, the Dominican Republic, and the Netherlands. None of the licenses, either individually or as a whole, currently represent a material amount of the revenues of the consolidated company.

Dynamic Buffer Technology - Diclofenac

As of June 13, 2022, APR' s diclofenac patent portfolio consists of multiple patent families comprising 39 granted patents world-wide, with expiration dates in either February 2026 or June 2026, exclusive of any patent term adjustments or extensions, or any form of potential exclusivity. The portfolio further includes 14 pending applications directed to new diclofenac formulations and methods of use. If granted, patents resulting from these pending applications will expire between 2026 and 2041, exclusive of any patent term adjustments or extensions, or any form of potential exclusivity.

Summary Description of Patent or Patent Application	United States or Foreign Jurisdiction	Expiration Date
Patent Family 1		
Diclofenac Formulations and Methods of Use	Granted: United States (Nos. 7,759,394, 8,097,651, 8,927,604 and 9,827,197), Australia, Canada*, Switzerland*, Germany**, European Patent Convention***, Spain*, France*, United Kingdom*, Greece*, Indonesia, Italy**, Jordan, Republic of Korea, Lebanon, Malta, Mexico, Norway, New Zealand, Pakistan, Poland, Portugal, Russian Federation, Thailand, Turkey, South Africa	June 16, 2026 (all United States Patents), June 8, 2026 (Lebanon), June 14, 2026 (Malta), June 15, 2026 (United Kingdom), June 16, 2026 (All other jurisdictions). Expiration of pending applications to be determined upon grant.
	Pending: United States (Application No. 16/716,511), China, Egypt, European Patent Convention, Gulf Cooperation Council**, Hong Kong	
	* Two Patents ** Three Patents *** Four Patents	

Summary Description of Patent or Patent Application	United States or Foreign Jurisdiction	Expiration Date
Diclofenac Formulations	Granted: Germany, Spain, France, United Kingdom, Italy,	June 15, 2026 (United Kingdom), June 16, 2026 (All other jurisdictions).
Patent Family 2		
Moisture Resistant Container Systems for Rapidly Bioavailable Dosage Forms	Granted: United States (Nos. 7,700,125 and 8,097,267)	February 7, 2026 (No. 8,097,267), October 11, 2026 (No. 7,700,125).
Patent Family 3		
Substantially Sodium Free Diclofenac Potassium Oral Solutions	Granted: United States (No. 11,123,318) Pending: United States (Application No. 17/463,154)	January 27, 2038 (United States Patent No. 11,123,318). Expiration of pending application to be determined upon grant.
Patent Family 4		
Ready to Use Diclofenacstick Paks	Granted: United States (No. 11,260,026), Pending: United States, European Patent Convention, Hong Kong	February 22, 2040 (United States Patent No. 11,260,026). Expiration of pending applications to be determined upon grant.
Patent Family 5		
Bioavailable Sugar-Based Diclofenac Formulations	Patent Cooperation Treaty	Expiration of pending applications to be determined upon grant.

APR has licensed Diclofenac to Assertio Therapeutics for its Cambia® product and to Novartis for its Voltaren® product. APR has also entered into a partnership agreement with Fidia Farmaceutici S.p.A. for diclofenac patches, and recognizes revenue of approximately CHF 1.3 million, CHF 900,000 and CHF 300,000, respectively, for each of those agreements on an annual basis. APR has also entered into License and Supply Agreements with MerckleGmbH and Zentiva k.s. and recognizes revenue of approximately CHF 423,000 and CHF 224,000, respectively, from those agreements on an annual basis.

APR sold the IT Patent for Diclofenac Patent Family 3 to Neilos s.r.l. (an affiliate of Shedir Pharma Group S.p.A), and the corresponding EP application to Dymalife Pharmaceutical S.R.L. (another affiliate of Shedir Pharma Group S.p.A.), but retained a non-exclusive and perpetual license right on such patent and patent for the production in the respective countries of drops solution for oral administration containing Diclofenac Potassium as sole active ingredient in a concentration of 5%. The Company believes that the sale of these properties will not have an effect on the license and supply agreements described in this section.

APR received a sublicense right in the territory of United States and China from Fidia Farmaceutici in relation to the following patents owned by IBSA Farmaceutici on Diclofenac transdermal patch:

Chinese Patent No. CN101001616B;

U.S. Patent No. 10,328,034.

APR does not believe that this license agreement is material to its business.

Oral Disposable Film - Ondansetron

As of June 13, 2022, APR' s ondansetron patent portfolio consists of two patent families comprising 3 pending applications and 6 granted patents with expiration dates ranging from 2027 to 2031, exclusive of any patent term adjustments or extensions, or any form of potential exclusivity.

Summary Description of Patent or Patent Application	United States or Foreign Jurisdiction	Expiration Date
Patent Family 1		
Non-Mucoadhesive Film Dosage Forms	United States (Patent Nos. 8,580,830 and 9,682,037), Canada, Republic of Korea	November 22, 2029 (United States Patent No. 8,580,830), October 2, 2027 (All other patents)
Patent Family 2		
Fast Dissolving Drug Delivery Systems	Granted: Russian Federation, South Africa Pending: Brazil, Egypt, Hong Kong	March 23, 2031. Expiration of pending applications to be determined upon grant.

APR has granted a license right on the abovementioned patents and patent applications to Takeda in Canada. This license does not represent a material amount of our revenues.

Other APR IP

In addition to the patents and applications described above, APR has several other pending applications and granted patents:

U.S. Patent No. 8,039,024, entitled "Device and composition for the delivery of a preservative-free balsamic cream" and patents in Canada, Russia and Ukraine entitled "Adhesive Label with Bittering Agent and Fluidifying Agents for Natural Airway Secretions" claim and cover a preservative-free, OTC decongestant stick pack which is no longer marketed, other than in Mexico, where it is marketed by Pisa Laboratories under the brand name "Agrifen". Sales of this product are not material.

PCT/IB2021/058174 related to dermal compositions, entitled "Dermal Compositions Replicating the Vernix Caseosa", cover and claim OTC formulations targeting atopic dermatitis as well as other moderate skin disorders. Patents granted from applications claiming priority to this PCT application will expire no earlier than September 8, 2041. A corresponding Italian priority application will, if granted, expire no earlier than September 8, 2040.

Manufacturing and supply

We do not own or operate facilities for the manufacture, packaging, labeling, storage or distribution of preclinical or clinical supplies of any of our drug candidates. We instead contract with and rely on third-party CMOs to manufacture, package, label, store test and distribute all preclinical development and clinical supplies of our drug candidates, and we plan to continue to do so for the foreseeable future. APR maintains laboratories for the testing of its products. Such laboratories are also used to develop new formulations.

Compliance with governing rules and quality requirements

The facilities used by our collaboration partners and CMOs to manufacture our product candidates are systematically audited by local authorities and occasionally inspected by competent authorities where the clinical studies are ongoing. The facilities where the commercial productions are performed must be approved by the FDA or other relevant regulatory authorities, pursuant to inspections that are conducted after we submit our NDA or comparable marketing applications. We perform periodic quality audits of the manufacturing facilities and CMOs to monitor their compliance with the regional laws, regulations and applicable cGMP standards and other laws and regulations, such as those related to environmental health and safety matters. The scope of our audits also involves monitoring the ability of our providers to maintain adequate QCs and QA systems including personnel qualification.

After manufacturing, our products are submitted to extensive characterization and QC testing plans performed by using properly developed analytical methods that are qualified or validated; this ensures the accuracy of the results generated and provides evidence of the quality of our products. In addition, our products are submitted to detailed and standardized stability programs aimed at demonstrating product stability during the storage period; this, in addition to guaranteeing the safety of the products, supports the definition of a suitable supply chain that may encompass the distribution of the products in different continents.

Contractual framework

We have established, with CMOs supplying drug substances or drug products under cGMP, quality agreements and master service agreements. Quality agreements define the quality standards required to develop, produce and supply the product, and also define the responsibilities related to the collaboration with regards to the quality related aspects. Manufacturing service agreements define the commercial and financial framework under which product manufacturing under cGMP is performed. Any failure to achieve and maintain compliance with the laws, regulations and standards, suspension of the manufacturing of our product candidates or revoke of cGMP permissions, which would adversely affect our business and reputation, are defined in the master service agreements and quality agreements. The risk that any third-party providers may breach the agreements they have with us because of factors beyond our control and the possibility that they may also terminate or refuse to renew their agreements because of their own financial difficulties or business priorities, potentially at a time that is costly or otherwise inconvenient for us, is managed by us with constant investments toward maintaining reserve stocks and in-depth process know-how.

Interaction with collaboration partners and CMOs

Finally, our partnership with CMOs is managed through an efficient project management platform in which teams are formed with the representatives of each key function from both parties. Meetings occur either through telephone conferences aimed at updating short-term actions or face-to-face conferences when mid- to long-term development plans are discussed.

Acquisition of AdVita Lifescience GmbH

On July 28, 2021, we announced the closing of a definitive agreement to acquire all of the outstanding shares of AdVita Lifescience GmbH. Under the agreement, the stockholders of AdVita received 135,741,063 of our common shares, representing 25 million (approximately CHF 27.4 million) in value based on a 60-day Volume Weighted Average Price of our common shares and are also eligible to receive additional contingent payments of up to 20 million (approximately CHF 21.9 million) in cash upon achievement of pre-agreed milestones involving (i) the issuance of a patent based on AdVita technology as set forth in the agreement, (ii) upon the first regulatory approval in the U.S. or Europe for the inhaled form of aviptadil for the prevention or therapy of acute respiratory distress system (ARDS) or acute lung injury (ALI), (iii) upon regulatory approval in the U.S. or Europe for the inhaled form of aviptadil for the treatment of sarcoidosis or berylliosis, and (iv) the identification of a partner for co-development or the start of a phase II clinical trial for checkpoint inhibitor-induced pneumonitis. In April 2022, we made an initial milestone payment of 5 million (approximately CHF 5.1 million) upon completion of the first milestone.

AdVita was founded in 2019 for the purpose of developing products and strategies to improve the therapy and diagnosis of rare lung diseases. Among AdVita' s assets are intellection property rights that may cover RLF-100 inhaled formulation specifications and the potential application of inhaled Aviptadil in the treatment of Acute Respiratory Distress Syndrome, Checkpoint Inhibitor-induced Pneumonitis and Sarcoidosis.

Collaboration Agreement with InveniAI LLC

On November 24, 2021, we announced that we had 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 biopharma and other industries, in order to identify promising drug candidates to treat rare and specialty diseases (the "InveniAI Collaboration Agreement").

Under the terms of the InveniAI Collaboration Agreement, InveniAI will use its proprietary platform for the identification of potential pharmaceutical product opportunities using its Pharma Big Innovation Data Lab, consisting of (i) its proprietary AlphaMeld platform, a cloud-based artificial intelligence 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 InvenAI will use its platform to navigate the volume of data for all regulatory agency approved drugs and their associated active ingredients to identify potential rate and specialty disease indications for development and commercialization by us ("product concepts") . InveniAI will seek to prioritize top product concepts, associated diseases, scientific packages and evidence to support the potential drug development opportunities by us. We anticipate that InveniAI' s platform will complement APR' s 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 InveniAI Collaboration Agreement, we paid InveniAi an initial up-front fee of $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 $500,000 per product candidate for which we exercise our option to acquire IP rights to $50 million for any required product reaching $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%.

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.

Regulation in the United States

The Company assumes that some of its product candidates will be submitted under New Drug Applications ("NDA") and that approval of not only the products but also their manufacture is required before starting to market them. According to the definition of the U.S. Code of Federal Regulations, a drug product is approved only after demonstrating that it meets standards that assure the product' s safety, purity, effectiveness and potency.

The design, pre-clinical and clinical study, manufacture, labeling, packaging, storage, holding, sale, distribution, marketing, and promotion of pharmaceutical products – including biologic products – are subject to extensive and rigorous government regulation. The Federal Food, Drug, and Cosmetic Act ("FFDCA") and other federal and state statutes and regulations govern or influence these activities. Non-compliance with applicable requirements can result in fines, recall or seizure of products, total or partial suspension of production and/or distribution, refusal of the government to enter into supply contracts or to approve NDAs, civil penalties and criminal prosecution.

Product Approval Process

Pharmaceutical products are subject to extensive regulation by the FDA. The FFDCA, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Pharmaceutical product development for a new product or certain changes to an approved product in the United States typically involves preclinical laboratory and animal tests, the submission to the FDA of an investigational new drug, or IND, which must become effective before clinical testing may commence, and adequate and well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the type, complexity and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the preclinical tests must comply with federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an Investigational New Drug Application ("IND") along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

The FDA' s Center for Drug Evaluation and Research fosters early communications between sponsors and new drug review divisions to provide guidance on the data necessary to warrant IND submission, and a 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the IND to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB' s requirements, or may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, after the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. Phase 2 usually involves trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 trial with other confirmatory evidence may be sufficient in instances where the study is a large multicenter trial demonstrating internal consistency and a statistically persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible.

In addition, the manufacturer of an investigational drug in a Phase 2 or Phase 3 clinical trial for a serious or life-threatening disease is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for expanded access.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all preclinical, clinical and other testing and a compilation of data relating to the product' s pharmacology, chemistry, manufacture and controls. The cost of preparing and submitting an NDA is substantial. The submission of most NDAs is additionally subject to a substantial application user fee, currently $2,875,842 for fiscal year 2021. Under an approved NDA, the applicant is subject to an annual program fee, currently $336,432 per prescription product for fiscal year 2021. These fees typically increase annually, though the application fee decreased slightly from 2020 to 2021.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be filed based on the agency' s threshold determination that it is sufficiently complete to permit substantive review. If the NDA submission is filed, the FDA reviews the NDA to determine, among other things, whether the proposed product is safe and effective for its intended use. The FDA has agreed to certain performance goals in the review of NDAs. Most such applications for standard review drug products are reviewed within ten to twelve months; most applications for priority review drugs are reviewed in six to eight months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment or provide a treatment where no adequate therapy exists. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA' s satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug' s safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Emergency Use Authorization

Emergency Use Authorization (EUA) authority is designed to allow the FDA to help strengthen public health protections against chemical, biological, radiological, and nuclear (CBRN) threats, including infectious diseases, by facilitating the availability and use of medical countermeasures (MCMs) needed during public health emergencies.

Under Section 564 of the FFDCA, the Commissioner of the FDA, acting under delegated authority from the Secretary of the Department of Health and Human Services (HHS), may issue an EUA authorizing (1) the emergency use of an unapproved drug, an unapproved or uncleared device, or an unlicensed biological product; or (2) an unapproved use of an approved drug, approved or cleared device, or licensed biological product. Before an EUA may be issued, the Secretary of HHS must declare that circumstances exist justifying the authorization based on one of four determinations: (1) A determination by the Secretary of Homeland Security that there is a domestic emergency, or a significant potential for a domestic emergency, involving a heightened risk of attack with a, chemical, biological, radiological, or nuclear ("CBRN") agent or agents; (2) the identification of a material threat by the Secretary of Homeland Security pursuant to section 319F-2 of the Public Health Service (PHS) Act sufficient to affect national security or the health and security of United States citizens living abroad; (3) a determination by the Secretary of Defense that there is a military emergency, or a significant potential for a military emergency, involving a heightened risk to United States military forces, including personnel operating under the authority of title 10 or title 50, of attack with (i) a biological, chemical, radiological, or nuclear agent or agents; or (ii) an agent or agents that may cause, or are otherwise associated with, an imminently life-threatening and specific risk to United States military forces; or (4) a determination by the Secretary that there is a public health emergency, or a significant potential for a public health emergency, that affects, or has a significant potential to affect, national security or the health and security of United States citizens living abroad, and that involves a CBRN agent or agents, or a disease or condition that may be attributable to such agent or agents.

Based on any of these four determinations, the Secretary of HHS may then declare that circumstances exist that justify the EUA, at which point the FDA Commissioner may issue an EUA if the criteria for issuance of an authorization under section 564 of the FFDCA are met.

On February 4, 2020, pursuant to section 564 the FFDCA, the Secretary of HHS determined that there was a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad and that involved COVID-19.

On March 27, 2020, on the basis of the determination of the Secretary of HHS of a public health emergency that had a significant potential to affect national security or the health and security of United States citizens living abroad and that involved the novel coronavirus, the Secretary of HHS declared that circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic, pursuant to section 564 of the FFDCA, subject to the terms of any authorization issued under that section.

Quality Assurance

The FDA regulates the facilities, processes and procedures used to manufacture and market pharmaceutical products in the United States. Manufacturing facilities, including those located outside the United States, must be registered with the FDA and all products made in such facilities must be manufactured in accordance with cGMP regulations enforced by the FDA. Compliance with cGMP regulations requires the dedication of substantial resources and requires significant expenditures. These cGMP standards are particularly stringent for biologic products. The FDA periodically inspects manufacturing facilities and procedures to assure compliance. The FDA may cause a suspension or withdrawal of product approvals if regulatory standards are not maintained. In the event an approved manufacturing facility is required by the FDA to curtail or cease operations, or otherwise becomes inoperable, or a third party contract manufacturing facility faces manufacturing problems, obtaining the required FDA authorization to manufacture at the same or a different manufacturing site could result in production delays, which could adversely affect the Company' s business, results of operations, financial condition and cash flow.

The FDA conducts pre-approval inspections of facilities engaged in the development, manufacture, processing, packing, testing and holding of the products subject to INDs. If the FDA concludes that the facilities to be used do not or did not meet cGMP, GLP or GCP requirements, it will not approve an IND application. Corrective actions to remedy the deficiencies must be performed and are usually verified in a sub-sequent inspection. In addition, manufacturers of both pharmaceutical products and active pharmaceutical ingredients (APIs) used to formulate the product also ordinarily undergo a pre-approval inspection, although the inspection can be waived when the manufacturer has had a passing cGMP inspection in the immediate past. Failure of any facility to pass a pre-approval inspection will result in delayed approval and would have a material adverse effect on the Company' s business, results of operations, financial condition and cash flows.

The FDA also conducts periodic inspections of facilities to assess their cGMP status. If the FDA were to find serious cGMP non-compliance during such an inspection, it could take regulatory actions that could adversely affect the Company' s business, results of operations, financial condition and cash flows. Imported API and other components needed to manufacture products could be rejected by U.S. Customs, usually after conferring with the FDA. In respect to domestic establishments, the FDA could initiate product seizures or request product recalls and seek to enjoin a product' s manufacture and distribution. In certain circumstances, violations could support civil penalties and criminal prosecutions. In addition, if the FDA concludes that a company is not in compliance with cGMP requirements, sanctions may be imposed that include classifying that company as an "unacceptable supplier", thereby disqualifying that company from selling products to federal agencies.

Marketing

Companies that market pharmaceutical products in the United States are subject to various federal and state laws pertaining to healthcare fraud and abuse, including prohibitions on the offer of payment or acceptance of kickbacks or other remuneration for the purchase of products, such as inducements to potential patients to request the company' s products. Specifically, the federal Anti-Kickback Statute prohibits persons or entities from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid pro-grams. Due to legislative changes, violations of the Anti-Kickback Statute also carry potential federal False Claims Act liability. Because of the sweeping language of the federal Anti-Kickback Statute, many potentially beneficial business arrangements would be prohibited if the statute were strictly applied. To avoid this outcome, the U.S. Department of Health and Human Services' Office of Inspector General has published regulations−known as "safe harbors"−that identify exceptions or exemptions to the statute' s prohibitions. Arrangements that do not fit within the safe harbors are not automatically deemed to be illegal, but must be evaluated on a case-by-case basis for compliance with the statute. Additionally, many states have adopted laws similar to the federal Anti-Kickback Statute. Some of these state prohibitions apply to referral of patients for healthcare items or services reimbursed by any third party payer, not only the Medicare and Medicaid programs, and do not contain identical safe harbors.

The Company is unaware of any violations of these laws. However, due to the breadth of the statutory provisions and the absence of uniform guidance in the form of regulations or court decisions, there can be no assurance that its practices will not be challenged under anti-kickback or similar laws. Violations of such restrictions may be punishable by civil and/or criminal sanctions, including fines and civil monetary penalties, as well as the possibility of exclusion from participation in U.S. federal and state healthcare programs (including Medicaid and Medicare). Any liability from such a violation could have a material adverse effect on our business, financial condition, results of operations and cash flows.

In addition, the FDA has the authority to regulate the claims made by a manufacturer in marketing its products to ensure that such claims are true, not misleading, supported by scientific evidence and consistent with the products approved or cleared labeling. Failure to comply with FDA requirements in this regard could result in, among other things, suspensions or withdrawal of approvals, product seizures, injunctions against the manufacture, holding, distribution, marketing and sale of a product, civil and criminal sanctions.

Also, the federal False Claims Act prohibits persons from knowingly filing, or causing to be filed, a false claim to, knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to, or the knowing use of false statements to obtain payment from, the government. When an entity is determined to have violated the False Claims Act, it may be required to pay up to three times the actual damages sustained by the government, plus civil penalties for each separate false claim. Various states have also enacted laws modeled after the federal False Claims Act. Federal and state authorities and private whistleblower plaintiffs have brought actions against pharmaceutical product manufacturers alleging that the manufacturers' activities constituted causing healthcare providers to submit false claims, alleging that the manufacturers themselves made false or misleading statements to the federal government, or alleging that the manufacturers improperly promoted their products for "off-label" uses not approved by the FDA, or offered inducements to referral sources that are prohibited by the federal Anti-Kickback Statute. To the extent the Company becomes the subject of any such investigations or litigation, it could be time-consuming and costly to the Company and could have a material adverse effect on its business. In addition, if its activities are found to violate federal or state False Claims Act statutes, it could have a material adverse effect on its business, financial conditions, results of operations and cash flows.

Product Liability

There are potential liability risks that arise from the testing, manufacturing, marketing and sale of pharmaceutical products. In addition to direct expenditures for damages, settlement and defense costs, there is a possibility of adverse publicity as a result of product liability claims. Some plaintiffs have received substantial damage awards in some jurisdictions against pharmaceutical companies based upon claims for injuries allegedly caused by the use of their products. In addition, it may be necessary for the Company to voluntarily or mandatorily recall or withdraw products that do not meet approved specifications or which subsequent data demonstrate may be unsafe or ineffective, which would also result in adverse publicity as well as in costs connected to the recall and loss of revenue.

Health Information Privacy and Security

The administrative simplification section of the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations, collectively "HIPAA", impose stringent requirements on "covered entities" (healthcare providers, health plans and healthcare clearinghouses) to safeguard the privacy and security of individually identifiable health information. Certain of the Company' s operations may be subject to these requirements. Penalties for non-compliance with these rules include both criminal and civil penalties. In addition, the Health Information Technology for Economic and Clinical Health Act (included in the American Recovery and Reinvestment Act of 2009) and its implementing regulations, collectively "HITECH", expanded federal health information privacy and security protections. Among other things, HITECH makes certain of HIPAA' s privacy and security standards directly applicable to "business associates" ‑ independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also set forth new notification requirements for certain breaches, increased the civil penalties that may be imposed against covered entities, business associates and possibly other persons for HIPAA violations, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorney' s fees and costs associated with pursuing federal civil actions.

Legislative and regulatory initiatives at the state and federal levels address concerns about the privacy and security of health information. HITECH expands the health information privacy and security protections under HIPAA and imposes new obligations to notify individuals and the U.S. Department of Health and Human Services Office for Civil Rights, or "OCR", of breaches of certain unsecured health information. Compliance with these laws and regulations may require the Company to spend substantial sums, including, but not limited to, purchasing new information technology, which could negatively impact financial results. Additionally, if the Company fails to comply with the HIPAA privacy, security and breach notification standards, it could suffer civil penalties of up to USD 1,500,000 per calendar year for violations of an identical standard and criminal penalties of up to USD 250,000 and 10 years in prison for offenses committed with the intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain or malicious harm. In addition, healthcare providers will continue to remain subject to any state laws that are more restrictive than the federal privacy regulations. These privacy laws vary by state and could impose additional penalties.

The provisions of HIPAA criminalize situations that previously were handled exclusively civilly through repayments of overpayments, offsets and fines by creating new federal healthcare fraud crimes. Further, as with the federal laws, general state criminal laws may be used to prosecute healthcare fraud and abuse. A violation could subject the Company to penalties, fines and/or possible exclusion from Medicare or Medicaid. Such sanctions could significantly reduce its financial results. Future healthcare legislation and regulation or other changes in the administration of or interpretation of existing legislation or regulations regarding governmental healthcare pro-grams could have an adverse effect on the Company' s business the results of its operations.

Regulation in the European Union

Product development, the regulatory approval process, and safety monitoring of medicinal products and their manufacturers in the EU proceed in much the same manner as they do in the U.S.. Therefore, many of the issues discussed above apply similarly in the context of the EU. In addition, drugs are subject to the extensive price and reimbursement regulations of the various EU Member States.

In the EEA, which is comprised of the 27 Member States of the EU plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a marketing authorization. There are two types of marketing authorization: the Community Marketing Authorization, which is issued by the EC through the Centralized Procedure based on the opinion of the Committee for Medicinal Products for Human Use (CHMP), a body of the EMA, and which is valid throughout the entire territory of the EEA; and the National Marketing Authorization, which is issued by the competent authorities of the Member States of the EEA and authorizes marketing only in that Member State' s national territory and not the EEA as a whole.

The Centralized Procedure is compulsory for human medicines for the treatment of human immunodeficiency virus or acquired immune deficiency syndrome (AIDS), cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions, and viral diseases; for veterinary medicines for use as growth or yield enhancers; for medicines derived from biotechnology processes, such as genetic engineering; for advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines; and for officially designated 'orphan medicines' (medicines used for rare human diseases). The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation, or for products that are in the interest of public health in the EU. The National Marketing Authorization is for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National Marketing Authorization can be recognized in another Member State through the Mutual Recognition Procedure. If the product has not received a National Marketing Authorization in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure, an identical dossier is submitted to the competent authorities of each of the Member States in which the marketing authorization is sought, one of which is selected by the applicant as the Reference Member State (RMS). If the RMS proposes to authorize the product, and the other Member States do not raise objections, the product is granted a National Marketing Authorization in all the Member States in which the authorization was sought. Before granting the marketing authorization, the EMA or the competent authorities of the Member States of the EEA assesses the risk‑benefit balance of the product on the basis of scientific criteria concerning its quality, safety and efficacy.

Clinical studies

As is the case in the U.S., the various phases of preclinical and clinical research in the EU are subject to significant regulatory controls. The Clinical Trials Directive 2001/20/EC, as amended and which will be replaced in 2021 or later by Regulation (EU) No 536/2014) provides a system for the approval of clinical studies in the European Union via implementation through national legislation of the Member States. Under this system, approval must be obtained from the competent national authorities of the EU Member States in which the clinical trial is to be conducted. Furthermore, a clinical trial may only be started after a competent ethics committee has issued a favorable opinion on the clinical trial application, which must be supported by an investigational medicinal product dossier with supporting information prescribed by the Clinical Trials Directive and corresponding national laws of the Member States, and further detailed in applicable guidance documents. A clinical trial may only be undertaken if provision has been made for insurance or indemnity to cover the liability of the investigator or sponsor. In certain countries, the sponsor of a clinical trial has a strict (faultless) liability for any (direct or indirect) damage suffered by trial subjects. The sponsor of a clinical trial, or its legal representative, must be based in the EEA. European regulators and ethics committees also require the submission of AE reports during a study and a copy of the final study report.

Marketing approval

Marketing approvals under the EU regulatory system may be obtained through a centralized or decentralized procedure. The centralized procedure results in the grant of a single marketing authorization, which is valid for all (currently 27) EU Member States and the three European Free Trade Association (EFTA) members (Norway, Iceland and Liechtenstein).

Pursuant to Regulation (EC) No. 726/2004, as amended, the centralized procedure is mandatory for drugs developed by means of specified biotechnological processes, advanced-therapy medicinal products, drugs for human use containing a new active substance for which the therapeutic indication is the treatment of specified diseases, including but not limited to AIDS, neurodegenerative disorders, auto-immune diseases and other immune dysfunctions, as well as drugs designated as orphan drugs. The CHMP also has the discretion to permit other products to use the centralized procedure if it considers them sufficiently innovative or they contain a new active substance.

In the marketing authorization application, the applicant has to properly and sufficiently demonstrate the quality, safety and efficacy of the drug. Under the centralized approval procedure, the CHMP, possibly in conjunction with other committees, is responsible for drawing up the opinion of the EMA on any matter concerning the admissibility of the files submitted in accordance with the centralized procedure, such as an opinion on the granting, variation, suspension or revocation of a marketing authorization, and pharmacovigilance.

The CHMP and other committees are also responsible for providing guidelines and have published numerous guidelines that may apply to our product candidates. These guidelines provide additional guidance on the factors that the EMA will consider in relation to the development and evaluation of drug products and may include, among other things, the preclinical studies required in specific cases, the manufacturing and control information that should be submitted in a marketing authorization application, and the post-approval measures required to monitor patients and evaluate the long-term efficacy and potential adverse reactions. Although these guidelines are not legally binding, we believe that our compliance with them is likely to be necessary to gain approval for any of our product candidates.

The maximum timeframe for the evaluation of a marketing authorization application by the CHMP under the centralized procedure is 210 days after receipt of a valid application. This period will be suspended until such time as the supplementary information requested by the CHMP has been provided by the applicant. Likewise, this time limit will be suspended for the time allowed for the applicant to prepare oral or written explanations. When an application is submitted for a marketing authorization in respect of a drug that is of major interest from the viewpoint of public health and in particular therapeutic innovation, the applicant may request an accelerated assessment procedure. If the CHMP accepts such a request, the time limit of 210 days will be reduced to 150 days, but it is possible that the CHMP can revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

If the CHMP concludes that the quality, safety and efficacy of the product are sufficiently proven, it adopts a positive opinion. This is sent to the EC, which drafts a decision within approximately 67 days following the CHMP opinion. After consulting with the Member States, the EC adopts a decision and grants a marketing authorization, which is valid for the whole of the EEA. The marketing authorization may be subject to certain conditions, which may include, without limitation, the performance of post-authorization safety and/or efficacy studies.

The EMA has various programs, including accelerated assessment, conditional approval and PRIority MEdicines (PRIME), which are intended to increase agency interactions, expedite or facilitate the process for reviewing drug candidates, and/or provide for initial approval on the basis of surrogate endpoints. One or more of our product candidates may qualify for some of these expedited development and review programs. However, even if a drug candidate qualifies for one or more of these programs, the EMA may later decide that the drug candidate no longer meets the conditions for qualification. Eligibility to the PRIME scheme is limited to products considered to offer a major therapeutic advantage in populations with high unmet need. PRIME is a voluntary scheme aimed at enhancing interaction and early dialogue with developers of promising medicines through achieving the early appointment of the Rapporteur for the product, optimizing development plans and speeding up evaluation so these medicines can reach patients earlier. Products benefiting from PRIME can expect to be eligible for accelerated assessment at the time of application for a marketing authorization application.

EU legislation also provides for a system of regulatory data and market exclusivity. According to Article 14(11) of Regulation (EC) No. 726/2004, as amended, and Article 10(1) of Directive 2001/83/EC, as amended, upon receiving marketing authorization, new chemical entities approved on the basis of a complete independent data package benefit from 8 years of data exclusivity and an additional 2 years of market exclusivity. Data exclusivity prevents regulatory authorities in the EU from referencing the innovator' s data to assess a generic (abbreviated) application. During the additional 2-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator' s data may be referenced, but no generic medicinal product can be marketed until the expiration of the market exclusivity. The overall 10-year period will be extended to a maximum of 11 years if, during the first 8 years of those 10 years, the marketing authorization holder (MAH) obtains an authorization for one or more new therapeutic indications that, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. Even if a compound is considered to be a new chemical entity and the innovator can gain the period of data exclusivity, another company nevertheless could also market another version of the drug if such company obtained marketing authorization based on a marketing authorization application with a completely independent data package of pharmaceutical test, preclinical tests and clinical studies. However, products designated as orphan medicinal products enjoy, upon receiving marketing authorization, a period of 10 years of orphan market exclusivity. See also "Orphan drug regulation" below. Depending upon the timing and duration of the EU marketing authorization process, products may be eligible for an SPC of up to 5 years' , pursuant to Regulation (EC) No. 469/2009. Such SPCs extend the rights under the basic patent for the drug.

In the EU, the pediatric regulation (Regulation (EC) No 1901/2006, as amended) requires sponsors to submit a pediatric investigation plan at the end of Phase 1. This plan will provide the details of the quality, non-clinical and clinical studies required to support the authorization of a pediatric indication. Additional rules apply to medicinal products for pediatric use under Regulation (EC) No. 1901/2006. Potential incentives include a six-month extension of any supplementary protection certificate granted pursuant to Regulation (EC) No. 469/2009, but not in cases in which the relevant product is designated as an orphan medicinal product pursuant to Regulation (EC) No. 141/2000, as amended. Instead, a medicinal product designated as an orphan medicinal product may enjoy an extension of the 10-year market exclusivity period granted under Regulation (EC) No. 141/2000 to 12 years subject to the conditions applicable to orphan drugs.

Orphan drug regulation

In the EU, Regulation (EC) No. 141/2000, as amended, states that a drug will be designated as an orphan drug if its sponsor can establish:

- that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than 5 in 10,000 persons in the EU when the application is made, or that it is intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition in the EU and that without incentives it is unlikely that the marketing of the drug in the EU would generate sufficient return to justify the necessary investment; and
- that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the EU or, if such method exists, that the drug will be of significant benefit to those affected by that condition.

Regulation (EC) No. 847/2000 sets out further provisions for implementation of the criteria for designation of a drug as an orphan drug. An application for the designation of a drug as an orphan drug must be submitted at any stage of development of the drug before filing of a marketing authorization application.

If a EU-wide community marketing authorization in respect of an orphan drug is granted or if all the EU Member States have granted marketing authorizations in accordance with the procedures for mutual recognition, the EU and the Member States will not, for a period of 10 years, accept another application for a marketing authorization, or grant a marketing authorization or accept an application to extend an existing marketing authorization, for the same therapeutic indication, in respect of a similar drug. This period may, however, be reduced to 6 years if, at the end of the fifth year, it is established, with respect to the drug concerned, that the criteria for orphan-drug designation are no longer met; in other words, when it is shown on the basis of available evidence that the product is sufficiently profitable not to justify maintenance of market exclusivity. Notwithstanding the foregoing, a marketing authorization may be granted, for the same therapeutic indication, to a similar drug if:

- the holder of the marketing authorization for the original orphan drug has given its consent to the second applicant;
- the holder of the marketing authorization for the original orphan drug is unable to supply sufficient quantities of the drug; or
- the second applicant can establish in the application that the second drug, although similar to the orphan drug already authorized, is safer, more effective or otherwise clinically superior.

Other incentives available to orphan drugs in the EU include financial incentives such as a reduction of fees or fee waivers and protocol assistance. Orphan-drug designation does not shorten the duration of the regulatory review and approval process.

Manufacturing and manufacturers' license

Pursuant to Directive 2003/94/EC, as transposed into the national laws of the Member States, the manufacturing of investigational medicinal products and approved drugs is subject to a separate manufacturer' s license and must be conducted in strict compliance with cGMP requirements, which mandate the methods, facilities and controls used in manufacturing, processing and packing of drugs to assure their safety and identity. Manufacturers must have at least one qualified person permanently and continuously at their disposal. The qualified person is ultimately responsible for certifying that each batch of finished product released onto the market has been manufactured in accordance with cGMP and the specifications set out in the marketing authorization or investigational medicinal product dossier. cGMP requirements are enforced through mandatory registration of facilities and inspections of those facilities. Failure to comply with these requirements could interrupt supply and result in delays, unanticipated costs and lost revenues, and subject the applicant to potential legal or regulatory action, including but not limited to warning letters, suspension of manufacturing, seizure of product, injunctive action, or possible civil and criminal penalties.

Wholesale distribution and license

Pursuant to Directive 2001/83/EC, the wholesale distribution of medicinal products is subject to the possession of an authorization to engage in activity as a wholesaler in medicinal products. Possession of a manufacturing authorization includes authorization to distribute by wholesale the medicinal products covered by that authorization. The distribution of medicinal products must comply with the principles and guidelines of cGDP.

Advertising

In the EU, the promotion of prescription medicines is subject to intense regulation and control, including EU and national legislation as well as self-regulatory codes (industry codes). Advertising legislation *inter alia* includes a prohibition on direct-to-consumer advertising. All advertising of prescription medicines must be consistent with the product' s approved Summary of Product Characteristics, and must be factual, accurate, balanced and not misleading. Advertising of prescription medicines pre-approval or off-label is not allowed. Some jurisdictions require that all promotional materials for prescription medicines be subjected to prior review and approval, either internal or regulatory.

Other regulatory requirements

A Marketing Authorization Holder ("MAH") for a medicinal product is legally obliged to fulfill a number of obligations by virtue of its status as an MAH. The MAH can delegate the performance of related tasks to third parties, such as distributors or marketing partners, provided that this delegation is appropriately documented and the MAH maintains legal responsibility and liability.

An MAH for a medicinal product is legally obliged to fulfill a number of obligations by virtue of its status as an MAH. The MAH can delegate the performance of related tasks to third parties, such as distributors or marketing partners, provided that this delegation is appropriately documented and the MAH maintains legal responsibility and liability.

The obligations of an MAH include the following:

Manufacturing and batch release. MAHs should guarantee that all manufacturing operations comply with relevant laws and regulations, applicable GMPs, and the product specifications and manufacturing conditions set out in the marketing authorization, and that each batch of product is subject to appropriate release formalities.

Availability and continuous supply. Pursuant to Directive 2001/83/EC, as transposed into the national laws of the Member States, the MAH for a medicinal product and the distributors of the said medicinal product actually placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medical product to pharmacies and persons authorized to supply medicinal products so that the needs of patients in the Member State in question are covered.

Advertising and promotion. MAHs remain responsible for all advertising and promotion of their products, including promotional activities by other companies or individuals on their behalf, and in some cases must conduct internal or regulatory pre-approval of promotional materials. Regulation in this area also covers interactions with healthcare practitioners and/or patient groups, and in some jurisdictions legal or self-regulatory obligations to disclose such interactions exist.

Medical affairs/scientific service. MAHs are required to disseminate scientific and medical information on their medicinal products to healthcare professionals, regulators and patients.

Legal representation and distributor issues. MAHs are responsible for regulatory actions or inactions of their distributors and agents.

Preparation, filing and maintenance of the application and subsequent marketing authorization. MAHs must maintain appropriate records, comply with the marketing authorization' s terms and conditions, fulfill reporting obligations to regulators, submit renewal applications and pay all appropriate fees to the authorities. We may hold any future marketing authorizations granted for our product candidates in our own name or appoint an affiliate or a collaboration partner to hold marketing authorizations on our behalf. Any failure by an MAH to comply with these obligations may result in regulatory action against an MAH and ultimately threaten our ability to commercialize our products.

International Regulation

In addition to regulations in the United States and Europe, a variety of foreign regulations govern clinical trials, commercial sales and distribution of product candidates. The approval process varies from country to country and the time to approval may be longer or shorter than that required for FDA or EMA approval.

Pharmaceutical coverage, pricing and reimbursement

In both domestic and foreign markets, our or our collaboration partners' sales of any approved products will depend in part on the availability of coverage and adequate reimbursement from third-party payors. Third-party payors include government authorities, managed care providers, private health insurers and other organizations. Patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients are unlikely to use our products, if approved, unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Sales of our products will therefore depend substantially, both domestically and abroad, on the extent to which the costs of our products will be paid by third-party payors. These third-party payors are increasingly focused on containing healthcare costs by challenging the price and examining the cost-effectiveness of medical products and services.

In addition, significant uncertainty exists as to the coverage and reimbursement status of newly approved healthcare product candidates. The market for our product candidates for which we may receive regulatory approval will depend significantly on access to third-party payors' drug formularies or lists of medications for which third-party payors provide coverage and reimbursement. The industry competition to be included in such formularies often lead to downward pricing pressures on pharmaceutical or biopharmaceutical companies. Additionally, third-party payors may refuse to include a particular branded drug in their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or another alternative is available. Because each third-party payor individually approves coverage and reimbursement levels, obtaining coverage and adequate reimbursement is a time-consuming, costly and sometimes unpredictable process. We may be required to provide scientific and clinical support for the use of any product to each third-party payor separately with no assurance that approval would be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. This process could delay the market acceptance of any product and could have a negative effect on our future revenues and operating results. We cannot be certain that our product candidates will be considered cost-effective. Because coverage and reimbursement determinations are made on a payor-by-payor basis, obtaining acceptable coverage and reimbursement from one payor does not guarantee we will obtain similar acceptable coverage or reimbursement from another payor. If we are unable to obtain coverage of, and adequate reimbursement and payment levels for, our product candidates from third-party payors, physicians may limit how much or under what circumstances they will prescribe or administer them and patients may decline to purchase them. This in turn could affect our ability to successfully commercialize our products and impact our profitability, results of operations, financial condition and future success.

In the EU, the pricing and reimbursement mechanisms by private and public health insurers vary largely by country and even within countries. The public systems reimbursement for standard drugs is determined by guidelines established by the legislator or responsible national authority. The approach taken varies by Member State. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. Other Member States allow companies to fix their own prices for medicines but monitor and control company profits and may limit or restrict reimbursement. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers to the entry of new products are being erected and some EU countries require the completion of studies that compare the cost-effectiveness of a particular product candidate with that of currently available therapies in order to obtain reimbursement or pricing approval. Special pricing and reimbursement rules may apply to orphan drugs. Inclusion of orphan drugs in reimbursement systems tend to focus on the medical usefulness, need, quality and economic benefits to patients and the healthcare system as for any drug. Acceptance of any medicinal product for reimbursement may come with cost, use and often volume restrictions, which again can vary by country. In addition, results based rules of reimbursement may apply.

Environmental, health, and safety laws and regulations

We are subject to numerous environmental, health and safety laws and regulations and permitting requirements, including those governing laboratory procedures, decontamination activities, and the handling, transportation, use, remediation, storage, treatment, and disposal of hazardous materials and wastes. Our operations involve the use of hazardous and flammable materials, and the risk of injury, contamination or noncompliance with environmental, health and safety requirements cannot be eliminated. Although compliance with such laws and regulations and permitting requirements has not had a material effect on our capital expenditures, earnings or competitive position, environmental, health and safety laws, and regulations and permitting requirements have tended to become increasingly stringent and, to the extent that legal or regulatory changes may occur in the future, they could result in, among other things, increased costs to us or the impairment of our research, development or production efforts.

C. ORGANIZATIONAL STRUCTURE

We are a Swiss stock corporation (*société anonyme*). We were originally formed in 2013, with our registered office and domicile in Geneva, Switzerland. Our Swiss enterprise identification number is CHE-113.516.874. We are located in the Canton of Geneva, City of Geneva, at Avenue de Sécheron 15, 1202 Genève, Switzerland.

As of the date of this Registration Statement we have the following subsidiaries:

Name	Domicile	Percent Owned
Relief Therapeutics International SA	Switzerland	100
Relief Therapeutics US, Inc.	Delaware (U.S.)	100
Relief Therapeutics, Inc.	Delaware (U.S.)	100
APR Applied Pharma Research SA	Switzerland	100
APR Applied Pharma Research Holding SA	Switzerland	100
APR Applied Pharma Research - Italy S.r.l.	Italy	100
APR Applied Pharma Research Deutschland GmbH	Germany	100
AdVita Lifescience GmbH	Germany	100
AdVita Lifescience AG	Switzerland	100
AdVita Lifescience, Inc.	Delaware (U.S.)	100

D. PROPERTY, PLANT AND EQUIPMENT

The Group leases approximately 1,800 square feet of office, lab space and representative offices located in Geneva and Balerna (Switzerland), Freiburg im Breisgau and Offenbach am Main (Germany), and Rome (Italy). Our headquarters are at Avenue de Sécheron 15, Geneva, Switzerland. We are not aware of any environmental issues or other constraints that would materially impact the intended use of our facilities. While we may require additional space and facilities our business expands, we believe that our current facilities are suitable and adequate to meet our current needs.

ITEM 4A. UNRESOLVED STAFF COMMENTS

None.

ITEM 5. OPERATING AND FINANCIAL REVIEW AND PROSPECTS

We are a company developing drugs via participation in active entities that have obtained intellectual properties through their own research activities, or via in-licensing, or via internal research and development activities. Historically, our development has focused primarily on clinical-stage projects based on molecules of natural origin (peptides and proteins) with a history of clinical testing and use in human patients or a strong scientific rationale. Following a pipeline expansion phase, we announced in August 2019 our intention to divest one of our subsidiaries, Relief Therapeutics SA, to Sonnet BioTherapeutics, Inc., which closed in March 2020. In 2021, we resumed our pipeline expansion with our acquisitions of APR Applied Pharma Research SA and Advita Lifescience GmbH. Our audited consolidated financial statements have been prepared in accordance with the International Financial Reporting Standards, International Accounting Standards, and Interpretations (IFRS) as issued by the International Accounting Standards Board (IASB).

The following discussion contains references to the financial statements of Relief Therapeutics Holding SA and its consolidated subsidiaries (also referred to as the Company). These financial statements consolidate the Company's subsidiaries and include the Company's interest in investments held at fair value. Subsidiaries are those entities over which the Company retains control. Where we have neither control nor significant influence for financial accounting purposes, we recognize our holding in such entity at fair value. For additional information regarding the accounting treatment of these entities, see Note 1 of our consolidated financial statements included in this registration statement. For additional information regarding our operating structure, see "Basis of Presentation and Consolidation" below.

A. OPERATING RESULTS

Overview

We are a commercial-stage biopharmaceutical company developing drug products for therapeutic use.

Historically, our development has focused primarily on clinical-stage projects with molecules of natural origin (peptides and proteins) that have a history of clinical testing and use in human patients and/or a strong scientific rationale. We announced in August 2019 our intention to divest one of our subsidiaries, Relief Therapeutics SA, to Sonnet BioTherapeutics, Inc., which divestiture closed in March 2020.

We are led by a proven and seasoned management team of business leaders with significant experience in discovering, developing and commercializing important new medicines, delivering them to market and maximizing shareholder value. Collectively, the members of our management team have overseen research and development of products supporting regulatory approvals as well as commercial launches of marketed products.

We are actively pursuing a strategy to diversify our portfolio and are continuously evaluating additional potential in-licensing and partnering opportunities. To bring assets as quickly as possible to the market, we are seeking partnerships with, or acquisitions of, companies that have late-stage clinical molecules, with a strong safety profile allowing for relatively short, capital-effective, clinical trials with objective endpoints. Our focus is on rare diseases with significant unmet medical need with an objective to maintain a lean organization, building a strong core of experienced, high performance experts that drive growth by effectively managing partnerships and efficiently allocating capital across the portfolio.

Aviptadil is a vasoactive intestinal peptide with predominant biological activity in the lungs. The clinical development program of RLF-100 is focused on various lung indications including; (i) COVID-19 induced acute respiratory distress syndrome ("ARDS"), (ii) COVID-19 non-acute lung injury ("NALI"); (iii) non-COVID-19 related ARDS; (iv) pulmonary sarcoidosis; (v) Berylliosis; and (vi) Checkpoint Inhibitor - induced Pneumonitis.

In March 2020, at the beginning of the first wave of the pandemic in the United States, our U.S. partner NeuroRx, Inc. ("NeuroRx") submitted an Investigational New Drug ("IND") application with the U.S. Food and Drug Administration (the "FDA") for a phase 2b/3 trial of RLF-100 for the intravenous ("IV") 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 subsequently treated in April 2020 at Thomas Jefferson University Hospital in Philadelphia. In June 2020, RLF-100 was awarded Fast Track designation by the FDA for the treatment of acute lung injury ("ALI") / ARDS associated with COVID-19. In July 2020, the FDA granted Expanded Access Protocol ("EAP") designation for treatment of respiratory failure induced by COVID-19 with RLF-100 IV. Treatment was available to patients who had exhausted standard therapies and were not eligible for the phase 2b/3 trial due to concomitant medical conditions.

In September 2020, we entered into a binding collaboration agreement with NeuroRx (the "Collaboration Agreement"). The Collaboration Agreement establishes the terms under which we and NeuroRx will collaborate and assist each other to maximize the revenues in their respective territories from the sale of aviptadil for intravenous and inhale use primarily for the treatment of COVID-19 related conditions. The collaboration agreement provides that NeuroRx will be responsible for developing and commercializing the product in the United States, Canada and Israel and that we will be responsible for developing and commercializing the product in the European Union, Switzerland, Iceland, Norway, the United Kingdom, the Channel Islands, Lichtenstein, Monaco, Andorra, San Marino and Vatican City. The collaboration agreement also provides that it will be conducted on an exclusive basis and that neither party may develop or commercialize any product that would be competitive with RLF-100.

The collaboration agreement includes profit sharing splits between the parties as follows: (i) net profits from sales of the product in NeuroRx' s territories will be split 50%/50% between Relief and NeuroRx, respectively; (ii) net profits from sales of the product in Relief' s territories will be split 85%/15% between Relief and NeuroRx, respectively; and (iii) net profits from sales of the product in the rest of the world will be split 80%/20% between Relief and NeuroRx, respectively.

In late 2020 and into early 2021, NeuroRx conducted a phase 2b/3 trial of intravenous aviptadil to evaluate its use in the treatment of respiratory failure due to COVID-19. In March 2021, NeuroRx reported the results of that trial. In its press release reporting those results, NeuroRx reported that across all patients and sites RLF-100 IV met the primary endpoint for successful recovery from respiratory failure at days 28 (p=0.14) and 60 (p=0.13) and also demonstrated a meaningful benefit in survival after controlling for ventilation status and treatment 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. On the basis of these findings, NeuroRx announced on June 1, 2021 that it had applied to the FDA for Emergency Use Authorization ("EUA") and that it planned to submit a New Drug Application with the FDA.

Also in March 2021, NeuroRx announced that RLF-100 had been selected for inclusion in "TESICO" (Therapeutics for Severely Ill Inpatients with COVID-19), a phase 3 multicenter clinical trial that will include sites in the United States and multiple foreign countries, that was being sponsored by the U.S. National Institutes of Health ("NIH"). On May 26, 2022, NRx reported that the Data and Safety Monitoring Board for the TESICO trial had determined that the evaluation of aviptadil in that trial should cease due to futility.

On June 16, 2021, NeuroRx' s parent corporation, NRx Pharmaceutical, Inc. ("NRx"), issued a press release reporting additional results from the aviptadil U.S. Expanded Access Protocol ("EAP"). The EAP included 240 patients in the intensive care unit (ICU) with critical COVID-19 respiratory failure requiring either invasive or non-invasive mechanical ventilation, or high flow rate oxygen by nasal cannula, and not eligible to participate in its phase 2b/3 clinical trial with IV aviptadil. According to NRx' s press release, these EAP data are being submitted by NeuroRx to the FDA as "real world" evidence in support of the findings from the phase 2b/3 trial.

On July 28, 2021, NRx issued a press release reporting that the Nation of Georgia' s Prime Minister and Minister of Health had issued an Emergency Use Authorization for intravenous aviptadil for the treatment of critical COVID-19, with the first doses being administered shortly thereafter. On March 9, 2022, NRx reported in a Form 8-K that in light of their strategic focus and the ongoing hostilities in Eastern Europe, it would not pursue opportunities in Georgia (which neighbors Russia and Ukraine), elsewhere in the Caucasus region or Europe. Further, NRx stated that its board of directors could not confirm the current status or effectiveness of the authorization for emergency use of ZYESAMI (aviptadil) in Georgia. NRx stated that although it engaged in an initial training of physicians, it has not sold any doses, and at this time, it has ceased efforts to pursue further regulatory drug interactions in Georgia or to conduct clinical trials there.

On November 5, 2021, NRx announced that the FDA had declined NeuroRx' s application for EUA of IV aviptadil for the treatment of acute respiratory failure due to critical COVID-19. In its press release, NRx stated that in the letter from the FDA denying EUA, the FDA noted that it has only reviewed safety data on 131 patients treated with aviptadil. NRx further announced in its press release that it will attempt to coordinate a review by the FDA of 150 or more additional patients treated with aviptadil through other trials. Additionally, NRx stated in its press release that the study' s Data Safety and Monitoring Board reviewing the trial found no safety issues. Further, on November 24, 2021, NRx reported that it was denied breakthrough therapy designation for the product. On June 10, 2022, NRx reported that its second application for Breakthrough Therapy Designation was also denied.

On January 6, 2022, NRx reported that NeuroRx had submitted an additional application to the FDA seeking EUA for the use of aviptadil to treat patients with critical COVID-19 who are at immediate risk for death from respiratory failure despite treatment with approved therapy, including Remdesivir. Additionally, on January 26, 2022, NRx issued a press release reporting NeuroRx' s receipt of a first safety report from a southwestern hospital where physicians have administered aviptadil to patients with COVID-19 respiratory failure. According to NRx' s press release, the patients were treated under the United States' Right to Try Act, which gives access to investigational medicines for patients who have been diagnosed with life-threatening diseases or conditions, who have tried all approved treatment options, and who are unable to participate in a clinical trial to access certain unapproved treatments. The press release stated that of the first 19 patients treated by December 31, 2021, three had died and sixteen (84%) were reported to be alive as of January 22, 2022. Further, NRx' s press release reported that 14 of these 16 patients had been discharged to a rehabilitation facility or to home. By way of comparison, according to "Clinical characteristics, risk factors and outcomes in patients with severe COVID-19 registered in the ISARIC WHO clinical characterisation protocol: a prospective, multinational, multicentre, observational study", published in the journal ERJ Open Research in January 2021, the overall 28-day fatality rate for COVID-19 patients admitted to the ICU was approximately 30.7%. The press release also indicated that this use of aviptadil had occurred during the then-current COVID-19 surge caused by the omicron variant, although patients were not necessarily tested for the specific COVID variant that caused their ICU admission. Finally, NRx stated that no serious adverse events were reported. There can be no assurance that NeuroRx' s reapplication seeking EUA for aviptadil for the treatment of acute lung disease caused by COVID-19 will be successful.

On November 29, 2021, NRx issued a press release announcing the results of a subsequent statistical analysis it commissioned from Dr. David Schoenfeld, a statistician with expertise in life-threatening diseases of the lung. According to the press release, Dr. Schoenfeld analyzed the subgroup of patients in the Phase 2b/3 trial that remained in respiratory failure despite treatment with remdesivir and stated that the analysis identified a statistically significant (p=0.03) 2.5-fold increased odds of a patient having survived and being free of respiratory failure at 60 days (the primary endpoint) and a statistically significant (p=0.006) four-fold higher odds of 60-day survival among patients treated with ZYESAMI compared to those treated with placebo.

On March 3, 2022, two U.S. Senators and two members of the House of Representatives sent a letter to Dr. Robert Califf, Commissioner of the FDA, and Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Disease regarding the results of the right-to-try administration of ZYESAMI. The letter discusses the results and seeks comment on the FDA review of the ZYESAMI EUA application and the FDA' s stance that the EUA will not be reviewed until the completion of clinical trials later this year. There can be no assurance that the letter will have any effect on the review and approval of the current EUA application.

While we have received a phase 2b/3 Study Report summary from NeuroRx and are reviewing the contents of the report to decide on the best path forward for the development of RLF-100 IV in Europe and other territories, NeuroRx has refused to share the full clinical trial data with us, which has prevented us from moving forward to seek approval for the product in its territories. They have also reported publicly their intent to file their own applications in Europe and the U.K. We believe that all of these actions, along with many others, constitute breaches of the Collaboration Agreement.

To that end, on October 7, 2021, we filed a lawsuit against NeuroRx and its then - CEO, Dr. Jonathan Javitt, for multiple breaches of the Collaboration Agreement between Relief and NeuroRx relating to the development and commercialization of RLF-100. The complaint was filed in the Supreme Court of the State of New York in Manhattan. The complaint alleges that the defendants are in breach of numerous provisions of the Collaboration Agreement. The complaint, among other remedies, seeks damages, an order compelling defendants to comply with multiple provisions of the Collaboration Agreement, and a declaration directing NeuroRx to deliver the entire data set from the Phase 2b/3 clinical trial of intravenously-administering aviptadil to Relief. On January 10, 2022, NeuroRx filed a complaint against us alleging that we are in breach of the Collaboration Agreement and have thus repudiated and cancelled the Collaboration Agreement. Additionally, NeuroRx claims that we, through our press releases and statements to investors, have defamed NeuroRx and Dr. Javitt. We believe that such claims are without merit. There can be no assurance as to the result of this litigation.

In March 2021, we signed a Collaboration and License Agreement with Acer Therapeutics, Inc. ("Acer") for the worldwide development and commercialization of ACER-001 for the treatment of Urea Cycle Disorders ("UCDs") and Maple Syrup Urine Disease ("MSUD"). ACER-001 is a proprietary powder formulation of sodium phenylbutyrate (NaPB) designed to be both taste-masked and immediate release.

In August 2021, Acer submitted an NDA for ACER-001 to the FDA for use as a treatment of UCD, which submission was accepted for filing in November 2021 with a PDUFA decision date of June 5, 2022. On June 7, 2022, Acer announced that it has not yet received a decision from the FDA on its NDA. Further, in accordance with our collaboration agreement with ACER, we are planning to submit an application for marketing authorization for this product to European and U.K. regulatory authorities, assuming ACER-001 is approved by the FDA.

On June 29, 2021, we announced that we had signed and closed a definitive agreement to acquire all outstanding shares of APR Applied Pharma Research SA ("APR"), a privately held Swiss pharmaceutical company with over 25 years' experience in identifying, developing and commercializing known molecules engineered with drug delivery systems in niche and rare diseases on a global basis.

APR is applying advanced patented pharma technologies, as well as proprietary delivery systems and novel dosage forms, to optimize the therapeutic potential of pharmaceuticals and improve patient outcomes. Its products are commercialized in about 50 countries worldwide. APR' s pipeline and portfolio include products for the treatment of rare or debilitating diseases. APR is, for example, commercializing Golike to improve metabolic control in patients suffering from phenylketonuria, a rare genetic metabolic disorder. A direct sales and marketing team is in place in selected European countries to support Golike, as well as established distribution partnerships for other countries in Europe and beyond. APR also has a strong pipeline of programs in development, including two orphan drug designations. Additionally, Sentinox, an intranasal spray to help block the transmission of the COVID-19 virus, recently received clearance as a Class III medical device in the EU.

On March 15, 2022, we announced that APR has signed a binding term sheet with Meta Healthcare Ltd. ("Meta"), our United Kingdom distribution partner for Golike, to acquire the worldwide commercialization rights, except in the United Kingdom and Ireland, for a novel dosage form of a prescription drug already approved by the FDA and intended for the treatment of patients with PKU. At this time, we plan to file an IND for the novel dosage form in the U.S. as soon as possible and to file for FDA regulatory approval sometime in the first half of 2023. Additionally, Meta has submitted a patent application in the United Kingdom and APR intends to seek a patent extension in all major territories including the U.S. and Europe.

We have also recently acquired all of the shares of AdVita Lifescience GmbH ("AdVita"), a Germany-based privately held pharmaceutical company developing effective products and strategies to improve the treatment and diagnosis of rare lung diseases. We believe that AdVita' s activities should help us further the development of RLF-100 for a range of lung diseases.

On November 24, 2021, we announced that we had 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 biopharma and other industries, in order to identify promising drug candidates to treat rare and specialty diseases (the "InveniAI Collaboration Agreement").

Under the terms of the InveniAI Collaboration Agreement, InveniAI will use its proprietary platform for the identification of potential pharmaceutical product opportunities using its Pharma Big Innovation Data Lab, consisting of (i) its proprietary AlphaMeld platform, a cloud-based artificial intelligence 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.

Material Agreements

We are party to certain agreements with third parties relating to licensing, collaboration, or other matters that are material to our business and performance.

NeuroRx

In September 2020, we entered into a collaboration agreement with NeuroRx for the global commercialization of RLF-100 and the selection of commercial partners. This partnership was designed to rapidly advance RLF-100 through clinical development so that it reaches COVID-19 patients worldwide as soon as possible. Under the agreement, NeuroRx is to lead commercialization in the United States, Canada, and Israel, while we are to lead commercialization in Europe and the rest of the world.

As described herein, we recently filed a lawsuit against NeuroRx and its CEO, Dr. Jonathan Javitt, alleging numerous breaches of this agreement. There can be no assurance as to the outcome of this matter.

Acer Therapeutics

On January 25, 2021, we entered into an option agreement with Acer Therapeutics Inc providing exclusivity for the right to negotiate a potential collaboration and license agreement ("CLA") for worldwide development and commercialization for ACER-001.

Under the terms of the option agreement, we paid Acer a $1 million USD non-refundable payment in return for exclusivity until June 30, 2021 to negotiate and enter into a definitive collaboration and license agreement for the development of ACER-001. Further, in connection with entering into the option agreement, we made a $4 million USD secured loan to Acer.

On March 22, 2021, both companies announced the execution of the CLA. Acer since received a $10 million USD cash payment (originally $14 million USD, offset by repayment of the $4 million USD outstanding balance of the prior loan, plus interest, to Acer). We have also paid Acer $20 million USD in U.S. development and commercial launch costs of the molecule for the treatment of the UCD and MSUD indications. Acer will retain development and commercialization rights in the U.S., Canada, Brazil, Turkey and Japan. The companies will split net profits from Acer' s territories 60%-40% in our favor. In addition, we have licensed the rights for the rest of the world, where Acer will receive from us a 15% royalty on all revenues received in our territories. Acer may also receive a total of $6 million USD in development milestone payments following the first European (EU) marketing approvals for UCDs and MSUD.

GEM Global Yield LLC SCS

On January 20, 2021, we signed a binding agreement with our largest shareholder, GEM Global Yield LLC SCS (GEM) for the implementation of a new Share Subscription Facility (SSF) in the amount of up to CHF 50 million.

Under the terms of the SSF, we have the right to periodically, during a timeframe of up to three years, issue and sell shares to GEM. Under the facility, GEM undertakes to subscribe to or acquire ordinary registered shares of the Company upon the Company' s exercise of a drawdown notice. In accordance with the customary terms of the SSF agreement, the Company controls the timing and maximum amount of any drawdown and retains the right, not the obligation, to draw down on the full commitment amount. Future subscription prices under the SSF will correspond to 90% of the average of the closing bid prices on the SIX Swiss Exchange during the reference period, which corresponds to fifteen trading days following Relief' s drawdown notice.

Shares issued under the SSF will not be registered under the Securities Act of 1933 and may not be sold in the U.S. securities market unless registered or unless an exemption from such registration is available.

We committed to pay GEM a commitment fee of CHF 1,250,000, payable upon proceeds from the first drawdown or on January 20, 2022. Pursuant to the terms at the SSF, this amount is currently outstanding as an interest-bearing loan.

APR Applied Pharma Research SA

On April 30, 2021, we entered into a binding term sheet with the then-current shareholders of APR Applied Pharma Research SA, a privately held Swiss company with over 25 years of experience in identifying developing and commercializing known molecules engineered with drug delivery systems in niche and rare diseases, to acquire all of the outstanding shares of APR. Under the term sheet, APR shareholders were to receive CHF 22 million in cash (plus or minus APR' s working capital adjustment), plus CHF 50 million payable in shares. APR' s shareholders may also be eligible to receive contingent payments in the form of a combination of cash and Relief registered ordinary shares upon achievement of pre-arranged contingent milestones. Further, APR had the right to designate an individual to stand for election as APR' s designee at Relief' s Annual General Meeting of Shareholders of June 18, 2021, and, it designated its CEO Paolo Galfetti for that purpose, who was appointed to the Board of Directors of Relief on that same date.

On June 28, 2021, the former shareholders of APR and Relief signed and closed a definitive agreement for Relief to acquire all outstanding shares of APR. Under the terms of the agreement APR' s shareholders have received from Relief CHF 21.5 million in cash and 206,786,784 Consideration Shares at a value of CHF 45 million when the consideration shares were issued and listed. The APR shareholders are also eligible to receive possible future contingent milestone payments in the aggregate maximum amount of up to CHF 35 million, upon achievement of pre-agreed objectives.

AdVita Lifescience GmbH

On January 20, 2021, we entered into an agreement with the then-current shareholders of AdVita Lifescience GmbH, a Germany-based, privately held pharmaceutical company developing effective products and strategies to improve the treatment and diagnosis of rare lung diseases, announced the signing of a binding term sheet for the Company to acquire all shares of AdVita in exchange for 25 million (approximately CHF 27.4 million) of the common shares of the Company, plus possible future contingent milestone payments of up to 20 million (approximately CHF 21.9 million). Under the terms of the agreement, we advanced a 2 million (approximately CHF 2.1 million) convertible secured loan to AdVita in two equal installments to fund the advancement of AdVita' s clinical development program of inhaled aviptadil for various pulmonary diseases.

On July 28, 2021, we announced the closing of a definitive agreement to acquire all of the outstanding shares of AdVita Lifescience GmbH. Under the agreement, the stockholders of AdVita received 135,741,063 of our common shares, representing 25 million (approximately CHF 27.1 million) in value based on a 60-day Volume Weighted Average Price of our common shares and are also eligible to receive additional contingent payments of up to 20 million (approximately CHF 21.9 million) in cash upon achievement of pre-agreed milestones.

In April 2022, we made an initial milestone payment of 5 million (approximately CHF 5.1 million) upon completion of the first milestone.

Arvato Service Agreement

Effective on September 1, 2018, APR entered into a Master Service Agreement with Arvato Services Italia S.R.L. ("Arvato"), which agreement was amended effective February 1, 2021 and again amended effective September 1, 2021. Pursuant to that agreement, Arvato provides logistic services for the commercialization of Golike in Europe, including order management, warehousing, transport management, financial services, returns management, customer service, and IT services. We are obligated to make payments to Arvato under this agreement for such services based on a pricing schedule. Arvato provides a monthly invoice with payments due 60 days after the invoice.

Royalty Purchase Agreement

APR is party to two agreements with SWK Funding LLC ("SWK") whereby APR transferred certain royalty revenues regarding Cambia sales to SWK, representing approximately half of such revenues. Only the net revenue received by APR is presented in its financial statements presented elsewhere in this Registration Statement on Form 20-F.

Basis of Preparation and Consolidation

Our consolidated financial statements have been prepared in accordance with IFRS, as issued by the IASB, and comply with Swiss law. They have been prepared under the historical cost convention, as modified by the revaluation of financial instruments at fair value, are presented in Swiss Francs (CHF), and all values are rounded to the nearest thousand (TCHF), except when otherwise indicated.

The consolidated financial statements comprise the financial statements of us and our subsidiaries as of December 31, 2021. Control is achieved when we are exposed, or have rights, to variable returns from our involvement with the investee and have the ability to affect those returns through our power over the investee.

Specifically, we control an investee if and only if we have:

- power over the investee (i.e., existing rights that give us the current ability to direct the relevant activities of the investee);
- exposure, or rights, to variable returns from our involvement with the investee; and
- the ability to use our power over the investee to affect our returns.

When we have less than a majority of the voting or similar rights over an investee, we consider all relevant facts and circumstances in assessing whether we have power over an investee, including:

- any contractual arrangement over the other vote holders of the investee;
- rights arising from other contractual arrangements; and
- our voting rights and potential voting rights.

We reassess whether or not we control an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control. Consolidation of a subsidiary begins when we obtain control over the subsidiary and ceases when we lose control of the subsidiary. Assets, liabilities, income and expenses of a subsidiary acquired or disposed of during the year are included in the statement of comprehensive income from the date we gain control until the date we cease to control the subsidiary.

Profit or loss and each component of other comprehensive income are attributed to the equity holders of RELIEF THERAPEUTICS Holding SA and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. When necessary, adjustments are made to the financial statements of subsidiaries to bring their accounting policies into line with our accounting policies. Inter-company transactions, balances and unrealized gains/losses on transactions between us and our subsidiaries are eliminated. The accounting policies of subsidiaries are consistent with the policies adopted by RELIEF THERAPEUTICS Holding SA.

Components of Our Results of Operations

Revenue

Prior to the acquisition of APR on June 28, 2021, we did not generate any revenue from product sales. At consolidated level, the acquisition of APR and AdVita led to the recognition of revenue only in the second half of 2021.

Research and Development Costs

Research and development expenses consist primarily of costs incurred for our research activities, which include:

- expenses related to research and development personnel;
- costs associated with preclinical testing and clinical trials of our product candidates; and
- expenses for research and development expenses (including under collaboration agreements and outsourced research and development expenses).

Any such costs are capitalized as current assets, except that where there is an identifiable asset that can be completed, that will generate probable future economic benefits and where the costs of such assets can be measured reliably, such assets will be capitalized as intangible assets.

We may also acquire in-process research and development assets, through purchases of specific assets or through business combinations. Such assets are capitalized as intangible assets and reviewed for impairment at each reporting date. Once available for use, these assets are amortized on a straight-line basis.

Employee benefits

Expenses relating to employee benefits include salaries, social security contributions (for our United States employee), paid annual and sick leave, bonuses, and non-monetary benefits. Such expenses are accrued in the year in which the associated services are rendered.

Our benefits under our defined benefit (pension) plan are determined using the projected unit credit method, pursuant to which costs are recognized immediately in the statement of financial position with a corresponding debit or credit to retained earnings through other comprehensive income in the period in which they occur.

Past service costs are recognized in profit or loss on the earlier of: the date of the plan amendment or curtailment, or the date that the restructuring-related costs are recognized.

The following changes in the net defined benefit obligation are recognized under ‘personnel expense’ in the consolidated statement of comprehensive income:

- service costs comprising of current service costs, past-service costs, gains and losses on curtailments and non-routine settlements; and
- net interest expense or income.

Share-based payments

The cost of share-based payments is recognized over the period in which the performance and/or service conditions are fulfilled. The cumulative expense recognized for such transactions at each reporting date reflects the extent to which the performance and/or service conditions underlying the share award are earned. The financial statements in any period represent the movement in cumulative expense recognized at the beginning and the end of such period.

No expense is recognized for awards that do not ultimately vest, except in certain cases.

Assets held for sale

Assets are classified as being held for sale if their carrying amount will be recovered through a sale transaction rather than from use. This condition is only met where the sale is highly probable, and the asset is available for immediate sale in its present condition. Management must be committed to the sale, and the sale must be expected to take place within one year of the date of classification. Where there is a commitment to a sale plan involving the loss of control of a subsidiary, all of the assets and liabilities of that subsidiary are classified as held for sale when those criteria are met, regardless as to whether there remains a non-controlling interest in the subsidiary.

Relief Financial Data

The following tables, which have been derived from our audited financial statements for the years ended December 31, 2021 and 2020, summarizes our balance sheet and results of our operations at the data and for the periods indicated, together with the changes for those items in thousands of CHF.

(in TCHF)	December 31,		
Statement of Operations Data	**2021**	**2020**	**Change (2021 to 2020)**
Revenue	3,321	–	3,321
Other gains	1,171	273	898
Total income	4,492	273	4,219
Raw materials and consumables expense	(750)	–	(750)
External selling and distribution expense	(365)	–	(365)
External research and develdopment expense	(19,024)	(13,672)	(5,352)
Personnel expense	(9,121)	(2,627)	(6,494)
Other administrative expense	(6,750)	(2,999)	(3,751)
Other losses	(752)	(1,260)	508
EBITDA	(32,270)	(20,285)	(11,985)
Reversal of impairment losses on intangible assets	–	11,200	(11,200)
Amortization and depreciation expense	(2,036)	–	(2,036)
Operating Result	(34,306)	(9,085)	(25,221)
Gain from disposal of a subsidiary	–	3,382	(3,382)
Financial income	97	7	90
Financial expense	(1,316)	(565)	(751)
Result before income taxes	(35,525)	(6,261)	(29,264)
Income taxes	820	(1,567)	2,387
Results for the Period	(34,705)	(7,828)	26,877

Balance Sheet Data	**December 31, 2021**
Current Assets	54,970
Total Assets	251,618
Equity	181,530
Non-Current Liabilities	50,355
Current Liabilities	19,733
Total equity and liabilities	251,618

APR Results of Operations

The following table, which has been derived from APR' s audited financial statements for the year ended December 31, 2020 and its unaudited financial statements for the period ended June 30, 2021 included herein, summarizes the result of APR' s operations for the periods indicated, in TCHF.

In thousands of CHF	Fiscal Year Ended December 31, 2020	Period Ended June 30, 2021
Statement of Operations Data:		
Revenue	10,100	3,590
Other gains	3,943	12
Total income	**14,043**	**3,602**
Goods and service expense	(6,069)	(1,686)
Personnel expense	(4,809)	(2,932)
Net impairment losses on financial and contract assets	(657)	117
General and administrative expense	(1,019)	(314)
Operating result	**1,489**	**(1,213)**
Depreciation and amortization expense	(1,053)	(547)
Profit before interest and taxes	**436**	**(1,760)**
Financial income and expense, net	(327)	(26)
Profit before income taxes	**109**	**(1,786)**
Income taxes	(315)	67
Loss for the year	**(206)**	**(1,719)**

Unaudited Pro Forma Financial Information of Relief and APR

The following unaudited pro forma condensed combined financial information is presented to illustrate the estimated effects of the acquisition by RELIEF THERAPEUTICS Holding SA (the "Company" or "Relief") of APR Applied Pharma Research SA ("APR") pursuant to a share purchase agreement (the "Share Purchase Agreement"), dated as of June 28, 2021, (the "Acquisition") by and among the Company and the then shareholders of APR (the "Sellers").

The following unaudited pro forma condensed combined financial information combines the historical consolidated financial information of Relief and APR (together the "Group"), after giving effect to the Company' s acquisition of APR as if it occurred on January 1, 2021.

As the acquisition of APR was completed prior to December 31, 2021, Relief' s balance sheet at that date includes the assets and liabilities of APR. Therefore, no pro forma balance sheet is required.

The unaudited pro forma condensed combined statement of operations for the year ended December 31, 2021 is based on the historical statements of operations of the Company and APR, after giving effect to the acquisition of APR as if it occurred on January 1, 2021 instead of its actual date (June 28, 2021). As APR' s statements of operations is consolidated within the Company' s consolidated statement of operations since July 1, 2021, APR' s statement of operations for the period from January 1, 2021 to June 30, 2021 is combined with the Company' s consolidated statement of operations for 2021 to obtain a combined statement of operations for the full year 2021.

The historical consolidated financial information has been adjusted to reflect factually supportable items that are directly attributable to the acquisition and, with respect to the unaudited pro forma condensed combined statements of operations only, expected to have a continuing impact on the combined results. Pro forma adjustments have been limited to only those adjustments that are directly attributable to APR acquisition, and, in the case of pro forma income statement adjustments, expected to have a continuing impact on the Company' s financial results.

The following unaudited pro forma condensed combined financial information has been prepared in accordance with Article 11 of Regulation S-X. The unaudited pro forma condensed combined financial statements are presented for informational purposes only and are not necessarily indicative of the condensed combined financial position or results of operations in future periods or the results that would have actually been realized if the acquisition had been completed as of the dates indicated. The unaudited pro forma condensed combined financial information does not purport to project the future financial position or results of operations of the combined entity.

The unaudited adjustments to the pro forma condensed combined financial information are described in the accompanying notes, which should be read together with the pro forma condensed combined financial information. The unaudited pro forma condensed combined financial information should be read together with the Company' s and APR' s historical financial statements, which are included elsewhere in this Form 20-F.

RELIEF THERAPEUTICS Holding SA
CONDENSED COMBINED STATEMENT OF OPERATIONS
For the year ended December 31, 2021
(in CHF thousands, except share and per share amounts)

	Relief (Historical)	APR (Historical-Unaudited)	Transaction Accounting Adjustments	Notes	Pro Forma Combined
Revenue	3,321	3,590			6,911
Other gains	1,171	12			1,183
Total Income	4,492	3,602			8,094
Raw materials and consumables expense	(750)	(751)			(1,501)
External selling and distribution expense	(365)	(194)			(559)
External research and development expense	(19,024)	(741)			(19,765)
Personnel expense	(9,121)	(2,932)			(12,053)
Other administrative expense	(6,750)	(314)			(7,064)
Other losses	(752)	–			(752)
Net impairment reversal gain on financial and contract assets	–	117			117
EBITDA	(32,270)	(1,213)			(33,483)
Amortization and depreciation expense	(2,036)	(547)	(1,496)	A	(4,079)
Operating result	(34,306)	(1,760)	(1,496)		(37,562)
Financial income	97	69			166
Financial expense	(1,316)	(95)			(1,411)
Net result before taxes	(35,525)	(1,786)	(1,496)		(38,807)
Income taxes	820	67	239	B	1,126
Net result for the period	(34,705)	(1,719)	(1,257)		(37,681)
OTHER COMPREHENSIVE INCOME					
Remeasurement of defined benefit obligation	152	505			657
Total items that will not be reclassified subsequently to profit or loss	152	505			657
Currency translation differences	255	88			343
Total items that may be reclassified subsequently to profit or loss	255	88			343
Total comprehensive income for the year, net of tax	407	593			1,000
Total comprehensive result for the period	(34,298)	(1,126)	(1,257)		(36,681)
EARNINGS PER SHARE					
Weighted average number of shares outstanding	3,593,069,451			C	3,711,233,327
Basic and diluted loss per share (in CHF)	(0.01)				(0.01)

RELIEF THERAPEUTICS Holding SA
NOTES TO THE UNAUDITED PRO FORMA CONDENSED COMBINED FINANCIAL STATEMENTS

1. Description of the Transaction

On June 28, 2021, the Company acquired all outstanding shares and voting rights of APR pursuant to the Share Purchase Agreement for (i) a cash consideration equal to CHF 21.5 million paid in June 2021 and (ii) 206,786,784 Relief common registered shares paid in July 2021. In addition, the Sellers are eligible to receive additional contingent payments up to CHF 35 million in a combination of cash and Relief common shares upon achievement of pre-agreed milestones.

2. Basis of presentation

The unaudited pro forma condensed combined financial information is based on the Company' s and APR' s historical consolidated financial information prepared in accordance with the International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB).

The Group' s historical financial information has been adjusted in the accompanying unaudited pro forma condensed combined financial information to reflect pro forma events that (i) are related to further transactions as part of APR acquisition, (ii) are a direct consequence of the purchase price allocation and have to be accounted for retroactively as of January 1, 2021 and (iii) are directly attributable to the acquisition and are not expected to have a continuing impact on the results of operations.

4. Pro Forma adjustments to the unaudited pro forma condensed combined financial statements

A/ Reflects the amortization of acquired intangible assets as if the Acquisition had occurred on January 1, 2021. The fair value of intangible assets acquired from APR has been estimated at TCHF 90,236, of which TCHF 39,358 accounts for the value of assets available to use in the meaning of IAS 38 and amortized over their useful lives on a straight-line basis. The useful lives, estimated on a per asset basis, range from 4 to 16 years with an overall value-weighted average of 14 years starting from January 1, 2021.

B/ Reflects the decrease of deferred tax liabilities in relation with the amortization of intangible assets described in adjustment A. Deferred tax liabilities attributable to the intangible assets of APR are calculated using APR' s effective income tax rate at the expected date of reversal of the temporary difference (15.96%).

C/ Reflects the increase in the weighted average number of shares outstanding following the issuance of 206,786,784 shares in connection with the Acquisition, as if the shares were outstanding as of the beginning of the period.

Comparison of the Years Ended December 31, 2021 and 2020

Revenue

(in TCHF)	2021	2020	Change
Revenue	3,321	–	3,321
Other gains	1,171	273	898
Total income	4,492	273	4,219

Revenue for 2021 was approximately CHF 3.32 million. Relief began generating revenue as a result of the business combination with APR at the end of June 2021, which generated net sales of approximately CHF 3.2 million in the six-month period from July 1, 2021 to December 31, 2021. In addition, revenue of CHF 0.1 million was derived from the sale of aviptadil by AdVita following its acquisition by Relief on July 28, 2021. Prior to these acquisitions, Relief had no revenues from product sales.

Other gains increased from approximately CHF 273,000 in 2020 to approximately CHF 1.17 million in 2021. These gains related mainly to non-recurring write-offs of liabilities.

APR generated revenue from sales, licensing fees, and royalties of approximately CHF 10.1 million in 2020, while APR' s combined pre- and post-acquisition revenue in 2021 was approximately CHF 6.8 million.

As disclosed elsewhere in this registration statement, APR' s 2021 annualized sales were less than its reported 2020 annual sales. In 2020, as indicated in note 19 of the accounts of APR for the fiscal year ended December 31, 2020, APR divested an exclusive license for the commercialization of Ondansetron RF in some of its territories. Such license accounted for approximately CHF 2.1 million in product sales in 2020 (0 in 2021). Ondansetron RF remains, however, commercialized by APR and its commercialization partners in other territories and accounts for approximately CHF 300,000 in annual revenue. Additionally, several of APR' s products are at the end of their life cycle. While there can be no assurance, the recently marketed product GOLIKE, the close-to-market nasal spray Sentinox, and the intended growth of development services provided to 3rd parties are expected to reverse the downward trend in the coming year.

Service expense

(in TCHF)	2021	2020	Change
Raw materials and consumables expense	750	–	750
External selling and distribution expense	365	–	365
Third-party research and development expense	19,024	13,672	5,352
Total service expense	19,459	13,672	6,467

Raw materials, consumables, selling and distribution expenses were incurred from July 1, 2021, with the acquisition of APR and AdVita and their respective selling activities. Our third-party research and development expenses for 2021 were approximately CHF 19.5 million, an increase of approximately 41% compared to CHF 13.7 million in 2020, and were primarily related to the development expenses incurred by Acer under the license and collaboration agreement and to the clinical development of RLF-100 (aviptadil). In 2020, third-party research and development expenses were primarily constituted by services provided by our collaboration partner, NeuroRx and other third parties in relation to clinical trials for RLF-100 in COVID-19 induced ARDS.

Personnel

(in TCHF)	2021	2020	Change
Salaries, including social security expense	4,485	76	4,409
Independent contractor fees	2,200	761	1,439
Share-based payment expense	1,143	1,048	95
Social security expense in relation to share-based payments	30	742	742
Service cost for other benefit obligations	1,243	–	1,243
Total personnel expense	9,101	2,627	6,474

Personnel expenses increased from CHF 2.6 million to CHF 9.1 million. The business combinations with APR and AdVita increased the number of full-time equivalents and consultants from a dozen to six dozen, before organizational adjustments realized in the fourth quarter of 2021. As of December 31, 2021, the Group employed 55 full time equivalents and consultants.

Other administrative expenses

(in TCHF)

	2021	2020	Change
Professional services	6,022	2,774	3,248
Capital tax	180	161	19
Other administrative expense	548	64	484
Total service expense	6,750	2,999	3,751

Our administrative expenses were approximately CHF 6.8 million in 2021, an increase of approximately 125.0% over 2020. The increase in 2021 was primarily attributable to our expanded activities with the addition of APR and AdVita, as well as to legal and consulting service needs to support our operations and development plans.

Other Losses

Our other losses for 2021 were approximately CHF 0.8 million and were primarily constituted by impairment losses on loans to third parties. In 2020, other losses amounted to CHF 1.26 million , of which CHF 1.2 million related to realized and unrealized valuation losses on the 757,933 shares of Sonnet BioTherapeutics Holdings, Inc. we had received in April 2020 as consideration for the sale of our subsidiary Relief Therapeutics SA.

Reversal of impairment losses on intangible assets

(in TCHF)

	2021	2020
Reversal of impairment losses on intangible assets	–	11,200

In 2020, we reversed the impairment recognized on our aviptadil asset in prior years for CHF 11.2 million. The impairment charge had entirely been recognized in 2019 as a result of the annual impairment test. Assumptions used in the valuation model assessing the recoverable value of the asset at December 31, 2019 did not consider the emergence of COVID-19 and our plan to develop aviptadil for the treatment of COVID-19. As our decision to pursue this development was taken in March 2020, after the balance sheet date, the then-new development plan was assessed as a non-adjusting subsequent event and the potential value of aviptadil for the treatment of COVID-19 was not factored in the valuation of the asset. The asset valuation at December 31, 2020 considered the possible use of aviptadil for COVID-19 and other indications. As a result, the impairment previously recognized was reversed.

Financial income (expense)

Our finance expenses for 2021 were CHF 1.32 million, an increase of 75.6% over finance expenses of CHF 713,000 in 2020. Significant financial expenses in 2021 were the partial recognition of the Share Subscription Facility fee, the change in fair value measurement of contingent liabilities, and negative interests charged on the Group' s Swiss francs deposits. In 2020, financial expenses were mainly constituted by foreign exchange losses.

Summary of critical accounting judgements and key sources of estimation uncertainty

Our operating and financial review and prospects were derived from our consolidated financial statements in conformity with IFRS as issued by the IASB. In the preparation of the financial statements, our management were required to make certain 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 judgements about carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates. The estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of our assets and liabilities within the next year are described below.

Valuation and impairment of intangible assets

Determining whether intangible assets are impaired requires our management to estimate the recoverable value of the cash-generating unit to which the intangible assets are attributable. If the recoverable value of the cash-generating unit is lower than the carrying amount of the cash-generating unit to which the intangible assets have been allocated, impairment is recorded. Changes to the assumptions may result in impairment losses or impairment reversals in subsequent periods.

Share-based compensation

The fair values of our options issued at their grant date have been assessed using the Black-Scholes valuation model and spread over the vesting period, with the significant inputs being share price, exercise price, expected life of the options, volatility, expected dividends on the underlying share for the expected term of the option, and risk-free interest rate.

Deferred income taxes

The determination of the recoverability of deferred income tax assets is based on the judgement of our management. Deferred income tax assets are only recognized where our management determines that it is probable that the assets can be used in the future. Whether or not they can actually be used, however, depends on whether they can be offset against future taxable profits. In order to assess this probability, our management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies. Deferred tax assets are only recorded when it becomes evident that sufficient future taxable profits are probable.

B. LIQUIDITY AND CAPITAL RESOURCES

Sources of Liquidity

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses. To date, we have funded our operations primarily through equity offerings and loans from our main shareholder GEM. Our ability to pursue and finance our operations and our intended development plans depends on our ability to raise financing.

We expect to continue to raise financing through sale of equity and license and development agreements in connection with collaborations. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of any additional securities may include liquidation or other preferences that adversely affect your rights as a shareholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through additional collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or to grant licenses on terms that may not be favorable to us.

We intend to use future expected proceeds, together with cash on hand, to finance our development 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. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant 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 collaborators. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations.

As of March 31, 2022, we had cash and cash equivalents of approximately CHF 37 million. As of June 28, 2022, we have cash and cash equivalents of approximately CHF 30.0 million.

Based on current financial current projections and available cash, we expect that we have sufficient resources to fund operations well into 2023, assuming timely approval of ACER-001. We also believe that that with a successful launch of ACER-001 and the potential expansion of our GOLIKE franchise into the United States, of which there can be no assurance, we could reach operating cash flow-positive operations during 2024, of which there can be no assurance. These forecasts of available cash assume no revenues from sales of RLF-100 (aviptadil). Accelerated growth strategy, potential milestone payments, and acquisitions will require significant additional funding. There can be no assurance that our commercialization efforts will be successful or if we need additional funding in the future, whether such funding will be available to us.

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 duration and severity of the COVID-19 pandemic;
- the timing amount of milestone payments we may have to pay in relation with 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 Group’ s borrowings; and
- a possible settlement agreement with NeuroRx.

Identifying potential product candidates and conducting preclinical studies and clinical trials is a time-consuming, expensive and uncertain process that takes many years to complete, and we may never generate the necessary data or results required to obtain marketing approval and achieve product sales. In addition, our product candidates, if approved, may not achieve commercial success.

If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market product candidates that we would otherwise prefer to develop and market ourselves.

Cash Flows

The following table summarizes our cash flows for each of the periods presented.

	December 31,		
In thousands	2021	2020	2019
Cash flow from operating activities	(35,718)	(18,254)	(728)
Cash flow from investing activities	(30,262)	3,005	–
Cash flow from financing activities	67,689	58,200	600
Net (decrease) increase in cash and cash equivalents	1,709	42,951	(128)
Cash and cash equivalents at end of period	44,761	43,154	137

Operating Activities

Net cash used in operating activities was approximately CHF 35.7 million in the year ended December 31, 2021, as compared to approximately CHF 18.3 million in the year ended December 31, 2020 and approximately CHF 728,000 in the year ended December 31, 2019. The gradual increase is mainly due to the funding of clinical trials for RLF-100, of ACER-001 development under our collaboration agreement with Acer, and of administrative expenses engaged for general corporate purpose.

Investing Activities

Cash used in investing activities was approximately CHF 30.3 million in the year ended December 31, 2021, as compared to cash flow from investing activities of approximately CHF 3.0 million in the year ended December 31, 2020, due to our acquisitions of APR Applied Pharma Research and ACER-001 license in 2021.

Financing Activities

Cash flow from financing activities was approximately CHF 67.7 million in the year ended December 31, 2021, as compared to approximately CHF 58.2 million in the year ended December 31, 2020 and approximately CHF 600,000 in the year ended December 31, 2019. Cash flow from financing activities came mainly from our Share Subscription Facility with GEM Global Yield LLC, private placements from third parties, and sale of treasury shares.

APR' s Intangible Assets

APR' s product portfolio is recorded on Relief' s December 31, 2021 balance sheet as follows:

	APR product portfolio					
TCHF	**PKU GOLIKE**	**Diclofenac**	**APR-TD011**	**Sentinox**	**Others**	**Total**
COST						
Balance at December 31, 2020	–	–	–	–	–	–
Acquired in APR business combination	31,244	7,705	47,392	3,487	408	**90,236**
Balance at December 31, 2021	**31,244**	**7,705**	**47,392**	**3,487**	**408**	**90,236**
ACCUMULATED AMORTIZATION						
Balance at December 31, 2020	–	–	–	–	–	–
Amortization expense	(1,008)	(799)	–	–	(33)	**(1,840)**
Balance at December 31, 2021	**(1,008)**	**(799)**	**–**	**–**	**(33)**	**(1,840)**
CARRYING AMOUNT						
at December 31, 2020	–	–	–	–	–	–
at December 31, 2021	**30,236**	**6,906**	**47,392**	**3,487**	**375**	**88,396**
Estimated remaining useful lives (years)	15.0	5.0	n/a	n/a	6.5	

The intangible assets acquired in the acquisition of APR are comprised of patents, trademarks, licenses, sub-licenses, technologies, in-process research and development products, and other assets without physical substance.

Products that have reached marketing phase consist mainly of:

PKU Golike®, an amino acid mix product commercialized for the treatment of phenylketonuria; and

Diclofenac, a product line indicated for the treatment of inflammatory conditions and for pain management. The active ingredient diclofenac is combined with APR' s proprietary technologies in products with immediate release formulation, or in the form of a topical patch. These products are commercialized by third parties under different brand names, including Cambia®, Voltfast® and Voltadol®.

The corresponding intangible assets will be amortized over their estimated remaining useful lives. Amortization is charged on a straight-line basis over the estimated economic or useful life, whichever is shorter.

In-process research and development ("IPR&D") projects consisted of:

APR-TD-011, a clinical-stage drug candidate for the treatment of epidermolysis bullosa; and

Sentinox™, a near-to-market product candidate for the reduction of the risk of infections caused by bacteria or viruses.

Amortization of IPR&D assets will commence when they are available for use.

Quantitative and Qualitative Disclosure about Financial Risks

We are exposed to various financial risks such as credit risk, liquidity risk and market risk (including interest rate and currency risk). The following is an overview of the extent of such risks and our processes employed to handle those risks.

Credit risk

Credit risk refers to the risk that a party will default on its contractual obligations to us, resulting in financial losses. We do not currently have any revenue and as a result we do not have credit risk with relation to our customers. Our financial assets consist of mainly cash, for which the risk is minimal as such deposits are at well-known banks in Switzerland with an "A" rating as per Standard & Poors.

Liquidity risk

Liquidity risk implicates our ability to maintain sufficient cash and cash equivalents to meet our financial obligations. Our management monitors our net liquidity through rolling forecasts of projected cash flows.

Interest rate risk

We have no interest-bearing assets or liabilities, except for short-term cash deposits and a fixed-interest third party loan. Cash deposits held in Swiss francs and Euros are subject to negative interest rates above certain thresholds defined by bank counterparties. We deem interest rate risk as being low.

Currency risk

We are exposed to foreign currency risk primarily through short-term cash deposits held in foreign currencies intended to fund operational expenditures in such currencies (mainly U.S. Dollars, Euros and Swiss francs). We are also exposed to foreign currency risk through third-party loans, other financial assets and trade payables, held or due in foreign currencies. We measure our exposure by periodically assessing future spending needs in foreign currencies.

Based on our analysis and considering that our cash balances in foreign currency are held for the settlement of expected invoices in those currencies, the risk is naturally hedged, and the foreign currency risk is limited.

During the years ended December 31, 2021 and 2020, we did not enter into any forward currency transactions nor any derivative currency contracts.

JOBS Act Exemptions and Foreign Private Issuer Status

We qualify as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act") in the United States. An emerging growth company may take advantage of specified reduced reporting and other requirements that are otherwise applicable generally to public companies. This includes an exemption from the auditor attestation requirement in the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002. We may take advantage of this exemption for up to five years or such earlier time that we are no longer an emerging growth company. We will cease to be an emerging growth company if we have more than $1.07 billion in total annual gross revenue, have more than $700 million in market value of our common shares held by non-affiliates or issue more than $1 billion of nonconvertible debt over a three-year period. We may choose to take advantage of some but not all of these provisions that allow for reduced reporting and other requirements.

Upon completion of the U.S. listing to which this registration statement relates, we will report under the Securities Exchange Act of 1934, as amended, or the Exchange Act, as a non-U.S. company with foreign private issuer status. Even after we no longer qualify as an emerging growth company, as long as we qualify as a foreign private issuer under the Exchange Act, we will be exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;
- sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time;
- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events; and
- Regulation FD, which regulates selective disclosures of material information by issuers.

C. RESEARCH AND DEVELOPMENT, PATENTS AND LICENSES, ETC.

See "Item 4. Information on the Company – B. Business Overview" and "Item 5. Operating and Financial Review and Prospects – A. Operating Results".

D. TREND INFORMATION

See "Item 5. Operating and Financial Review and Prospects – A. Operating Results and B. Liquidity and Capital Resources"

E. OFF-BALANCE SHEET ARRANGEMENTS

As of the date of this Registration Statement, the Company had the following contingent liabilities:

License and collaboration agreement with Acer

Under the license and collaboration agreement with Acer, the Group has committed to make possible milestone payments of up to USD 6 million in cash upon the achievement of certain regulatory milestones. Further, Relief has agreed to pay royalties of 15% on future net revenue of ACER-001 in Relief s territories.

Business combination with APR

The acquisition agreement with APR contains possible future contingent milestone payments in the aggregate maximum amount of up to CHF 35 million in a combination of cash and Relief common registered shares, upon achievement of pre-agreed objectives.

Acquisition of AdVita

The acquisition agreement with AdVita contains possible future contingent payments of EUR 15 million (approximately CHF 15.7 million) in cash, upon achievement of pre-agreed objectives.

NeuroRx claim

NRx Pharmaceuticals, Inc., the parent company of NeuroRx, has stated in its SEC filings that Relief has not paid NeuroRx approximately USD 13.8 million for costs associated with, among other matters, the phase 2b/3 clinical trial of aviptadil and the formulation and clinical development of aviptadil. Further, NeuroRx claims damages in excess of $185 million. Relief believes it has paid all amounts required to be paid under the Collaboration Agreement. Since the entire amount due to NeuroRx is in dispute, no provision for any liability has been recognized as of December 31, 2021. There can be no assurance as to the amount, if any, that the Company might ultimately be obligated to pay to NeuroRx.

There were no other material off-balance sheet arrangements.

F. TABULAR DISCLOSURE OF CONTRACTUAL ARRANGEMENTS

The following table summarizes our contractual commitments as of December 31, 2021:

(CHF thousands)	Less than 1 year	1 to 3 years	4 to 5 years	More than 5 years	Total
Lease liabilities (1)	352	88	29	0	469
Financial borrowings (2)	5,170	0	0	0	5,170
Total	5,522	88	29	0	5,639

(1) Represents the minimum lease payments due under our operating leases for offices, laboratory space, company cars, and office and labs material.
(2) Bank loans are classified as short term due to the absence of contractual repayment date that renders their repayment date uncertain and dependent on the creditor' s demand.

The table does not include trade payables and certain other liabilities that are reported on the consolidated balance sheet of the Group as of December 31, 2021 found elsewhere in this document. The table also does not include contractual obligations acquired in the business combination with AdVita in July 2021. We believe these contractual obligations are not material.

We have certain contingent payment obligations under the license agreement with Acer Therapeutics and under the acquisition contracts with the sellers of APR and AdVita. These obligations are described in section E above and are not included in this table as the timing and likelihood of such payments are not known.

Further, as described elsewhere in this document, we have committed to pay royalties on any revenue derived from the sale of aviptadil and ACER-001, to NeuroRx and Acer Therapeutics, respectively. We currently do not generate any revenue from these two compounds qualifying for royalty payments and therefore have no current payment obligations.

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

G. SAFE HARBOR

This registration statement contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, and as defined in the Private Securities Litigation Reform Act of 1995. See "Special Note with Respect to Forward Looking Statements" included elsewhere in this registration statement.

ITEM 6. DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. DIRECTORS AND SENIOR MANAGEMENT

For information about our directors and senior management, see "Item 1. Identity of Directors, Senior Management and Advisers – A. Directors and Senior Management".

B. COMPENSATION

Compensation in General

We are subject to the Directive on Information Relating to Corporate Governance of the SIX Swiss Exchange ("Corporate Governance Directive") and the Swiss Ordinance against Excessive Compensation in Public Companies of November 20, 2013, as amended from time to time ("Compensation Ordinance").

In line with the requirements of the Compensation Ordinance, the Company' s Articles of Association and the Organizational Regulation include provisions on the following governance and compensation-related matters:

- number of permissible mandates in the supreme governing bodies of other legal entities;
- maximum terms of employment contracts and maximum notice period for members of the Executive Committee;
- principles of compensation applicable to the Board of Directors and Executive Committee;
- shareholders' binding vote on compensation of the Board of Directors and Executive Committee;
- additional amount for members of the Executive Committee hired after the vote on compensation by the Annual General Meeting; and
- loans, credit facilities and post-employment benefits for members of the Board of Directors and of the Executive Committee.

Role of the Compensation Committee

The Nomination and Compensation Committee ("NCC") assists the Board of Directors in all nomination and compensation matters. As detailed in the Organizational Rules of the Company, the NCC is responsible for ensuring the best possible leadership and management talent for the company and an appropriate compensation policy. In particular, the NCC is responsible for the following activities:

- identification of suitable candidates for positions on the Board of Directors and on the Executive Committee;

recommendation and proposal of compensation principles and programs, including share-based compensation plans;

recommendation and proposal of the compensation for the members of the Board of Directors and Executive Committee; and

recommendation and proposal of specific compensation packages for other members of management.

The decision-making authorities in compensation matters are summarized in the table below:

Level of Authority	CEO*	Nomination and Compensation Committee	Board of Directors	Annual General Meeting
Compensation policy including share-based plans		proposes	approves	
Aggregate compensation of the Board of Directors		proposes	reviews	approves
Individual remuneration of the Board of Directors members		proposes	approves	
Aggregate compensation of the Executive Committee		proposes	reviews	approves
Individual compensation of the CEO		proposes	approves	
Individual compensation of Executive Committee members	proposes	reviews	approves	
Compensation report		proposes	approves	

* The authority ascribed to the former CEO was transferred to the NCC on an interim basis, until a new CEO is appointed.

The NCC consists of members of the Board of Directors who are elected individually and annually by the Annual General Meeting ("AGM") for the period until the following AGM. At the AGM 2022, each of the existing members of the NCC, Dr. Selvaraju and Dr. Plitz, were re-elected.

The NCC meets as often as the business requires, but at least once a year. The NCC Chairman may invite the Chairman of the Board, the CEO or other members of the Executive Committee to join the meeting in an advisory capacity. However, the executives do not take part in the meeting, or parts of meeting, during which their own compensation is discussed. The NCC Chairman reports to the Board of Directors on the activities of the committee after each meeting. The minutes of the NCC meetings are made available to all members of the Board of Directors. The NCC may retain external advisors to get support in fulfilling its duties.

Role of Shareholders and Say-On-Pay Vote

The Extraordinary General Meeting (EGM) held on January 28, 2022 approved a maximum amount of CHF 2.5 million for members of the Board of Directors for the period from AGM 2021 to AGM 2022. The AGM 2021 had previously accepted a maximum amount of CHF 1.5 million. The maximum compensation amount payable to members of the executive committee for the 2022 fiscal year was approved at the AGM 2021.

At the AGM 2022, held on May 31, 2022, the shareholders approved a maximum amount of CHF 2.5 million (both fixed and variable compensation, including stock options and other benefits, but excluding employer social security contributions) for members of the Board of Directors for the period from the AGM 2022 to the AGM 2023. In addition, the AGM approved a maximum total compensation of CHF 5 million (both fixed and variable compensation, including stock options and other benefits, but excluding employer social security contributions) for the members of the Executive Committee for the financial year 2023.

Method of Determination of Compensation

Based on the recommendation of the NCC, the Board of Directors decides upon the compensation of the Board of Directors and Executive Committee at its own discretion, which is ultimately approved by the AGM. When preparing the compensation proposals, the NCC takes the following factors into consideration:

affordability and overall situation of the Company;

business financial results and individual performance; and

level of compensation paid by other companies that are deemed to be comparable in terms of industry (where they compete for talent) and complexity (defined by their size and geographic scope).

The compensation of the Board of Directors and Executive Committee is reviewed annually on the basis of those factors; however, the review does not necessarily lead to any adjustment.

Executive Compensation

In accordance with the laws of Switzerland, we do not report executive compensation on an individualized basis. The disclosure below includes all forms of compensation given by us in exchange for services rendered in 2021 by members of the Executive Committee.

In 2020 and 2021, members of the Executive Committee received total remuneration as follows:.

Compensation of the Executive Committee for the 2021 Calendar Year, in CHF

	Fixed Compensation	Cash Bonus	Pension Benefits	Options (2)	Total (3)
Total Executive Committee (1)	1,763,451	231,340	30,151	1,947,634	3,972,476

(1) The highest paid member of the Executive Committee in 2021 was our Chief Financial Officer, Jack Weinstein, who received CHF 460,614 of fixed compensation, CHF 175,000 of variable cash compensation and CHF 1,096,799 of options.
(2) Reflects the value of share-based payments in accordance with IFRS 2 at grant date independently of the vesting schedule. Such stock option values are theoretical values at grant date and do not reflect taxable income nor realized income.
(3) Does not include the Company' s mandatory contribution to social security (AHV) of CHF 82,953

Compensation of the Executive Committee for the 2020 Calendar Year, in CHF

	Fixed Compensation	Cash Bonus	Pension Benefits	Options (2)	Total (3)
Total Executive Committee (1)	442,316	–	–	26,016	468,332

(1) The highest paid member of the Executive Committee in 2020 was our former Chief Medical Officer, Dr. Della Corte, who received CHF 99,357 of fixed compensation as a contractor from September 1, 2020.
(2) Reflects the value of share-based payments in accordance with IFRS 2 at grant date independently of the vesting schedule. Such values are theoretical and do not reflect taxable income.
(3) Does not include the Company' s mandatory contribution to social security (AHV) of CHF 5,691.

During the 2021 fiscal year, remuneration to the executive committee amounted to CHF 3,972,476. This was within the limit of CHF 5,000,000 approved by the AGM 2021. During the 2020 fiscal year, remuneration to the Executive Committee totaled CHF 468,332. This was within the limit of CHF 1.2 million approved by our Annual General Meeting in 2020.

In 2021, we did not issue any payment to a former member of the Executive Committee. However, former members of the Executive Committee have exercised options granted in previous years, which resulted in an obligation to pay mandatory social security contributions of CHF 94,775. In 2020, we issued payments of CHF 4,650 to a former member of the Executive Committee in exchange for consulting services. In addition, former members of the Executive Committee exercised options granted in 2017 and 2018, which resulted in an obligation for the Company to pay employer' s contribution to social security estimated at CHF 635,000 as of December 31, 2020.

Employment Arrangements

We have entered into employment letters with each of our executive officers. These agreements provide for a base salary and annual incentive cash and option bonus opportunities as well as payments upon termination. Mr. Galfetti' s agreement may be terminated upon twelve months' advance notice, while each of our other executive officers are employed on an at-will basis.

Principles and Compensation Architecture

Our compensation principles are aligned with our strategy of becoming profitable by generating new business and increasing revenue, while improving cost efficiency and restructuring business processes. The compensation principles are:

balance between competitiveness and affordability: as far as possible within our financial ability, compensation levels are competitive and aligned with market practice for similar functions in comparable companies;

pay for performance: part of compensation is directly linked to the performance of the business and to the achievement of individual objectives; and

alignment with shareholders' interests: part of compensation is delivered in the form of stock options and is thus directly tied to our long-term share performance.

The compensation of our executive officers consists of a fixed base salary, possibly a performance-based cash bonus, a grant of share options, and benefits.

Compensation model for executive officers

	Vehicle	Purpose	Drivers	Performance
Fixed Base Salary	Monthly Cash	Attract & Retain	Market practice	–
Performance bonus	Cash bonus	Pay for performance	Business and individual performance	Company' s profitability, individual performance
Employee Participation Program	Share options	Align to shareholders' interests	Level of the role	Share price
Benefits	Pension/insurance plans	Protect against risk	Market practice	–

Fixed base salary. The fixed base salary pays for the function and depends on our financial ability, the market value of the function and the profile of the individual in terms of qualifications and skill set.

Performance bonus. The performance bonus rewards the profitability of the business and the achievement of individual objectives over a period of one year. The target performance bonus is expressed as a percentage of fixed base salary. Generally, there is no bonus payout if we do not generate a profit. When we are profitable or at the discretion of the Board of Directors and NCC, a decision to grant a bonus may be taken. The bonus amount effectively paid out is then determined by the Board of Directors, based upon the proposal of the NCC. The performance bonus is paid in cash or options, usually in April of the following year.

Employee Participation Program. The Employee Participation Program provides an incentive for management to make significant contributions towards our long-term success and aligns their interests to those of our shareholders. The Board of Directors determines the individual allocation of stock options at its own discretion, taking into account the level of the role and economic considerations. The value of the options for financial reporting purpose is calculated according to the Black-Scholes valuation model.

Benefits. Executive Officers participate in the regular pension and retirement plans applicable to all employees in their country of employment. The provisions of those pension and retirement plans are in line with local regulations and prevailing market practice. Further, executive officers may be entitled to benefits in kind, in line with local market practice, such as a company car or other benefits.

Contractual provisions. The employment contracts of our executive officers are concluded for an indefinite period and without a notice period. They do not contain any agreement on severance provisions.

NON-EMPLOYEE DIRECTOR COMPENSATION

The disclosure of compensation below includes all forms of compensation given by us in exchange for services rendered by members of our Board of Directors in 2020 and 2021, in CHF.

Board of Directors	Cash Fee 2021	Cash Fee 2020	Options 2021 (1)	Options 2020 (1)	Total 2021 (2)	Total 2020 (2)
Raghuram Selvaraju Chairman since May 25, 2016	475,000	–	248,470	418,548	723,470	418,548
Thomas Plitz Member since December 17, 2020	125,000	–	266,103	–	391,103	–
Patrice Jean Member since June 18, 2021	76,998	–	16,330	–	93,329	–
Paolo Galfetti (3) Member since June 18, 2021	79,722	–	–	–	79,722	–
Michelle Lock Member since January 28, 2022	–	–	–	–	–	–
Thomaz Burckhardt Member until February 8, 2021	7,500	127,500	–	253,340	7,500	380,840
Peter de Svastich Member until December 17, 2020	–	–	–	308,403	–	308,403
Total	764,220	127,500	530,903	980,291	1,295,123	1,107,791

(1) Reflects value of share-based payments in accordance with IFRS 2 at grant date independently of the vesting schedule. Such stock option values are theoretical values at grant date and do not reflect taxable income nor realized income.

(2) Does not include the Company' s mandatory contribution to social security of CHF 18,628 (2020: nil). In 2021, the Company did not incur any social security costs in relation with options exercised by former members of the Board (2020: CHF 102,186)

(3) As President of Relief Europe and CEO of APR, Mr. Galfetti received a remuneration of CHF 226,090 in cash (including pension contribution) and CHF 655,801 in options for the period from the date the Company acquired APR to year-end 2021. His executive compensation is reported above.

In 2021, no compensation was granted to former members of the Board of Directors or related parties.

Option Grants to members of the Board of Directors and Executive Committee

During 2020 and 2021, the following options to purchase shares of the Company' s common stock as listed on the SIX Swiss Exchange were granted to members of the Board of Directors and Executive Committee:

Date of Grant	Options Granted	Strike Price (in CHF)	Expiration Date
August 2020	7,063,197	0.0100	August 2026
October 2020	100,000	0.4950	October 2024
January 2021	100,000	0.2690	December 2025
May 2021	6,000,000	0.0100	1/2 in each of May 2027 and 2028
September 2021	1,900,000 3,200,000	0.0100 0.1540	1/3 in each of September 2027, 2028 and 2029
December 2021	3,000,000	0.0100	December 2027
December 2021	15,500,000 11,000,000	0.0610 0.0100	1 1/3rd in each of December 2027, 2028 and 2029

C. BOARD PRACTICES

Our Board of Directors currently consists of five members, with three members determined by the Board at Directors to be independent. As a foreign private issuer, under the listing requirements and rules of the Nasdaq Global Market, we are not required to have independent directors on our Board of Directors, except that our audit committee is required to consist fully of independent directors, subject to certain phase-in schedules.

Overview

The Board of Directors is self-constituting and determines our internal organization. The Chairman convenes the Board as often as our affairs require and presides (or in his absence, another Board member specifically designated by the majority of the other members present at the meeting) over the Board meetings. Each Board member is entitled to request to the Chairman, in writing, a meeting of the Board by indicating the grounds for such a request. The Chairman decides on the agenda items and motions. Every Director is entitled to request to the Chairman, in writing, the inclusion of a specific agenda item by indicating the grounds for such a request.

To pass a valid resolution, the majority of the Board members has to attend the meeting. Meetings may also be held by telephone or video conference, to which all the Board members are invited. No quorum is required for confirmatory resolutions and adaptations of the Articles in connection with capital increases. The Board of Directors passes its resolutions by way of simple majority. The members of the Board may only vote in person, not in proxy. In the event of a tie vote, the Chairman has the deciding vote. Minutes of deliberations and resolutions are kept and signed by the Chairman and the designated Secretary.

The Board has established the following permanent committees to further strengthen our corporate governance structure.

Audit and Finance Committee

The Audit and Finance Committee (AFC) advises the Board of Directors in the performance of its supervisory duties. In particular, the AFC reviews the financial reporting to shareholders and the general public as well as the relationship with the external auditors; satisfies itself that our financial risk management and our internal controls are of an appropriate standard; ensures that its activities are consistent and compliant with the Organizational Regulations; assesses adherence to the relevant 'best practice' corporate governance provisions, to the extent such practice has effect on the activities and the functions of the AFC; satisfies itself that our overall fraud prevention procedures are of an appropriate standard and ensures that appropriate procedures to enable employees to confidentially and anonymously submit their concerns regarding accounting, internal controls or auditing matters are in place.

Nomination and Compensation Committee

The Nominating and Compensation Committee advises the Board of Directors in the performance of its supervisory duties related to nomination and compensation matters. It is responsible for ensuring the best possible leadership and management of the Company and for determining compensation policies, including share-based incentive programs, for the Company' s top management and Board of Directors.

Corporate Governance Committee

The Corporate Governance Committee advises the Board on all matters of corporate governance. It is responsible for carrying out in-depth analysis of specific corporate governance-related matters and monitors compliance with corporate governance principles and policies.

Other Corporate Governance Matters

The Sarbanes-Oxley Act of 2002, as well as related rules subsequently implemented by the SEC, requires foreign private issuers, including our company, to comply with various corporate governance practices. In addition, Nasdaq rules provide that foreign private issuers may follow home country practice in lieu of the Nasdaq corporate governance standards, subject to certain exceptions and except to the extent that such exemptions would be contrary to U.S. federal securities laws.

We intend to take all actions necessary for us to maintain compliance as a foreign private issuer under the applicable corporate governance requirements of the Sarbanes-Oxley Act of 2002, the rules adopted by the SEC and Nasdaq' s listing standards.

Because we are a foreign private issuer, our directors and senior management are not subject to short-swing profit and insider trading reporting obligations under Section 16 of the U.S. Securities Exchange Act of 1934, as amended, or the Exchange Act. They will, however, be subject to the obligations to report changes in share ownership under Section 13 of the Exchange Act and related SEC rules.

Indemnification of Officers and Directors

Under Swiss law, a corporation may indemnify its officers and directors against losses and expenses, except for such losses and expenses arising from willful misconduct or negligence (although some legal scholars advocate that at least gross negligence be required), including attorney' s fees, judgments, fines, and settlement amounts actually and reasonably incurred in a civil or criminal action, suit or proceeding by reason of having been the representative of, or serving at the request of, the corporation.

Subject to Swiss law, our articles of association provide for indemnification of the exiting and former members of our board of directors, executive management, and the heirs, executors and administrators, against liabilities arising in connection with the performance of their duties in such capacity, and permits us to advance the expenses of defending any act, suit or proceeding to members of our board of directors and executive management. In addition, under general principles of Swiss employment law, an employer may be required to indemnify an employee against losses and expenses incurred by such employee in the proper execution of their duties under their employment agreement with the company.

We have entered into indemnification agreements with each of the members of our board of directors and with our executive officers.

D. EMPLOYEES

At December 31, 2021, we had a total of 55 employees. Our relationship with our employees is good and no employees are covered by a labor union. We did not employ any temporary employees during 2021.

E. SHARE OWNERSHIP

For information about share ownership by our directors and senior management, see "Item 7. Major Shareholders and Related Party Transactions - A. Major Shareholders".

ITEM 7. MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. MAJOR SHAREHOLDERS

The following table sets forth information with respect to the beneficial ownership of our common shares as of March 31, 2022 by:

- each of our executive officers;
- each of our directors; and
- each person, or group of affiliated persons, who is known by us to beneficially own more than 3 percent of our outstanding common shares.

As of June 28, 2022, we had 4,416,334,617 ordinary shares outstanding.

Beneficial ownership is determined in accordance with the rules and regulations of the SEC and includes voting or investment power with respect to our common shares. Common shares subject to options that are currently exercisable or exercisable within 60 days after March 31, 2022 are considered outstanding and beneficially owned by the person holding the options for the purpose of calculating the percentage ownership of that person but not for the purpose of calculating the percentage ownership of any other person. Except as otherwise noted, the persons and entities in this table have sole voting and investment power with respect to all of the common shares beneficially owned by them, subject to community property laws, where applicable. Except as otherwise set forth below, the address of the beneficial owner is c/o the Company. The information in the table below is based on information known to us or ascertained by us from public filings made by the shareholders. We have also set forth below information known to us regarding any significant change in the percentage ownership of our common shares by any major shareholders during the past three years. The major shareholders listed below do not have voting rights with respect to their common shares that are different from the voting rights of other holders of our common shares.

Name	Shares	Options	Percentage	
3 Percent Stockholders				
GEM Global Yield LLC SCS†	1,158,000,000	0	26.24	%*
Executive Officers and Directors				
Jack Weinstein	135,000	3,100,000	*	*
Anthony M. Kim	0	3,000,000	*	*
Jeremy Meinen	140,655	1,100,000	*	*
Nermeen Varawalla	0	3,000,000	*	*
Marco Marotta	0	1,500,000	*	*
Raghuram Selvaraju	0	8,963,197	*	*
Thomas Plitz	0	1,500,000	*	*
Patrice Jean	140,000	200,000	*	*
Paolo Galfetti	18,250,174	1,500,000	*	*
Michelle Lock	0	0	*	*

† As set forth in a filing with the SIX Swiss Stock Exchange on May 10, 2022. Pursuant to such filing, Christopher Brown, a resident of the State of New York, is a beneficial owner of such shares.
* Calculated at the date of notification based on the number of outstanding shares registered at the Commercial Register of Geneva.
** Less than one percent.

We are not aware of any arrangement, the operation of which may result in a change of control of the Company.

B. RELATED PARTY TRANSACTIONS

The following is a description of related party transactions we have entered into with the beneficial owners of 10 percent or more of our common shares, which are our only voting securities, senior management and members of our Board of Directors, since January 1, 2021.

GEM Global Yield LLC SCS

On January 20, 2021, we signed a binding agreement with our largest shareholder, GEM Global Yield LLC SCS ("GEM") for the implementation of a new Share Subscription Facility ("SSF") in the amount of up to CHF 50 million.

Under the terms of the SSF, we have the right to periodically, during a timeframe of up to three years, issue and sell shares to GEM. Under the facility, GEM undertakes to subscribe to or acquire ordinary registered shares of the Company upon the Company' s exercise of a drawdown notice. In accordance with the customary terms of the SSF agreement, the Company controls the timing and maximum amount of any drawdown and retains the right, not the obligation, to draw down on the full commitment amount. Future subscription prices under the SSF will correspond to 90% of the average of the closing bid prices on the SIX Swiss Exchange during the reference period, which corresponds to fifteen trading days following Relief' s drawdown notice.

Under the terms of the SSF, we will be required to pay GEM a commitment fee of CHF 1.25 million, which is currently outstanding as an interest-bearing loan pursuant to the SSF.

The following additional transactions were carried out with our executive officers and members of our board of directors

Key Management Compensation, in TCHF	2021	2020
Fees, salaries and other short-term employee benefits	2,759	570
Post-employment benefits	30	–
Share-based compensation	814	1,006
Total compensation for key management	3,603	1,576

C. INTERESTS OF EXPERTS AND COUNSEL

None.

ITEM 8. FINANCIAL INFORMATION

A. CONSOLIDATED STATEMENTS AND OTHER FINANCIAL INFORMATION

Consolidated Financial Statements

Our audited financial statements for the fiscal years ended December 31, 2021 and 2020 and APR' s audited financial statements for the fiscal year ended December 31, 2020 are included in Item 18 of this registration statement.

Legal Proceedings

From time to time, we may become involved in legal, governmental or arbitration proceedings or be subject to claims arising in the ordinary course of our business. We are currently in litigation with our U.S. partner for RLF-100, NeuroRx; for additional information on that litigation, see Item 4. Information on the Company- B. Business Overview − Dispute and Litigation with NeuroRx. Except as set forth therein or elsewhere in this Registration Statement, we are not presently a party to any legal, governmental or arbitration proceeding that could have a material adverse effect on the Group' s financial performance or results of operations. Regardless of the outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Dividend Distribution Policy

We have not paid any dividends since our incorporation. Even if future operations lead to significant levels of distributable profits, we currently intend that any earnings will be reinvested in our business and that dividends will not be paid until we have an established revenue stream to support continuing dividends. Under our articles of association, the declaration of dividends requires a resolution passed by a simple majority of the votes cast at a shareholders' meeting regardless of abstentions and empty or invalid votes. The proposal to pay future dividends to shareholders will in addition effectively be at the discretion of our board of directors after considering various factors including our business prospects, liquidity requirements, financial performance and new product development. In addition, payment of future dividends is subject to certain limitation pursuant to Swiss law or by our articles of association. Accordingly, investors cannot rely on dividend income from our common shares and any returns on an investment in our common shares will likely depend entirely upon any future appreciation in the price of our common shares.

B. SIGNIFICANT CHANGES

As disclosed elsewhere in this registration statement, APR' s 2021 annualized sales were less than its reported 2020 annual sales. In 2020, as indicated in note 19 of the accounts of APR for the fiscal year ended December 31, 2020, APR divested an exclusive license for the commercialization of Ondansetron RF in some of its territories. Such license accounted for approximately CHF 2.1 million in product sales in 2020 (0 in 2021). Ondansetron RF remains, however, commercialized by APR and its commercialization partners in other territories and accounts for approximately CHF 300,000 in annual revenue. Additionally, several of APR' s products are at the end of their life cycle. While there can be no assurance, the recently marketed product GOLIKE, the close-to-market nasal spray Sentinox, and the intended growth of development services provided to 3rd parties are expected to reverse the downward trend in the coming year.

Except as otherwise disclosed above or elsewhere in this registration statement, there has been no significant change since the date of the most recent financial statements included in this registration statement.

ITEM 9. THE OFFER AND LISTING

A. OFFER AND LISTING DETAILS

The principal trading market for our common shares is the main market of the SIX Swiss Exchange, where our common shares have been traded since our inception under the ticker symbol "RLF." Our common shares are also traded on the over-the-counter market under the symbol "RLFTF".

In early November 2021, we took the first step to establish a Level 1 American Depositary Receipt (ADR) program in the United States by filing a registration statement on Form F-6 with the U.S. Securities and Exchange Commission. The Registration Statement became effective on November 12, 2021, and our ADRs have begun trading in the over-the-counter (OTC) market under the symbol "RLFTY". Our ADR program will complement our existing primary listing on the SIX Swiss Exchange. JPMorgan Chase Bank, N.A. has been appointed as the depositary bank for the Level 1 ADR program. This filing is the first step in a process through which we hope to transition our ADR program from a Level 1 ADR program to a Level 2 ADR program, with the ultimate goal of listing our ADRs on the NASDAQ Stock Market during the first half of 2022. For a description of the rights of our ADRs, see "Item 12. Description of Securities Other Than Equity Securities – D. American Depositary Receipts."

B. PLAN OF DISTRIBUTION

Not applicable.

C. MARKETS

Our common shares trade on the SIX Swiss Exchange (SIX) under the symbol "RLF" and over the counter in the United States under the symbol "RLFTF". Our ADRs trade in the over-the-counter market under the symbol "RLFTY," and we intend in the future to seek to list our ADRs on the NASDAQ Stock Market. We make no representation that such application will be approved or that our ADRs will trade on such market either now or at any time in the future.

D. SELLING SHAREHOLDERS

Not applicable.

E. DILUTION

Not applicable.

F. EXPENSES OF THE ISSUE

Not applicable.

ITEM 10. ADDITIONAL INFORMATION

A. SHARE CAPITAL

Issued Share Capital

Our issued share capital as of June 28, 2022 is 4,416,334,617 shares with a par value of CHF 0.01 per share which includes 227,108,394 shares held in treasury. Each issued common share is fully paid. We currently have no deferred shares in our issued share capital.

Common Shares

To the extent dividends are paid, holders of common shares are entitled to receive dividends in proportion to the number of common shares held by them and according to the amount paid up on such common shares during any portion or portions of the period in respect of which the dividend is paid. Holders of common shares are entitled, in proportion to the number of common shares held by them and to the amounts paid up thereon, to share in any surplus in the event of our winding up. The holders of common shares are entitled to receive notice of, attend either in person or by proxy or, being a corporation, by a duly authorized representative, and vote at general meetings of shareholders.

B. MEMORANDUM AND ARTICLES OF ASSOCIATION

Please read this section in conjunction with our Articles of Association, which are attached to this registration statement as Exhibit 3.1.

Ordinary Capital Increase, Authorized and Conditional Share Capital

Under Swiss law, we may increase our share capital (*capital-actions*) with a resolution of the general meeting of shareholders (ordinary capital increase) that must be carried out by the board of directors within three months of the respective general meeting in order to become effective. Under our articles of association and Swiss law, in the case of subscription and increase against payment of contributions in cash, a resolution passed by an absolute majority of the shares represented at the general meeting of shareholders is required. In the case of subscription and increase against contributions in kind or to fund acquisitions in kind, when shareholders' statutory pre-emptive subscription rights or advance subscription rights are limited or withdrawn or where transformation of freely disposable equity into share capital is involved, a resolution passed by two-thirds of the shares represented at a general meeting of shareholders and the absolute majority of the par value of the shares represented is required.

Furthermore, under the Swiss Code of Obligations (CO), our shareholders, by a resolution passed by two-thirds of the shares represented at a general meeting of shareholders and the absolute majority of the par value of the shares represented, may empower our board of directors to issue shares of a specific aggregate par value up to a maximum of 50% of the share capital in the form of:

- conditional share capital (capital-actions conditional) for the purpose of issuing shares in connection with, among other things, (i) option and conversion rights granted in connection with warrants and convertible bonds of the Company or one of our subsidiaries or (ii) grants of rights to employees, members of our board of directors or consultants or to our subsidiaries or other persons providing services to the Company or a subsidiary to subscribe for new shares (conversion or option rights); or

authorized share capital (capital-actions autorisé) to be utilized by the board of directors within a period determined by the shareholders but not exceeding two years from the date of the shareholder approval.

Pre-Emptive and Advance Subscription Rights

Pursuant to the CO, shareholders have pre-emptive subscription rights (*droits de souscription*) to subscribe for new issuances of shares. With respect to conditional capital in connection with the issuance of conversion rights, convertible bonds or similar debt instruments, shareholders have advance subscription rights (*droit de souscrire préalablement*) for the subscription of such conversion rights, convertible bonds or similar debt instruments.

A resolution passed at a general meeting of shareholders by two-thirds of the shares represented and the absolute majority of the par value of the shares represented may authorize our board of directors to withdraw or limit pre-emptive subscription rights or advance subscription rights in certain circumstances.

If pre-emptive subscription rights are granted, but not exercised, the board of directors may allocate the unexercised pre-emptive subscription rights at its discretion.

Our Authorized Share Capital

Under our articles of association, our board of directors is authorized at any time to increase our common shares, at any time through May 30, 2024, to increase our share capital by a maximum amount of CHF 22,000,000.00 by issuing up to 2,220,000,000 registered shares to be fully paid up with a par value of CHF 0.01 each. An increase in partial amounts is permitted.

Increases in partial amounts are permitted. The board of directors has the power to determine the type of contributions, the issue price and the date on which the dividend entitlement starts.

With respect to our authorized share capital, the board of directors is authorized by our articles of association to withdraw or to limit the pre-emptive subscription rights of shareholders, and to allocate them to third parties or to us, in the event that the newly issued shares are issued under the following circumstances:

- for the acquisition of businesses, business divisions or participations, or for new investment projects, or in the event of share placement for the financing or refinancing of such transactions;
- for the participation of employees, members of the Board of Directors and consultants of the Company or its subsidiaries in accordance with one or more regulations adopted by the Board;
- in connection with an offering of securities in order to cover the green shoe option (surplus allocation option) granted to one or more banks;
- for investment projects and/or financial instruments which are used in national or international capital markets, or for raising capital in a fast and flexible manner, which would hardly be achieved without the exclusion of the statutory subscription rights of the existing shareholders; or
- for other valid grounds pursuant to Article 652b, paragraph 2 of the Swiss Code of Obligations.

This authorization is exclusively linked to the particular available authorized share capital set out in the respective article. If the period to increase our share capital out of authorized share capital lapses without having been used by the board of directors, the authorization to withdraw or to limit the pre-emptive subscription rights lapses simultaneously with such capital.

Our Conditional Share Capital

Our conditional share capital may be increased by the issuance of up to 1,671,769,814 shares with a nominal value of CHF 0.01 each in the aggregate nominal value of CHF 16,717,698.14, as follows:

- 1,563,000,000 registered shares to be fully paid up, each with a nominal value of CHF 0.01 to the nominal value of CHF 15,630,000.00 through the exercise of conversion or option rights granted to entitled parties in connection with bonds and similar financial instruments or loans of the Company or its subsidiaries that allow for conversion into shares of the Company, or option rights granted to existing and/or new shareholders in connection with capital increases.

- 108,769,814 registered shares to be fully paid up, each with a nominal value of CHF 0.01 to a nominal value of CHF 1,087,698.14 through the exercise of options granted to employees, members of the Board of Directors and consultants of the Company or its subsidiaries.

As to the conditional share capital described in the first bullet point above, the subscription rights of shareholders are excluded. The Board of Directors determines the conversion and option terms, the issue price and the date of dividend entitlement. The Board of Directors is authorized to limit or exclude the pre-emptive rights of existing shareholders in the event of: (1) the financing or refinancing of the acquisition of businesses, business divisions or participations, or for new investment projects, (2) the financing or refinancing of the Company or its subsidiaries, (3) the issuance of convertibles and/or option bonds for the purpose of placement on national or international capital markets (including private placements) or (4) for purposes of the underwriting of such bonds and other financial instruments by one or more banks with subsequent public offer.

As to the conditional share capital described in the second bullet point above, the rights of pre-emption and subscription rights of shareholders are excluded.

When issuing convertible bonds, warrants or similar instruments, the board of directors is authorized to withdraw or to limit the advance subscription right of shareholders:

- for the purpose of financing or refinancing, or the payment for, the acquisition of enterprises, parts of enterprises, participations, intellectual property rights, licenses or investments;

- if the issuance occurs in domestic or international capital markets, including private placements;

- following a shareholder or a group of shareholders acting in concert having accumulated shareholdings in excess of 20% of the share capital registered in the Commercial Register without having submitted to all other shareholders a takeover offer recommended by the board of directors; or

- for the defense of an actual, threatened or potential takeover bid that the board of directors, upon consultation with an independent financial adviser retained by it, has not recommended to the shareholders to accept on the basis that the board of directors has not found the takeover bid to be financially fair to the shareholders or not to be in the Company' s interest.

To the extent that the advance subscription rights are withdrawn or limited, (i) the convertible bonds, warrants or similar instruments are to be issued at market conditions; (ii) the term to exercise the convertible bonds, warrants or similar instruments may not exceed ten years from the date of issue of the respective instrument and (iii) the conversion, exchange or exercise price of the convertible bonds, warrants or similar instruments has to be set with reference to or be subject to change based upon the valuation of the Company' s equity or market conditions.

Uncertificated Securities

Our shares are in the form of uncertificated securities (*droits-valeurs*, within the meaning of Article 973c of the CO). In accordance with Article 973c of the CO, we will maintain a non-public register of uncertificated securities (*registre des droits-valeurs*). We may at any time convert uncertificated securities into share certificates (including global certificates), one kind of certificate into another, or share certificates (including global certificates) into uncertificated securities. Following entry in the share register, a shareholder may at any time request from us a written confirmation in respect of his or her shares. Shareholders are not entitled, however, to request the conversion and/or printing and delivery of share certificates. We may print and deliver certificates for shares at any time.

General Meeting of Shareholders

Ordinary/Extraordinary Meetings, Powers

The general meeting of shareholders is our supreme corporate body. Under Swiss law, an annual general meeting of shareholders must be held annually within six months after the end of a corporation' s financial year. In our case, this generally means on or before June 30. In addition, extraordinary general meetings of shareholders may be held.

The following powers are vested exclusively in the general meeting of shareholders:

- adopting and amending the articles of association, including the change of a company' s purpose or domicile;
- electing the members of the board of directors, the chairman of the board of directors, the members of the compensation committee, the auditors and the independent proxy;
- approving the business report, the annual statutory and consolidated financial statements, and deciding on the allocation of profits as shown on the balance sheet, in particular with regard to dividends;
- approving the aggregate amount of compensation of members of the board of directors and the executive committee;
- discharging the members of the board of directors and the executive committee from liability with respect to their conduct of business;
- dissolving a company with or without liquidation; and
- deciding matters reserved to the general meeting of shareholders by law or the articles of association or submitted to it by the board of directors.

An extraordinary general meeting of shareholders may be called by a resolution of the board of directors or the general meeting of shareholders or, under certain circumstances, by a company' s auditor, liquidator or the representatives of bondholders, if any. In addition, the board of directors is required to convene an extraordinary general meeting of shareholders if shareholders representing at least 10% of our share capital request such general meeting of shareholders in writing. Such request must set forth the items to be discussed and the proposals to be acted upon. The board of directors must convene an extraordinary general meeting of shareholders and propose financial restructuring measures if, based on our stand-alone annual statutory balance sheet, half of our share capital and statutory reserves are not covered by our assets.

Voting and Quorum Requirements

Shareholder resolutions and elections (including elections of members of the board of directors) require the affirmative vote of the absolute majority of shares represented at the general meeting of shareholders, unless otherwise stipulated by law or our articles of association.

Under Swiss law and our articles of association, a resolution of the general meeting of the shareholders passed by two-thirds of the shares represented at the meeting, and the absolute majority of the par value of the shares represented is required for:

a change in our corporate purpose;

the introduction and abolition of voting shares;

restrictions on the transferability of registered shares;

authorized or conditional capital increase;

capital increase from equity for investment in kind or for the purpose of acquisition of assets and the granting of special privileges;

the restriction or abolition of subscription rights;

the transfer of our headquarters;

facilitating or waiving restrictions on transferability of registered shares; or

the dissolution of the Company.

The same voting requirements apply to resolutions regarding transactions among corporations based on Switzerland' s Federal Act on Mergers, Demergers, Transformations and the Transfer of Assets of 2003, as amended (Swiss Merger Act).

In accordance with Swiss law and generally accepted business practices, our articles of association do not provide quorum requirements generally applicable to general meetings of shareholders. To this extent, our practice varies from Nasdaq listing standards, which require an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting shares.

Notice

General meetings of shareholders must be convened by the board of directors at least 20 days before the date of the meeting. The general meeting of shareholders is convened by way of a notice appearing in our official publication medium, currently the Swiss Official Gazette of Commerce. Registered shareholders may also be informed by ordinary mail or e-mail. The notice of a general meeting of shareholders must state the items on the agenda, the motions to the shareholders and, in case of elections, the names of the nominated candidates. A resolution on a matter which is not on the agenda may not be passed at a general meeting of shareholders, except for motions to convene an extraordinary general meeting of shareholders or to initiate a special investigation, on which the general meeting of shareholders may vote at any time. No previous notification is required for motions concerning items included in the agenda or for debates that do not result in a vote.

All of the owners or representatives of our shares may, if no objection is raised, hold a general meeting of shareholders without complying with the formal requirements for convening general meetings of shareholders (a universal meeting). This universal meeting of shareholders may discuss and pass binding resolutions on all matters within the purview of the general meeting of shareholders, provided that the owners or representatives of all the shares are present at the meeting.

Agenda Requests

Pursuant to Swiss law and our articles of association, one or more shareholders, whose combined shareholdings represent the lower of (i) one tenth of our share capital and (ii) an aggregate par value of at least CHF 1,000,000 may request that an item be included in the agenda for a general meeting of shareholders. To be timely, the shareholder' s request must be received by us generally at least 45 calendar days in advance of the meeting. The request must be made in writing and shall specify the agenda item and the shareholders' proposals.

In addition, if the shareholder intends to solicit proxies from the shareholders of a company, such shareholder shall notify the company of this intent in accordance with SEC Rule 14a-4 and/or Rule 14a-8.

Our business report, the compensation report and the auditor' s report must be made available for inspection by the shareholders at our registered office no later than 20 days prior to the general meeting of shareholders. Shareholders of record may be notified of this in writing.

Voting Rights

Each of our common shares entitles a holder to one vote. The common shares are not divisible. The right to vote and the other rights of share ownership may only be exercised by shareholders (including any nominees) who are entered in the share register at a cut-off date determined by the board of directors. Those entitled to vote in the general meeting of shareholders may be represented by the independent proxy holder (annually elected by the general meeting of shareholders), by its legal representative, who does not have to be a shareholder, or by another shareholder with voting rights. The chairman has the power to decide whether to recognize a power of attorney.

Dividends and Other Distributions

Our board of directors may propose to shareholders that a dividend or other distribution be paid but cannot itself authorize the distribution. Dividend payments require a resolution passed by an absolute majority of the shares represented at a general meeting of shareholders. In addition, our auditors must confirm that the dividend proposal of our board of directors conforms to Swiss statutory law and our articles of association.

Under Swiss law, we may pay dividends only if we have sufficient distributable profits from the previous business year (*bénéfice de l' exercice*) or brought forward from the previous business years (*report des bénéfices*), or if we have distributable reserves (*réserves à libre disposition*), each as evidenced by the Company' s audited stand-alone statutory balance sheet prepared pursuant to Swiss law, and after allocations to reserves required by Swiss law and by the articles of association have been deducted. We are not permitted to pay interim dividends out of profit of the current business year.

Distributable reserves are generally booked either as "free reserves" (*réserves libres*) or as "reserve from capital contributions" (*apports de capital*). Under the CO, if our general reserves (*réserve générale*) amount to less than 20% of our share capital recorded in the Commercial Register (i.e., 20% of the aggregate par value of our issued capital), then at least 5% of our annual profit must be retained as general reserves. In addition, if our general reserves amount to less than 50% of our share capital recorded in the Commercial Register, 10% of the amounts distributed beyond payment of a dividend of 5% must be retained as general reserves. The CO permits us to accrue additional general reserves. Further, a purchase of our own shares (whether by us or a subsidiary) reduces the distributable reserves in an amount corresponding to the purchase price of such own shares. Finally, the CO under certain circumstances requires the creation of revaluation reserves which are not distributable.

Distributions out of issued share capital (i.e., the aggregate par value of our issued shares) are not allowed and may be made only by way of a share capital reduction. Such a capital reduction requires a resolution passed by an absolute majority of the shares represented at a general meeting of shareholders. The resolution of the shareholders must be recorded in a public deed and a special audit report must confirm that claims of our creditors remain fully covered despite the reduction in our share capital recorded in the Commercial Register. Our share capital may be reduced below CHF 100,000 only if and to the extent that at the same time the statutory minimum share capital of CHF 100,000 is reestablished by sufficient new fully paid-up capital. Upon approval by the general meeting of shareholders of the capital reduction, the board of directors must give public notice of the capital reduction resolution in the Swiss Official Gazette of Commerce three times and notify creditors that they may request, within two months of the third publication, satisfaction of or security for their claims. The reduction of our share capital may be implemented only after expiration of this time limit.

Our board of directors determines the date on which the dividend entitlement starts. Dividends are usually due and payable shortly after the shareholders have passed the resolution approving the payment, but shareholders may also resolve at the annual general meeting of shareholders to pay dividends in quarterly or other installments.

For a discussion of the taxation of dividends, see "E. Taxation" below.

Transfer of Shares

Shares in uncertificated form (droits-valeurs) may only be transferred by way of assignment. Shares or the beneficial interest in shares, as applicable, credited in a securities account may only be transferred when a credit of the relevant intermediated securities to the acquirer' s securities account is made in accordance with applicable rules. Our articles of association provide that in the case of securities held with an intermediary such as a registrar, transfer agent, trust corporation, bank or similar entity, any transfer, grant of a security interest or usufructuary right in such intermediated securities and the appurtenant rights associated therewith requires the cooperation of the intermediary in order for such transfer, grant of a security interest or usufructuary right to be valid against us.

Voting rights may be exercised only after a shareholder has been entered in the share register (registre des actions) with his or her name and address (in the case of legal entities, the registered office) as a shareholder with voting rights.

Inspection of Books and Records

Under the CO, a shareholder has a right to inspect the share register with respect to his or her own shares and otherwise to the extent necessary to exercise his or her shareholder rights. No other person has a right to inspect the share register. Our books and correspondence may be inspected with the express authorization of the general meeting of shareholders or by resolution of the board of directors and subject to the safeguarding of our business secrets and other legitimate interests. See Differences in Corporate Law−Inspection of Books and Records."

Special Investigation

If the shareholders' inspection rights as outlined above prove to be insufficient in the judgment of the shareholder, any shareholder may propose to the general meeting of shareholders that specific facts be examined by a special examiner in a special investigation. If the general meeting of shareholders approves the proposal, we or any shareholder may, within 30 calendar days after the general meeting of shareholders, request a court at our registered office in Geneva, Switzerland to appoint a special examiner. If the general meeting of shareholders rejects the request, one or more shareholders representing at least 10% of our share capital or holders of shares in an aggregate par value of at least CHF 2,000,000 may request that the court appoint a special examiner. The court will issue such an order if the petitioners can demonstrate that the board of directors, any member of the board of directors or our executive committee infringed the law or our articles of association and thereby caused damages to the Company or the shareholders. The costs of the investigation would generally be allocated to us and only in exceptional cases to the petitioners.

Compulsory Acquisitions; Appraisal Rights

Business combinations and other transactions that are governed by the Swiss Merger Act (i.e., mergers, demergers, transformations and certain asset transfers) are binding on all shareholders. A statutory merger or demerger requires approval of two-thirds of the shares represented at a general meeting of shareholders and the absolute majority of the par value of the shares represented.

If a transaction under the Swiss Merger Act receives all of the necessary consents, all shareholders are compelled to participate in such transaction.

Swiss corporations may be acquired by an acquirer through the direct acquisition of the shares of the Swiss corporation. The Swiss Merger Act provides for the possibility of a so-called "cash-out" or "squeeze-out" merger with the approval of holders of 90% of the issued shares. In these limited circumstances, minority shareholders of the corporation being acquired may be compensated in a form other than through shares of the acquiring corporation (for instance, through cash or securities of a parent corporation of the acquiring corporation or of another corporation). For business combinations effected in the form of a statutory merger or demerger and subject to Swiss law, the Swiss Merger Act provides that if equity rights have not been adequately preserved or compensation payments in the transaction are unreasonable, a shareholder may request the competent court to determine a reasonable amount of compensation.

In addition, under Swiss law, the sale of "all or substantially all of our assets" by us may require the approval of two-thirds of the number of shares represented at a general meeting of shareholders and the absolute majority of the par value of the shares represented. Whether a shareholder resolution is required depends on the particular transaction, including whether the following test is satisfied:

- a core part of our business is sold without which it is economically impracticable or unreasonable to continue to operate the remaining business;
- our assets, after the divestment, are not invested in accordance with our corporate purpose as set forth in the articles of association; and

the proceeds of the divestment are not earmarked for reinvestment in accordance with our corporate purpose but, instead, are intended for distribution to our shareholders or for financial investments unrelated to our corporate purpose.

A shareholder of a Swiss corporation participating in certain major corporate transactions may, under certain circumstances, be entitled to appraisal rights. As a result, such shareholder may, in addition to the consideration (be it in shares or in cash) receive an additional amount to ensure that the shareholder receives the fair value of the shares held by the shareholder. Following a statutory merger or demerger, pursuant to the Swiss Merger Act, shareholders can file an appraisal action against the surviving company. If the consideration is deemed inadequate, the court will determine an adequate compensation payment.

Board of Directors

Pursuant to Swiss law and according to our articles of association, the board of directors shall consist of at least one member. Swiss law requires that any listed company exceeding two of the three thresholds specified in art. 727 para.1 no. 2 of the CO in two successive financial years shall have each gender represented by at least 30% on the board of directors and 20% on the executive management team. If a company fails to comply, it must be disclosed in the remuneration report, including an explanation and a designation of measures to be taken to reconcile the failed compliance. For our board of directors, this rule will apply, subject to meeting the thresholds required under the CO, from the business year 2026, whereas for the executive management from the business year 2031. The triggering thresholds are (i) a balance sheet total of 20 million CHF, (ii) sales revenue of 40 million CHF and (iii) an average of 250 full-time per year.

The members of our board of directors are elected by the general meeting of shareholders for a term of one year. A year within the meaning of this provision is the period between two ordinary general meetings of shareholders. If a member of the board of directors retires or is replaced, his successor shall continue in office until the end of his predecessor' s term. Each member of our board of directors must be elected individually.

Powers

The board of directors has the following non-delegable and inalienable powers and duties:

the ultimate direction of the business of the Company and issuing of the relevant directives;

laying down the organization of the Company;

formulating accounting procedures, financial controls and financial planning;

nominating and removing persons entrusted with the management and representation of the Company and regulating the power to sign for the Company;

the ultimate supervision of those persons entrusted with management of the Company, with particular regard to adherence to law, our articles of association, and regulations and directives of the Company;

issuing the business report and the compensation report, and preparing for the general meeting of shareholders and carrying out its resolutions; and

informing the court in case of over-indebtedness.

The board of directors may, while retaining such non-delegable and inalienable powers and duties, delegate some of its powers, in particular direct management, to a single or to several of its members, committees or to third parties (such as executive officers) who need be neither members of the board of directors nor shareholders. Pursuant to Swiss law and our articles of association, details of the delegation and other procedural rules such as quorum requirements have been set in the organizational rules established by the board of directors.

Indemnification of Executive Officers and Directors

We continuously seek to maintain appropriate and cost-effective liability insurance coverage in connection with our products and for purposes of indemnifying our directors and officers for claims against them. In addition, under general principles of Swiss employment law, an employer may be required to indemnify an employee against losses and expenses incurred by such employee in the proper execution of his or her duties under the employment agreement with the employer. See "Differences in Corporate Law−Indemnification of Directors and Executive Management and Limitation of Liability."

Conflict of Interest

Swiss law does not have a general provision regarding conflicts of interest. However, the CO contains a provision that requires our directors and executive officers to safeguard the Company' s interests and imposes a duty of loyalty and duty of care on our directors and executive officers. This rule is generally understood to disqualify directors and executive officers from participation in decisions that directly affect them. Our directors and executive officers are personally liable to us for breaches of these obligations. In addition, Swiss law contains provisions under which directors and all persons engaged in the Company' s management are liable to the Company, each shareholder and the Company' s creditors for damages caused by an intentional or negligent violation of their duties. Furthermore, Swiss law contains a provision under which payments made to any of the Company' s shareholders or directors or any person related to any such shareholder or director, other than payments made at arm' s length, must be repaid to the Company if such shareholder or director acted in bad faith.

Our board of directors has adopted a Code of Business Conduct and Ethics and will adopt, upon the closing of this offering, other policies that will cover a broad range of matters, including the handling of conflicts of interest.

Principles of the Compensation of the Board of Directors

Pursuant to Swiss law, our shareholders must annually, upon becoming a public company whose shares are listed for trade by the public, approve the compensation of the board of directors and the persons whom the board of directors has, fully or partially, entrusted with the management of the Company. The board of directors must issue, on an annual basis, a written compensation report that must be reviewed together with a report on our business by our auditor. The compensation report must disclose all compensation, loans and other forms of indebtedness granted by the Company, directly or indirectly, to current or former members of the board of directors and executive management to the extent related to their former role within the Company or not on customary market terms.

The disclosure concerning compensation, loans and other forms of indebtedness must include the aggregate amount for the board of directors and the executive management as well as the particular amount for each member of the board of directors and executive officer, specifying the name and function of each respective person.

Certain forms of compensation are prohibited for members of our board of directors and executive management, such as:

- severance payments provided for either contractually or in the articles of association (compensation due until the termination of a contractual relationship does not qualify as severance payment);
- advance compensation;
- incentive fees for the acquisition or transfer of corporations or parts thereof by the Company or by companies being, directly or indirectly, controlled by us;
- loans, other forms of indebtedness, pension benefits not based on occupational pension schemes and performance-based compensation not provided for in the articles of association; and
- equity securities and conversion and option rights awards not provided for in the articles of association.

Compensation to members of the board of directors and executive management for activities in entities that are, directly or indirectly, controlled by the Company is prohibited if the compensation (i) would have been prohibited if it was paid directly by the Company, (ii) is not provided for in the articles of association or (iii) has not been approved by the general meeting of shareholders.

The general meeting of shareholders votes on the compensation received directly or indirectly by the board of directors, the executive management and the advisory board. The general meeting of shareholders must vote annually on the compensation of its board of directors, executive management and the advisory board, and accordingly, at such a meeting, the vote of the general meeting of shareholders shall have a binding effect.

In the event that the general meeting of shareholders votes prospectively on the compensation of the executive management, the articles of association may provide for an additional amount for the compensation of the members of the executive management appointed after the vote.

The additional amount may only be used if the total amount of the compensation of the executive management decided by the general meeting of shareholders is not sufficient for the compensation of the new members until the next vote of the general meeting of the shareholders.

The general meeting of shareholders shall not vote on the additional amount of compensation.

Borrowing Powers

Neither Swiss law nor our articles of association restrict in any way our power to borrow and raise funds. The decision to borrow funds is made by or under the direction of our board of directors, and no approval by the shareholders is required in relation to any such borrowing.

Repurchases of Shares and Purchases of Own Shares and Other Limitations on the Right to Own Securities

The CO limits our right to purchase and hold our own shares. We and our subsidiaries may purchase shares only if and to the extent that (i) freely disposable equity capital is available in the required amount; and (ii) the combined nominal value of all such shares does not exceed 10% of the share capital. Pursuant to Swiss law, where shares are acquired in connection with a transfer restriction set out in the articles of association, the foregoing upper limit is 20%. We currently do not have any transfer restriction in our articles of association. If we own shares that exceed the threshold of 10% of our share capital, the excess must be sold or cancelled by means of a capital reduction within a reasonable time.

Shares held by us or our subsidiaries are not entitled to vote at the general meeting of shareholders but are entitled to the economic benefits applicable to the shares generally, including dividends and pre-emptive rights in the case of share capital increases.

Swiss law and/or our articles of association do not impose any restrictions on the exercise of voting or any other shareholder rights by shareholders residing outside of Switzerland.

Notification and Disclosure of Substantial Share Interests, Opting out of Mandatory Tender Offer

The Swiss Federal Financial Market Infrastructure Act, as amended from time to time, ("FMIA") requires persons who directly, indirectly or in concert with other parties acquire or dispose of listed shares of a Swiss company or purchase or sale rights or obligations relating to the listed shares, and, thereby, directly, indirectly or in concert with other parties reach, exceed or fall below a threshold of 3%, 5%, 10%, 15%, 20%, 25%, $33^{1/3}$%, 50% or $66^{2/3}$% of the company' s voting rights (whether exercisable or not) to notify the company and SIX Exchange Regulation AG of such acquisition or disposal in writing within four trading days. Within two trading days after the receipt of such notification, the company must publish such information through SIX Exchange Regulation AG' s electronic reporting and publishing platform.

We have included in our articles of association a so-called opting out of the mandatory tender offer, i.e., of the requirement that the Swiss takeover regime imposes a duty on any person or group of persons who acquires more than one-third of a company' s voting rights to make a mandatory offer for all of the company' s outstanding listed equity securities.

Pursuant to Article 663c of the CO, Swiss corporations whose shares are listed on a stock exchange must specify the significant shareholders and their shareholdings in the notes to the balance sheet, where these are known or ought to be known. Significant shareholders are defined as shareholders and groups of shareholders linked through voting rights who own more than five percent of all voting rights.

Stock Exchange Listing

Our common shares are listed on the SIX Swiss Exchange under the symbol "RLF" and over the counter in the United States under the symbol "RLFTF." Our ADRs trade in the over-the-counter market under the symbol "RLFTY," and we hope to list our ADRs on the Nasdaq Stock Market in the future.

Differences in Corporate Law

The Swiss laws applicable to Swiss corporations and their shareholders differ from laws applicable to U.S. corporations and their shareholders. The following table summarizes significant differences in shareholder rights between the applicable provisions of the CO and the Compensation Ordinance (as a company incorporated in Switzerland and listed on a stock exchange) and the Delaware General Corporation Law, applicable to companies incorporated in Delaware and their shareholders. Please note that this is only a general summary of certain provisions applicable to companies in Delaware. Certain Delaware companies may be permitted to exclude certain of the provisions summarized below in their charter documents.

DELAWARE CORPORATE LAW	SWISS CORPORATE LAW
Mergers and similar arrangements	
Under the Delaware General Corporation Law, with certain exceptions, a merger, consolidation, sale, lease or transfer of all or substantially all of the assets of a corporation must be approved by the board of directors and a majority of the outstanding shares entitled to vote thereon. A shareholder of a Delaware corporation participating in certain major corporate transactions may, under certain circumstances, be entitled to appraisal rights pursuant to which such shareholder may receive cash in the amount of the fair value of the shares held by such shareholder (as determined by a court) in lieu of the consideration such shareholder would otherwise receive in the transaction. The Delaware General Corporation Law also provides that a parent corporation, by resolution of its board of directors, may merge with any subsidiary of which it owns at least 90.0% of each class of capital stock without a vote by the shareholders of such subsidiary. Upon any such merger, dissenting shareholders of the subsidiary would have appraisal rights.	Under Swiss law, with certain exceptions, a merger or a division of the corporation or a sale of all or substantially all of the assets of a corporation must be approved by two-thirds of the shares represented at the respective general meeting of shareholders as well as the absolute majority of the share capital represented at such shareholders' meeting. The articles of association may increase the voting threshold. A shareholder of a Swiss corporation participating in a statutory merger or demerger pursuant to the Swiss Merger Act can file an appraisal right lawsuit against the surviving company. As a result, if the consideration is deemed "inadequate," such shareholder may, in addition to the consideration (be it in shares or in cash) receive an additional amount to ensure that such shareholder receives the fair value of the shares held by such shareholder. Swiss law also provides that a parent corporation, by resolution of its board of directors, may merge with any subsidiary of which it owns at least 90.0% of the shares without a vote by shareholders of such subsidiary, if the shareholders of the subsidiary are offered the payment of the fair value in cash as an alternative to shares.
Shareholder Lawsuits	
Class actions and derivative actions generally are available to shareholders of a Delaware corporation for, among other things, breach of fiduciary duty, corporate waste and actions not taken in accordance with applicable law. In such actions, the court has discretion to permit the winning party to recover attorneys' fees incurred in connection with such action.	Class actions and derivative actions as such are not available under Swiss law. Nevertheless, certain actions may have a similar effect. A shareholder is entitled to bring suit against directors for breach of, among other things, their fiduciary duties and claim the payment of the company' s damages to the corporation. Likewise, an appraisal lawsuit won by a shareholder will indirectly compensate all shareholders. Under Swiss law, the winning party is generally entitled to recover attorneys' fees incurred in connection with such action, provided, however, that the court has discretion to permit the shareholder whose claim has been dismissed to recover attorneys' fees incurred to the extent he acted in good faith.

DELAWARE CORPORATE LAW	SWISS CORPORATE LAW
Shareholder Vote on Board and Management Compensation	
Under the Delaware General Corporation Law, the board of directors has the authority to fix the compensation of directors, unless otherwise restricted by the certificate of incorporation or bylaws.	Pursuant to the Compensation Ordinance, applicable to Swiss companies traded on exchanges, such as Nasdaq, the general meeting of shareholders has the non-transferable right, amongst others, to vote separately (in a binding vote) on the aggregate compensation due to the board of directors, executive management and advisory boards.
Annual vote on Board Renewal	
Unless otherwise specified in the certificate of incorporation or bylaws of the corporation, directors shall be elected by a plurality of votes of the shareholders on a date and at a time designated by or in the manner provided in the bylaws. Re-election is possible.	The general meeting of shareholders elects annually (i.e., until the following general meeting of shareholders), by a plurality of votes, the members of the board of directors (including the chairman) and the members of the compensation committee individually for a term of office of one year. Re-election is possible.
Indemnification of Directors and Executive Management and Limitation of Liability	
The Delaware General Corporation Law provides that a certificate of incorporation may contain a provision eliminating or limiting the personal liability of directors, officers, employees or agents of the corporation for monetary damages for breach of a fiduciary duty as a director, except no provision in the certificate of incorporation may eliminate or limit the liability of a director for: • any breach of a director' s duty of loyalty to the corporation or its shareholders; • acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law; • statutory liability for unlawful payment of dividends or unlawful share purchase or redemption; or • any transaction from which the director derived an improper personal benefit.	Under Swiss corporate law, an indemnification of a director or member of the executive management in relation to potential personal liability is not effective to the extent the director or member of the executive management intentionally or negligently violated his or her corporate duties towards the corporation (certain views advocate that at least a grossly negligent violation is required to exclude the indemnification). Most violations of corporate law are regarded as violations of duties towards the corporation rather than towards the shareholders. In addition, indemnification of other controlling persons is not permitted under Swiss corporate law, including shareholders of the corporation. Nevertheless, a corporation may obtain and pay for directors' and officers' liability insurance, which typically covers negligent acts as well.

DELAWARE CORPORATE LAW	SWISS CORPORATE LAW

Indemnification of Directors and Executive Management and Limitation of Liability (Continued)

A Delaware corporation may indemnify any person who was or is a party or is threatened to be made a party to any proceeding, other than an action by or on behalf of the corporation, because the person is or was a director or officer, against liability incurred in connection with the proceeding if the director or officer acted in good faith and in a manner reasonably believed to be in, or not opposed to, the best interests of the corporation; and the director or officer, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful.

Unless ordered by a court, any foregoing indemnification is subject to a determination that the director or officer has met the applicable standard of conduct:

- by a majority vote of the directors who are not parties to the proceeding, even though less than a quorum;
- by a committee of directors designated by a majority vote of the eligible directors, even though less than a quorum;
- by independent legal counsel in a written opinion if there are no eligible directors, or if the eligible directors so direct; or by the shareholders.

Moreover, a Delaware corporation may not indemnify a director or officer in connection with any proceeding in which the director or officer has been adjudged to be liable to the corporation unless and only to the extent that the court determines that, despite the adjudication of liability but in view of all the circumstances of the case, the director or officer is fairly and reasonably entitled to indemnity for those expenses which the court deems proper.

DELAWARE CORPORATE LAW	SWISS CORPORATE LAW
Directors' Fiduciary Duties	
A director of a Delaware corporation has a fiduciary duty to the corporation and its shareholders. This duty has two components: the duty of care and the duty of loyalty.	A director of a Swiss corporation has a fiduciary duty to the corporation only. This duty has two components: the duty of care and the duty of loyalty.
The duty of care requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of, and disclose to shareholders, all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director act in a manner he reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. This duty prohibits self-dealing by a director and mandates that the best interest of the corporation and its shareholders take precedence over any interest possessed by a director, officer or controlling shareholder and not shared by the shareholders generally. In general, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties.	The duty of care requires that a director act in good faith, with the care that an ordinarily prudent director would exercise under similar circumstances. Under this duty, a director must inform himself of, and disclose, all material information reasonably available regarding a significant transaction.
Should such evidence be presented concerning a transaction by a director, a director must prove the procedural fairness of the transaction, and that the transaction was of fair value to the corporation.	The duty of loyalty requires that a director act in a manner he reasonably believes to be in the best interest of the corporation. He must not use his corporate position for personal gain or advantage. This duty prohibits in principle self-dealing by a director and mandates that the best interest of the corporation take precedence over any interest possessed by a director or officer.
	The burden of proof for a violation of these duties is with the corporation or with the shareholder bringing a suit against the director.
	Directors also have an obligation to treat shareholders equally proportionate to their share ownership.

DELAWARE CORPORATE LAW	SWISS CORPORATE LAW
Shareholder Action by Written Consent	
A shareholder of a Delaware corporation has the right to put any proposal before the annual meeting of shareholders, provided it complies with the notice provisions in the governing documents. A special meeting may be called by the board of directors or any other person authorized to do so in the governing documents, but shareholders may be precluded from calling special meetings.	At any general meeting of shareholders any shareholder may put proposals to the meeting if the proposal is part of an agenda item. Unless the articles of association provide for a lower threshold or for additional shareholders' rights: • one or several shareholders representing 10.0% of the share capital may ask that a general meeting of shareholders be called for specific agenda items and specific proposals; and • one or several shareholders representing 10.0% of the share capital or CHF 1.0 million of nominal share capital may ask that an agenda item including a specific proposal be put on the agenda for a regularly scheduled general meeting of shareholders, provided such request is made with appropriate notice. Any shareholder can propose candidates for election as directors without prior written notice. In addition, any shareholder is entitled, at a general meeting of shareholders and without advance notice, to (i) request information from the Board on the affairs of the company (note, however, that the right to obtain such information is limited), (ii) request information from the auditors on the methods and results of their audit and (iii) request, under certain circumstances and subject to certain conditions, a special audit.
Cumulative Voting	
Under the Delaware General Corporation Law, cumulative voting for elections of directors is not permitted unless the corporation' s certificate of incorporation provides for it.	A Swiss corporation may remove, with or without cause, any director at any time with a resolution passed by an absolute majority of the shares represented at a general meeting of shareholders. The articles of association may provide for a qualified majority for the removal of a director.

DELAWARE CORPORATE LAW	SWISS CORPORATE LAW
Removal of Directors	
Unless there is cumulative voting or there is a classified board, generally a director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors	A Swiss corporation may remove, with or without cause, any director at any time with a resolution passed by an absolute majority of the shares represented at a general meeting of shareholders. The articles of association may provide for a qualified majority for the removal of a director.
Transactions with Interested Shareholders	
The Delaware General Corporation Law generally prohibits a Delaware corporation from engaging in certain business combinations with an "interested shareholder" for three years following the date that such person becomes an interested shareholder. An interested shareholder generally is a person or group who or which owns or owned 15.0% or more of the corporation' s outstanding voting shares within the past three years.	No such rule applies to a Swiss corporation.
Variation of Rights of Shares	
A Delaware corporation may vary the rights of a class of shares with the approval of a majority of the outstanding shares of such class, unless the certificate of incorporation provides otherwise.	The general meeting of shareholders of a Swiss corporation may resolve that preference shares be issued or that existing shares be converted into preference shares with a resolution passed by a majority of the shares represented at the general meeting of shareholders. Where a company has issued preference shares, further preference shares conferring preferential rights over the existing preference shares may be issued only with the consent of both a special meeting of the adversely affected holders of the existing preference shares and of a general meeting of all shareholders, unless otherwise provided in the articles of association. Shares that are granted more voting power are not regarded as a special class for these purposes.

DELAWARE CORPORATE LAW	SWISS CORPORATE LAW
Amendment of Governing Documents	
A Delaware corporation' s governing documents may be amended with the approval of a majority of the outstanding shares entitled to vote, unless the certificate of incorporation provides otherwise.	By way of a public deed, the articles of association of a Swiss corporation may be amended with a resolution passed by an absolute majority of the shares represented at such meeting, unless otherwise provided in the articles of association. There are a number of resolutions, such as an amendment of the stated purpose of the corporation and the introduction of authorized and conditional capital, that require the approval by two-thirds of the votes and an absolute majority of the nominal value of the shares represented at a shareholders' meeting. The articles of association may increase the voting thresholds.
Inspection of Books and Records	
Shareholders of a Delaware corporation, upon written demand under oath stating the purpose thereof, have the right during the usual hours for business to inspect for any proper purpose, and to obtain copies of list(s) of shareholders and other books and records of the corporation and its subsidiaries, if any, to the extent the books and records of such subsidiaries are available to the corporation.	Shareholders of a Swiss corporation may only inspect books and records if the general meeting of shareholders or the board of directors approved such inspection. The inspection right is limited in scope and only extends to information required for the exercise of shareholder rights and does not extend to confidential information. The right to inspect the share register is limited to the right to inspect that shareholder' s own entry in the share register.
Payment of Dividends	
The board of directors may approve a dividend without shareholder approval. Subject to any restrictions contained in its certificate of incorporation, the board may declare and pay dividends upon the shares of its capital stock either: out of its surplus, or in case there is no such surplus, out of its net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year.	Dividend payments are subject to the approval of the general meeting of shareholders. The board of directors may propose to shareholders that a dividend shall be paid but cannot itself authorize the distribution. Payments out of the Company' s share capital (in other words, the aggregate nominal value of the Company' s registered share capital) in the form of dividends are not allowed and may be made by way of a capital reduction only. Dividends may be paid only from the profits brought forward from the previous business years or if the Company has distributable reserves, each as will be presented on the Company' s audited annual stand-alone balance sheet. The dividend may be determined only after the allocations to reserves required by the law and the articles of association have been deducted.

DELAWARE CORPORATE LAW	SWISS CORPORATE LAW
Creation and Issuance of New Shares	
Shareholder approval is required to authorize capital stock in excess of that provided in the charter. The corporation must file a certificate of amendment to its certificate of incorporation before the creation of additional authorized shares may become effective.	All creation of shares requires a shareholders' resolution documented by way of a public deed. The creation of authorized or conditional share capital requires at least two-thirds of the voting rights represented at the general meeting of shareholders and an absolute majority of the nominal value of shares represented at such meeting. The board of directors may issue shares out of the authorized share capital during a period of up to two years. Shares are created and issued out of conditional share capital through the exercise of options or of conversion rights that the board of directors may grant in relation to, e.g., debt instruments or to employees.
The board of directors may, without shareholder consent, authorize capital stock to be issued for consideration consisting of cash, any tangible or intangible property or any benefit to the corporation, or any combination thereof.	

C. MATERIAL CONTRACTS

Except as otherwise disclosed in this registration statement on Form 20-F (including the exhibits hereto), we are not currently, and have not been in the past 2 years, party to any material contract, other than contracts entered into in the ordinary course of business.

D. EXCHANGE CONTROLS

There are no Swiss governmental laws, decrees or regulations that restrict, in a manner material to us, the export or import of capital, including any foreign exchange controls, or that generally affect the remittance of dividends or other payments to non-residents or non-citizens of Switzerland who hold our common shares.

E. TAXATION

The following summary contains a description of the material Swiss and U.S. federal income tax consequences of the acquisition, ownership and disposition of common shares, but it does not purport to be a comprehensive description of all the tax considerations that may be relevant to a decision to purchase common shares. The summary is based upon the tax laws of Switzerland and regulations thereunder and on the tax laws of the U.S. and regulations thereunder as of the date hereof, which are subject to change.

Swiss tax considerations

This summary of material Swiss tax consequences is based on Swiss law and regulations and the practice of the Swiss tax administration as in effect on the date hereof, all of which are subject to change (or subject to changes in interpretation), possibly with retroactive effect. The summary does not purport to consider the specific circumstances of any particular shareholder or potential investor and does not relate to persons in the business of buying and selling common shares or other securities. The summary is not intended to be, and should not be interpreted as, legal or tax advice to any particular potential shareholder, and no representation with respect to the tax consequences to any particular shareholder is made.

Current and prospective shareholders are advised to consult their own tax advisors in light of their particular circumstances as to the Swiss tax laws, regulations and regulatory practices that could be relevant to them in connection with the acquiring, owning and selling or otherwise disposing of common shares and receiving dividends and similar cash or in-kind distributions on common shares (including dividends on liquidation proceeds and stock dividends) or distributions on common shares based upon a capital reduction (*remboursements de la valeur nominale*) or reserves paid out of capital contributions (*réserves issues d' apports en capital*) and the consequences thereof under the tax laws, regulations and regulatory practices of Switzerland.

Taxation

We are, through Relief, subject to corporate Swiss federal, cantonal and communal taxation in Switzerland, Canton of Geneva, City of Geneva, respectively, and through APR, we are subject to corporate Swiss federal, cantonal and communal taxation in Switzerland, Canton of Ticino, City of Balerna.

We are entitled under Swiss laws to carry forward any losses incurred for a period of 7 years and can offset our losses carried forward against future taxable profit. As of December 31, 2021, we had consolidated tax loss carry-forwards totaling approximately CHF 136 million. There is no certainty that we will make sufficient profits to be able to utilize these tax loss carry-forwards in full.

The effective corporate income tax rate (federal, cantonal and communal) where we are domiciled in the Canton of Geneva is currently 13.99% and is 18.47% in the Canton of Ticino.

Federal, cantonal and communal individual income tax and corporate income tax

Non-resident shareholders

Shareholders who are not resident in Switzerland for tax purposes, and who, during the relevant taxation year, have not engaged in a trade or business carried on through a permanent establishment or fixed place of business situated in Switzerland for tax purposes (all such shareholders for purposes of this section termed, "Non-resident shareholders"), will not be subject to any Swiss federal, cantonal and communal income tax on dividends and similar cash or in-kind distributions on Shares (including liquidation proceeds and stock dividends) (for the purposes of this section, "dividends"), distributions based upon a capital reduction capped to the nominal value (e.g. *réduction de la valeur nominale des actions*), and distributions paid out of reserves from capital contributions (*réserves issues d' apports en capital*) on shares, or capital gains realized on the sale or other disposition of shares (see, however, "*Swiss federal withholding tax"* below for a summary of Swiss federal withholding tax on dividends.)

Resident private shareholders

Swiss-resident individuals who hold their shares as private assets are required to include dividends, but not distributions based upon a capital reduction capped to the nominal value (e.g. *réduction de la valeur nominale des actions*), and distributions paid out of reserves from capital contributions (*réserves issues d' apports en capital*), in their personal income tax return and are subject to Swiss federal, cantonal and communal income tax on any net taxable income for the relevant taxation period, including the dividends, but not the distributions based upon a capital reduction capped to the nominal value (e.g. *réduction de la valeur nominale des actions*), and distributions paid out of reserves from capital contributions (*réserves issues d' apports en capital)*. Shareholders holding at least 10% of the share capital of the Company may be able to deduct their taxable dividends at 30% at the federal level and up to 50% at the cantonal level, depending on their respective cantonal rates, as partial relief from economic double taxation. Capital gains resulting from the sale or other disposition of shares are, subject to a few exceptions, not subject to Swiss federal, cantonal and communal income tax, and conversely, capital losses are not tax-deductible for resident private shareholders (the shareholders referred to in this paragraph for the purposes of this section, "Resident private shareholders"). See "*Domestic commercial shareholders*" below for a summary of the taxation treatment applicable to Swiss-resident individuals, who, for income tax purposes, are classified as "professional securities dealers" or are otherwise deemed to hold Company shares in their commercial wealth.

Domestic commercial shareholders

Corporate and individual shareholders who are resident in Switzerland for tax purposes, and corporate and individual shareholders who are not resident in Switzerland, and who, in each case, hold their shares as part of a trade or business carried on in Switzerland, in the case of corporate and individual shareholders not resident in Switzerland, through a permanent establishment or fixed place of business situated, for tax purposes, in Switzerland, are required to recognize dividends, distributions based upon a capital reduction capped to the nominal value (e.g. *réduction de la valeur nominale des actions*) and distributions paid out of reserves from capital contributions (*réserves issues d'apports en capital*) received on shares and capital gains or losses realized on the sale or other disposition of shares in their income statement for the relevant taxation period and are subject to Swiss federal, cantonal and communal individual or corporate income tax, as the case may be, on any net taxable earnings for such taxation period. The same taxation treatment also applies to Swiss-resident private individuals who, for income tax purposes, are classified as "professional securities dealers" for reasons of, *inter alia*, frequent dealing, or leveraged investments, in shares and other securities (the shareholders referred to in this paragraph for purposes of this section, "Domestic commercial shareholders"). Domestic commercial shareholders who are corporate taxpayers may be eligible for tax relief (*réduction pour participations*) in respect of dividends and distributions based upon a capital reduction capped to the nominal value (e.g. *réduction de la valeur nominale des actions*), and distributions paid out of reserves from capital contributions (*réserves issues d'apports en capital*), as well as capital gains on sales of shares, if the Shares held by them as part of a Swiss business have an aggregate market value of at least CHF 1 million or represent 10% or more of the outstanding share capital of the Company (in the case of capital gains, if the shares have been held for at least one year).

Swiss cantonal and communal private wealth tax and capital tax

Non-resident shareholders

Non-resident shareholders are not subject to Swiss cantonal and communal private wealth tax or capital tax.

Resident private shareholders and domestic commercial shareholders

Resident private shareholders and domestic commercial shareholders who are individuals are required to report their shares as part of their private wealth or their Swiss business assets, as the case may be, and will be subject to Swiss cantonal and communal private wealth tax on any net taxable wealth (including shares), in the case of domestic commercial shareholders to the extent the aggregate taxable wealth is allocable to Switzerland. Domestic commercial shareholders who are corporate taxpayers are subject to Swiss cantonal and communal capital tax on taxable capital to the extent the aggregate taxable capital is allocable to Switzerland.

Swiss federal withholding tax

Dividends that the Company pays on the shares are subject to Swiss Federal withholding tax *(impôt anticipé)* at a rate of 35% on the gross amount of the dividend. The Company is required to withhold the Swiss federal withholding tax from the dividend and remit it to the Swiss Federal Tax Administration. Distributions based upon a capital reduction capped to the nominal value (e.g. *réduction de la valeur nominale des actions*) and distributions paid out of reserves from contributions (*réserves issues d'apports en capital*) are not subject to Swiss federal withholding tax.

The Swiss federal withholding tax on a dividend will be refundable in full to a resident private shareholder and to a domestic commercial shareholder, who, in each case, *inter alia,* as a condition to a refund, duly reports the dividend in his individual income tax return as income or recognizes the dividend in his income statement as earnings, as applicable.

A Non-resident shareholder may be entitled to a partial or full refund, as the case may be, of the Swiss federal withholding tax on a dividend if the country of his or her residence for tax purposes has entered into an international treaty for the avoidance of double taxation with Switzerland and the conditions of such treaty are met. Such shareholders should be aware that the procedures for claiming treaty benefits (and the time required for obtaining a refund) might differ from country to country. For example, a shareholder who is a resident of the U.S. for the purposes of the bilateral tax treaty between the U.S. and Switzerland is eligible for a partial refund of the amount of the withholding tax in excess of the 15% treaty rate, provided such shareholder: (i) qualifies for benefits under this treaty and qualifies as beneficial owner of the dividends; (ii) holds, directly or indirectly, less than 10% of the voting stock of the Company; (iii) does not qualify as a pension scheme or retirement arrangement for the purpose of the bilateral treaty; and (iv) does not conduct business through a permanent establishment or fixed base in Switzerland to which the shares are attributable. Such an eligible U.S. shareholder may apply for a refund of the amount of the withholding tax in excess of the 15% treaty rate. The applicable refund request form may be filed with the Swiss Federal Tax Administration following receipt of the dividend and the relevant deduction certificate, however no later than 31 December of the third year following the calendar year in which the dividend was payable.

Swiss federal stamp taxes

The Company will be subject to and pay to the Swiss Federal Tax Administration a 1% Swiss federal issuance stamp duty (droit de timbre *d'émissions*) on the consideration received for the issuance of the shares less certain costs incurred in connection with the issuance, where the share capital increase exceeds the nominal value of the shares. The issuance and delivery of the shares to the initial shareholders at the offering price is not subject to Swiss federal securities transfer stamp duty (*droit de timbre de négociation*).

Any subsequent dealings in the shares, for which a bank or another securities dealer in Switzerland, as defined in the Swiss Federal Stamp Tax Act, acts as an intermediary, or is a party, to the transaction, are, subject to certain exemptions provided for in the Swiss Federal Stamp Tax Act, subject to Swiss securities transfer stamp duty tax at an aggregate tax rate of up to 0.15% of the consideration paid for such shares.

Material U.S. federal income tax considerations for U.S. Holders

The following summary of the material U.S. federal income tax consequences of the acquisition, ownership and disposition of our common shares or ADRs is based upon current law and does not purport to be a comprehensive discussion of all the tax considerations that may be relevant to a decision to purchase our common shares or ADRs. This summary is based on current provisions of the Internal Revenue Code of 1986, as amended, or the Code, existing, final, temporary and proposed U.S. Treasury Regulations, administrative rulings and judicial decisions, in each case as available on the date of this registration statement. All of the foregoing are subject to change, which change could apply retroactively and could affect the tax consequences described below.

This section summarizes the material U.S. federal income tax consequences to U.S. holders and certain non-U.S. holders, each as defined below, of our common shares or ADRs. This summary addresses only the U.S. federal income tax considerations for holders that acquire our common shares or ADRs at their original issuance and hold our common shares or ADRs as capital assets. This summary does not address all U.S. federal income tax matters that may be relevant to a particular holder. **Each prospective investor should consult a professional tax advisor with respect to the tax consequences of the acquisition, ownership or disposition of our common shares or ADRs**. This summary does not address tax considerations applicable to a holder of our common shares or ADRs that may be subject to special tax rules including, without limitation, the following:

banks or other financial institutions;

insurance companies;

dealers or traders in securities, currencies, or notional principal contracts;

tax-exempt entities, including an "individual retirement account" or "Roth IRA" retirement plan;

regulated investment companies or real estate investment trusts;

"qualified foreign pension funds," or entities wholly owned by a "qualified foreign pension fund";

persons who have elected to mark securities to market;

persons that hold the common shares as part of a hedge, straddle, conversion, constructive sale or similar transaction involving more than one position;

holders (whether individuals, corporations or partnerships) that are treated as expatriates for some or all U.S. federal income tax purposes;

persons who acquired the ADRs as compensation for the performance of services;

persons holding the ADRs in connection with a trade or business conducted outside of the United States;

holders that own (or are deemed to own) 10 percent or more of our common shares or ADRs, by vote or value; and

holders that have a "functional currency" other than the U.S. dollar.

Further, this summary does not address any aspects of any U.S. state, local or non-U.S. tax law, alternative minimum tax, gift or estate consequences, the rules regarding qualified small business stock within the meaning of Section 1202 of the Code, any election to apply Section 1400Z-2 of the Code to gains recognized with respect to our common shares, any other U.S. federal tax other than the income tax or the indirect effects on the holders of equity interests in entities that own our common shares or ADRs.

For the purposes of this summary, a "U.S. holder" is a beneficial owner of common shares or ADRs that is (or is treated as), for U.S. federal income tax purposes:

an individual who is either a citizen or resident of the United States;

a corporation, or other entity that is treated as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States or any state thereof or of the District of Columbia;

an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or

a trust, if a court in the United States is able to exercise primary supervision over its administration and one or more U.S. persons has the authority to control all of the substantial decisions of such trust or has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person.

If a partnership holds common shares or ADRs, the tax treatment of a partner will generally depend upon the status of the partner and upon the activities of the partnership. This discussion does not address the tax treatment of partnerships or other entities that are pass-through entities for U.S. federal income tax purposes or persons that hold their common shares or ADRs through partnerships or other pass-through entities. A partner in a partnership or other pass-through entity that will hold our common shares or ADRs should consult his, her or its tax advisor regarding the tax consequences of acquiring, holding and disposing of our common shares or ADRs through a partnership or other pass-through entity, as applicable.

We will not seek a ruling from the U.S. Internal Revenue Service, or IRS, with regard to the U.S. federal income tax treatment of an investment in our common shares or ADRs, and we cannot assure you that the IRS will agree with the conclusions set forth below.

PERSONS CONSIDERING AN INVESTMENT IN COMMON SHARES OR ADRs SHOULD CONSULT THEIR TAX ADVISORS AS TO THE PARTICULAR TAX CONSEQUENCES APPLICABLE TO THE ACQUISITION, OWNERSHIP AND DISPOSITION OF THE ORDINARY SHARES OR ADRs, INCLUDING THE APPLICABILITY OF U.S. FEDERAL, STATE AND LOCAL TAXES.

Ownership of ADRs

For U.S. federal income tax purposes, a holder of ADRs will generally be treated as the owner of the common shares represented by such ADRs. Gain or loss will generally not be recognized on account of exchanges of common shares for ADRs, or of ADRs for common shares. References to common shares in this discussion are deemed to include ADRs, unless context otherwise required.

Taxation of distributions

As discussed above, we do not currently expect to make distributions on our common shares. In the event that we do make distributions of cash or other property, subject to the PFIC rules described below, distributions paid on common shares, other than certain pro rata distributions of common shares, will generally be treated as dividends to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Because we do not maintain calculations of our earnings and profits under U.S. federal income tax principles, we expect that distributions generally will be reported to U.S. Holders as dividends. For so long as our common shares are listed on Nasdaq or we are eligible for benefits under the Treaty, dividends paid to certain non-corporate U.S. Holders will be eligible for taxation as "qualified dividend income" and therefore, subject to applicable limitations, will be taxable at rates not in excess of the long-term capital gain rate applicable to such U.S. Holder.

U.S. Holders should consult their tax advisors regarding the availability of the reduced tax rate on dividends in their particular circumstances. The amount of a dividend will include any amounts withheld by us in respect of Swiss income taxes. The amount of the dividend will be treated as foreign-source dividend income to U.S. Holders and will not be eligible for the dividends-received deduction generally available to U.S. corporations under the Code. Dividends will be included in a U.S. Holder' s income on the date of the U.S. Holder' s receipt of the dividend. The amount of any dividend income paid in Swiss Francs will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of actual or constructive receipt, regardless of whether the payment is in fact converted into U.S. dollars at that time. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt.

Subject to applicable limitations, some of which vary depending upon the U.S. Holder' s particular circumstances, Swiss income taxes withheld from dividends on common shares at a rate not exceeding the rate provided by the Treaty will be creditable against the U.S. Holder' s U.S. federal income tax liability. The rules governing foreign tax credits are complex and U.S. Holders should consult their tax advisors regarding the creditability of foreign taxes in their particular circumstances. In lieu of claiming a foreign tax credit, U.S. Holders may, at their election, deduct foreign taxes, including any Swiss income tax, in computing their taxable income, subject to generally applicable limitations under U.S. law. An election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the taxable year.

Sale or other disposition of common shares

Subject to the PFIC rules described below, gain or loss realized on the sale or other disposition of common shares will be capital gain or loss and will be long-term capital gain or loss if the U.S. Holder held the common shares for more than 1 year. The amount of the gain or loss will equal the difference between the U.S. Holder' s tax basis in the common shares disposed of and the amount realized on the disposition, in each case as determined in U.S. dollars. This gain or loss will generally be U.S.-source gain or loss for foreign tax credit purposes. The deductibility of capital losses is subject to various limitations.

Passive foreign investment company (PFIC) rules

Under the Code, we will be a PFIC for any taxable year in which, after the application of certain "look-through" rules with respect to subsidiaries, either (i) 75% or more of our gross income consists of "passive income," or (ii) 50% or more of the average quarterly value of our assets consists of assets that produce, or are held for the production of, "passive income." For purposes of the above calculations, we will be treated as if we hold our proportionate share of the assets of, and directly receive our proportionate share of the income of, any other corporation in which we directly or indirectly own at least 25%, by value, of the shares of such corporation. Passive income generally includes interest, dividends, rents, certain non-active royalties and capital gains.

If we were deemed to be a PFIC in any year during which a U.S. investor held or holds common shares (assuming such U.S. Holder has not made a timely mark-to-market election, as further described below), any gain recognized by a U.S. Holder on a sale or other disposition (including certain pledges) of the common shares would be allocated ratably over the U.S. Holder' s holding period for the common shares. The amounts allocated to the taxable year of the sale or other disposition and to any year before we became a PFIC would be taxed as ordinary income. The amount allocated to any other taxable year would be subject to tax at the highest rate in effect for individuals or corporations, as appropriate, for that taxable year, and an interest charge would be imposed on the amount allocated to that taxable year. Further, to the extent that any distribution received by a U.S. Holder on its common shares exceeds 125% of the average of the annual distributions on the common shares received during the preceding 3 years or the U.S. Holder' s holding period, whichever is shorter, that distribution would be subject to taxation in the same manner as gain, described immediately above.

A U.S. Holder can avoid certain of the adverse rules described above by making a mark-to-market election with respect to its common shares, provided that the common shares are "marketable." Common shares will be marketable if they are "regularly traded" on a "qualified exchange" or other market within the meaning of applicable Treasury regulations. If a U.S. Holder makes the mark-to-market election, it generally will recognize as ordinary income any excess of the fair market value of the common shares at the end of each taxable year over their adjusted tax basis, and will recognize an ordinary loss in respect of any excess of the adjusted tax basis of the common shares over their fair market value at the end of the taxable year (but only to the extent of the net amount of income previously included as a result of the mark-to-market election). If a U.S. Holder makes this election, the holder' s tax basis in the common shares will be adjusted to reflect the income or loss amounts recognized. Any gain recognized on the sale or other disposition of common shares in a year when we are a PFIC will be treated as ordinary income and any loss will be treated as an ordinary loss (but only to the extent of the net amount of income previously included as a result of the mark-to-market election).

In addition, in order to avoid the application of the foregoing rules, a U.S. person who owns stock in a PFIC for U.S. federal income tax purposes may make a "qualified electing fund" (QEF) election with respect to such PFIC if the PFIC provides the information necessary for such election to be made. If a U.S. person makes a QEF election with respect to a PFIC, the U.S. person will be currently taxable on their pro rata share of the PFIC' s ordinary earnings and net capital gain (at ordinary income and capital gain rates, respectively) for each taxable year that the entity is classified as a PFIC and will not be required to include such amounts in income when actually distributed by the PFIC. We do not intend to provide the information necessary for U.S. Holders to make QEF elections.

In addition, if we were a PFIC or, with respect to particular U.S. Holder, were treated as a PFIC for the taxable year in which we paid a dividend or for the prior taxable year, the preferential dividend rates discussed above with respect to dividends paid to certain non-corporate U.S. Holders would not apply.

If a U.S. Holder owns common shares during any year in which we are a PFIC, the holder generally must file annual reports containing such information as the U.S. Treasury may require on Internal Revenue Service (IRS) Form 8621 (or any successor form) with respect to us, generally with the holder' s federal income tax return for that year.

U.S. Holders should consult their tax advisors concerning our potential PFIC status and the potential application of the PFIC rules.

Information reporting and backup withholding

Payments of dividends and sales proceeds that are made within the U.S. or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that they are not subject to backup withholding.

The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the holder' s U.S. federal income tax liability and may entitle the Holder to a refund, provided that the required information is furnished in a timely manner to the IRS.

Information with respect to foreign financial assets

Certain U.S. Holders who are individuals (and, under proposed regulations, certain entities) may be required to report information relating to an interest in our common shares, subject to certain exceptions (including an exception for common shares held in accounts maintained by certain U.S. financial institutions). U.S. Holders should consult their tax advisors regarding the effect, if any, of this legislation on their ownership and disposition of the common shares.

F. DIVIDENDS AND PAYING AGENTS

Not applicable.

G. STATEMENT BY EXPERTS

The consolidated financial statements of RELIEF THERAPEUTICS Holding SA contained herein have been included in reliance on the report of MAZARS SA, independent registered public accounting firm, appearing elsewhere herein, and upon the authority of said firm as experts in accounting and auditing.

H. DOCUMENTS ON DISPLAY

When this registration statement on Form 20-F becomes effective, we will be subject to the information reporting requirements of the Exchange Act applicable to foreign private issuers, and under those requirements will file reports with the SEC. The SEC also maintains a website at http://www.sec.gov from which filings may be accessed.

I. SUBSIDIARY INFORMATION

For information about our subsidiaries, see "Item 4. Information on the Company – C. Organizational Structure."

ITEM 11. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

For information about our quantitative and qualitative disclosures about market risk, see "Item 5. Operating and Financial Review and Prospects – B. Liquidity and Capital Resources."

ITEM 12. DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. DEBT SECURITIES

Not Applicable.

B. WARRANTS AND RIGHTS

Not Applicable.

C. OTHER SECURITIES

Not applicable.

D. AMERICAN DEPOSITARY RECEIPTS

J.P. Morgan Chase Bank, N.A. ("J.P. Morgan") is acting as the depositary bank for the American Depositary Receipts. J.P. Morgan' s depositary offices are located at 383 Madison Avenue, Floor 11, New York, New York 10179. American Depositary Shares are sometimes referred to as "ADRs" and represent ownership interests in securities that are on deposit with the depositary bank. ADRs may be represented by certificates that are commonly known as "American Depositary Receipts" or "ADRs." The depositary bank typically appoints a custodian to safekeep the securities on deposit. In this case, the custodian is The Corporation Trust Company, located at 1209 Orange Street, Wilmington, Delaware 19801.

A copy of the deposit agreement is on file with the SEC under cover of a Registration Statement on Form F-6. You may obtain a copy of the deposit receipt from the SEC' s Public Reference Room at 100 F Street, N.E., Washington, DC 20549 and from the SEC' s website at www.sec.gov. Please refer to Relief Therapeutics Holding SA and Registration Number 333-260712 when retrieving such copy.

We are providing you with a summary description of the material terms of the ADRs and of your material rights of a holder of ADRs. Please remember that summaries by their nature lack the precision of the information. summarized and that the rights and obligations of an owner of ADRs will be determined by reference to the terms of the deposit agreement and not by this summary. We urge you to review the deposit agreement in its entirety. The portions of this summary description that are italicized describe matters that may be relevant to the ownership of ADRs but that may not be contained in the deposit agreement.

Each ADR represents the right to receive, and to exercise the beneficial ownership interests in, ordinary shares that are on deposit with the depositary bank and/or custodian. An ADR also represents the right to receive, and to exercise the beneficial interests in, any other property received by the depositary bank or the custodian on behalf of the owner of the ADR but that has not been distributed to the owners of ADRs because of legal restrictions or practical considerations. We and the depositary bank may agree to change the ADR-to-Share ratio by amending the deposit agreement. This amendment may give rise to, or change, the depositary fees payable by ADR owners. The custodian, the depositary bank and their respective nominees will hold all deposited property for the benefit of the holders and beneficial owners of ADRs. The deposited property does not constitute the proprietary assets of the depositary bank, the custodian or their nominees. Beneficial ownership in the deposited property will under the terms of the deposit agreement be vested in the beneficial owners of the ADRs. The depositary bank, the custodian and their respective nominees will be the record holders of the deposited property represented by the ADRs for the benefit of the holders and beneficial owners of the corresponding ADRs. A beneficial owner of ADRs may or may not be the holder of ADRs. Beneficial owners of ADRs will be able to receive, and to exercise beneficial ownership interests in, the deposited property only through the registered holders of the ADRs, the registered holders of the ADRs (on behalf of the applicable ADR owners) only through the depositary bank, and the depositary bank (on behalf of the owners of the corresponding ADRs) directly, or indirectly, through the custodian or their respective nominees, in each case upon the terms of the deposit agreement.

If you become an owner of ADRs, you will become a party to the deposit agreement and therefore will be bound to its terms and to the terms of any ADR that represents your ADRs. The deposit agreement and the ADR specify our rights and obligations as well as your rights and obligations as owner of ADRs and those of the depositary bank. As an ADR holder you appoint the depositary bank to act on your behalf in certain circumstances. The deposit agreement and the ADRs are governed by New York law. However, our obligations to the holders of ordinary shares will continue to be governed by Swiss law which may be different from the laws of the United States.

In addition, applicable laws and regulations may require you to satisfy reporting requirements and obtain regulatory approvals in certain circumstances. You are solely responsible for complying with such reporting requirements and obtaining such approvals. Neither the depositary bank, the custodian, us or any of their or our respective agents or affiliates shall be required to take any actions whatsoever on your behalf to satisfy such reporting requirements or obtain such regulatory approvals under applicable laws and regulations.

As an owner of ADRs, we will not treat you as one of our shareholders and you will not have direct shareholder rights. The depositary bank will hold on your behalf the shareholder rights attached to the ordinary shares underlying your ADRs. As an owner of ADRs you will be able to exercise the shareholders rights for the ordinary shares represented by your ADRs through the depositary bank only to the extent contemplated in the deposit agreement. To exercise any shareholder rights not contemplated in the deposit agreement you will, as an ADR owner, need to arrange for the cancellation of your ADRs and become a direct shareholder.

The manner in which you own the ADRs (e.g., in a brokerage account vs. as registered holder, or as holder of certificated vs. uncertificated ADRs) may affect your rights and obligations, and the manner in which, and extent to which, the depositary bank' s services are made available to you. As an owner of ADRs, you may hold your ADRs either by means of an ADR registered in your name, through a brokerage or safekeeping account, or through an account established by the depositary bank in your name reflecting the registration of uncertificated ADRs directly on the books of the depositary bank (commonly referred to as the "direct registration system" or "DRS"). The direct registration system reflects the uncertificated (book-entry) registration of ownership of ADRs by the depositary bank. Under the direct registration system, ownership of ADRs is evidenced by periodic statements issued by the depositary bank to the holders of the ADRs. The direct registration system includes automated transfers between the depositary bank and The Depository Trust Company DTC, the central book-entry clearing and settlement system for equity securities in the United States. If you decide to hold your ADRs through your brokerage or safekeeping account, you must rely on the procedures of your broker or bank to assert your rights as ADR owner. Banks and brokers typically hold securities such as the ADRs through clearing and settlement systems such as DTC. The procedures of such clearing and settlement systems may limit your ability to exercise your rights as an owner of ADRs. Please consult with your broker or bank if you have any questions concerning these limitations and procedures. All ADRs held through DTC will be registered in the name of a nominee of DTC. This summary description assumes you have opted to own the ADRs directly by means of an ADR registered in your name and, as such, we will refer to you as the "holder." When we refer to "you," we assume the reader owns ADRs and will own ADRs at the relevant time.

The registration of the ordinary shares in the name of the depositary bank or the custodian shall, to the maximum extent permitted by applicable law, vest in the depositary bank or the custodian the record ownership in the applicable ordinary shares with the beneficial ownership rights and interests in such ordinary shares being at all times vested with the beneficial owners of the ADRs representing the ordinary shares. The depositary bank or the custodian shall at all times be entitled to exercise the beneficial ownership rights in all deposited property, in each case only on behalf of the holders and beneficial owners of the ADRs representing the deposited property.

Dividends and Distributions

As a holder of ADRs, you generally have the right to receive the distributions we make on the securities deposited with the custodian. Your receipt of these distributions may be limited, however, by practical considerations and legal limitations. Holders of ADRs will receive such distributions under the terms of the deposit agreement in proportion to the number of ADRs held as of the specified record date, after deduction of the applicable fees, taxes and expenses.

Distributions of Cash

Whenever we make a cash distribution for the securities on deposit with the custodian, we will deposit the funds with the custodian. Upon receipt of confirmation of the deposit of the requisite funds, the depositary bank will arrange for the funds received in a currency other than U.S. dollars to be converted into U.S. dollars and for the distribution of the U.S. dollars to the holders, subject to the laws and regulations of Switzerland.

The conversion into U.S. dollars will take place only if practicable and if the U.S. dollars are transferable to the United States. The depositary bank will apply the same method for distributing the proceeds of the sale of any property (such as undistributed rights) held by the custodian in respect of securities on deposit.

The distribution of cash will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. The depositary bank will hold any cash amounts it is unable to distribute in a non-interest-bearing account for the benefit of the applicable holders and beneficial owners of ADRs until the distribution can be effected or the funds that the depositary bank holds must be escheated as unclaimed property in accordance with the laws of the relevant states of the United States.

Distributions of Shares

Whenever we make a free distribution of ordinary shares for the securities on deposit with the custodian, we will deposit the applicable number of ordinary shares with the custodian. Upon receipt of confirmation of such deposit, the depositary bank will either distribute to holders new ADRs representing the ordinary shares deposited or modify the ADR-to-ordinary shares ratio, in which case each ADR you hold will represent rights and interests in the additional ordinary shares so deposited. Only whole new ADRs will be distributed. Fractional entitlements will be sold and the proceeds of such sale will be distributed as in the case of a cash distribution.

The distribution of new ADRs or the modification of the ADR-to-ordinary shares ratio upon a distribution of ordinary shares will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes or governmental charges, the depositary bank may sell all or a portion of the new ordinary shares so distributed.

No such distribution of new ADRs will be made if it would violate a law (e.g., the U.S. securities laws) or if it is not operationally practicable. If the depositary bank does not distribute new ADRs as described above, it may sell the ordinary shares received upon the terms described in the deposit agreement and will distribute the proceeds of the sale as in the case of a distribution of cash.

Distributions of Rights

Whenever we intend to distribute rights to subscribe for additional ordinary shares, we will give prior notice to the depositary bank and we will assist the depositary bank in determining whether it is lawful and reasonably practicable to distribute rights to subscribe for additional ADRs to holders.

The depositary bank will establish procedures to distribute rights to subscribe for additional ADRs to holders and to enable such holders to exercise such rights if it is lawful and reasonably practicable to make the rights available to holders of ADRs, and if we provide all of the documentation contemplated in the deposit agreement (such as opinions to address the lawfulness of the transaction). You may have to pay fees, expenses, taxes and other governmental charges to subscribe for the new ADRs upon the exercise of your rights. The depositary bank is not obligated to establish procedures to facilitate the distribution and exercise by holders of rights to subscribe for new ordinary shares other than in the form of ADRs.

The depositary bank will *not* distribute the rights to you if:

- We do not timely request that the rights be distributed to you or we request that the rights not be distributed to you;
- We fail to deliver satisfactory documents to the depositary bank; or
- It is not reasonably practicable to distribute the rights.

The depositary bank will sell the rights that are not exercised or not distributed if such sale is lawful and reasonably practicable. The proceeds of such sale will be distributed to holders as in the case of a cash distribution. If the depositary bank is unable to sell the rights, it will allow the rights to lapse.

Elective Distributions

Whenever we intend to distribute a dividend payable at the election of shareholders either in cash or in additional shares, we will give prior notice thereof to the depositary bank and will indicate whether we wish the elective distribution to be made available to you. In such case, we will assist the depositary bank in determining whether such distribution is lawful and reasonably practicable.

The depositary bank will make the election available to you only if it is reasonably practicable and if we have provided all of the documentation contemplated in the deposit agreement. In such case, the depositary bank will establish procedures to enable you to elect to receive either cash or additional ADRs, in each case as described in the deposit agreement.

If the election is not made available to you, you will receive either cash or additional ADRs, depending on what a shareholder in Switzerland would receive upon failing to make an election, as more fully described in the deposit agreement.

Other Distributions

Whenever we intend to distribute property other than cash, ordinary shares or rights to subscribe for additional ordinary shares, we will notify the depositary bank in advance and will indicate whether we wish such distribution to be made to you. If so, we will assist the depositary bank in determining whether such distribution to holders is lawful and reasonably practicable.

If it is reasonably practicable to distribute such property to you and if we provide to the depositary bank all of the documentation contemplated in the deposit agreement, the depositary bank will distribute the property to the holders in a manner it deems practicable.

The distribution will be made net of fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes and governmental charges, the depositary bank may sell all or a portion of the property received.

The depositary bank will *not* distribute the property to you and will sell the property if:

- We do not request that the property be distributed to you or if we request that the property not be distributed to you;
- We do not deliver satisfactory documents to the depositary bank; or

The depositary bank determines that all or a portion of the distribution to you is not reasonably practicable.

The proceeds of such a sale will be distributed to holders as in the case of a cash distribution.

Redemption

Whenever we decide to redeem any of the securities on deposit with the custodian, we will notify the depositary bank in advance. If it is practicable and if we provide all of the documentation contemplated in the deposit agreement, the depositary bank will provide notice of the redemption to the holders.

The custodian will be instructed to surrender the shares being redeemed against payment of the applicable redemption price. The depositary bank will convert into U.S. dollars, upon the terms of the deposit agreement, the redemption funds received in a currency other than U.S. dollars and will establish procedures to enable holders to receive the net proceeds from the redemption upon surrender of their ADRs to the depositary bank. You may have to pay fees, expenses, taxes and other governmental charges upon the redemption of your ADRs. If less than all ADRs are being redeemed, the ADRs to be retired will be selected by lot or on a pro rata basis, as the depositary bank may determine.

Changes Affecting Ordinary Shares

The ordinary shares held on deposit for your ADRs may change from time to time. For example, there may be a change in nominal or par value, split-up, cancellation, consolidation or any other reclassification of such ordinary shares or a recapitalization, reorganization, merger, consolidation or sale of assets of the company.

If any such change were to occur, your ADRs would, to the extent permitted by law and the deposit agreement, represent the right to receive the property received or exchanged in respect of the ordinary shares held on deposit.

The depositary bank may in such circumstances deliver new ADRs to you, amend the deposit agreement, the ADRs and the applicable Registration Statement(s) on Form F-6, call for the exchange of your existing ADRs for new ADRs and take any other actions that are appropriate to reflect as to the ADRs the change affecting the ordinary shares. If the depositary bank may not lawfully distribute such property to you, the depositary bank may sell such property and distribute the net proceeds to you as in the case of a cash distribution.

Issuance of ADRs upon Deposit of Ordinary Shares

Upon effectiveness of this registration statement, the ordinary shares will be deposited by us with the custodian. Upon receipt of confirmation of such deposit, the depositary bank will issue ADRs to the underwriters named in the registration statement.

After the effectiveness of this registration statement, the depositary bank may create ADRs on your behalf if you or your broker deposit ordinary shares with the custodian. The depositary bank will deliver these ADRs to the person you indicate only after you pay any applicable issuance fees and any charges and taxes payable for the transfer of the ordinary shares to the custodian. Your ability to deposit ordinary shares and receive ADRs may be limited by U.S. and English legal considerations applicable at the time of deposit.

The issuance of ADRs may be delayed until the depositary bank or the custodian receives confirmation that all required approvals have been given and that the ordinary shares have been duly transferred to the custodian. The depositary bank will only issue ADRs in whole numbers.

When you make a deposit of ordinary shares, you will be responsible for transferring good and valid title to the depositary bank. As such, you will be deemed to represent and warrant that:

The ordinary shares are duly authorized, validly issued, fully paid, non-assessable and legally obtained.

All preemptive (and similar) rights, if any, with respect to such ordinary shares have been validly waived or exercised.

You are duly authorized to deposit the ordinary shares.

The ordinary shares presented for deposit are free and clear of any lien, encumbrance, security interest, charge, mortgage or adverse claim, and are not, and the ADRs issuable upon such deposit will not be, "restricted securities" (as defined in the deposit agreement).

The ordinary shares presented for deposit have not been stripped of any rights or entitlements.

If any of the representations or warranties are incorrect in any way, we and the depositary bank may, at your cost and expense, take any and all actions necessary to correct the consequences of the misrepresentations.

Transfer, Combination and Split Up of ADRs

As an ADR holder, you will be entitled to transfer, combine or split up your ADRs and the ADRs evidenced thereby. For transfers of ADRs, you will have to surrender the ADRs to be transferred to the depositary bank and also must:

ensure that the surrendered ADR is properly endorsed or otherwise in proper form for transfer;

provide such proof of identity and genuineness of signatures as the depositary bank deems appropriate;

provide any transfer stamps required by state or federal law; and

pay all applicable fees, charges, expenses, taxes and other government charges payable by ADR holders pursuant to the terms of the deposit agreement, upon the transfer of ADRs.

To have your ADRs either combined or split up, you must surrender the ADRs in question to the depositary bank with your request to have them combined or split up, and you must pay all applicable fees, charges and expenses payable by ADR holders, pursuant to the terms of the deposit agreement, upon a combination or split up of ADRs.

Withdrawal of Ordinary Shares Upon Cancellation of ADRs

As a holder, you will be entitled to present your ADRs to the depositary bank for cancellation and then receive the corresponding number of underlying ordinary shares at the custodian' s offices. Your ability to withdraw the ordinary shares held in respect of the ADRs may be limited by U.S. and English law considerations applicable at the time of withdrawal. In order to withdraw the ordinary shares represented by your ADRs, you will be required to pay to the depositary bank the fees for cancellation of ADRs and any charges and taxes payable upon the transfer of the ordinary shares. You assume the risk for delivery of all funds and securities upon withdrawal. Once canceled, the ADRs will not have any rights under the deposit agreement.

If you hold ADRs registered in your name, the depositary bank may ask you to provide proof of identity and genuineness of any signature and such other documents as the depositary bank may deem appropriate before it will cancel your ADRs. The withdrawal of the ordinary shares represented by your ADRs may be delayed until the depositary bank receives satisfactory evidence of compliance with all applicable laws and regulations. Please keep in mind that the depositary bank will only accept ADRs for cancellation that represent a whole number of securities on deposit.

You will have the right to withdraw the securities represented by your ADRs at any time except for:

Temporary delays that may arise because (i) the transfer books for the ordinary shares or ADRs are closed, or (ii) ordinary shares are immobilized on account of a shareholders' meeting or a payment of dividends.

Obligations to pay fees, taxes and similar charges.

Restrictions imposed because of laws or regulations applicable to ADRs or the withdrawal of securities on deposit.

The deposit agreement may not be modified to impair your right to withdraw the securities represented by your ADRs except to comply with mandatory provisions of law.

Each holder and beneficial owner of ADRs agrees to provide such information as the company may request in a disclosure notice given pursuant to the Swiss Code of Obligations (CO), or the Articles of Association. Each holder and beneficial owner of ADRs acknowledges that it understands that failure to comply with such request may result in the imposition of sanctions against the holder of the ordinary shares in respect of which the non-complying person is or was, or appears to be or has been, interested as provided in the CO and the Articles of Association which currently include, the withdrawal of the voting rights of such Shares and the imposition of restrictions on the rights to receive dividends on and to transfer such Shares.

Voting Rights

As a holder, you generally have the right under the deposit agreement to instruct the depositary bank to exercise the voting rights for the ordinary shares represented by your ADRs. The voting rights of holders of ordinary shares are described in "Description of Share Capital and Articles of Association−Articles of Association."

At our request, the depositary bank will distribute to you any notice of shareholders' meeting received from us together with information explaining how to instruct the depositary bank to exercise the voting rights of the securities represented by ADRs. In lieu of distributing such materials, the depositary bank may distribute to holders of ADRs instructions on how to retrieve such materials upon request.

If the depositary bank timely receives voting instructions from a holder of ADRs, it will endeavor to vote the securities (in person or by proxy) represented by the holder' s ADRs as follows:

In the event of voting by show of hands, the depositary bank will vote (or cause the custodian to vote) all ordinary shares held on deposit at that time in accordance with the voting instructions received from a majority of holders of ADRs who provide timely voting instructions.

In the event of voting by poll, the depositary bank will vote (or cause the Custodian to vote) the ordinary shares held on deposit in accordance with the voting instructions received from the holders of ADRs.

Securities for which no voting instructions have been received will not be voted (except as otherwise contemplated in the deposit agreement). Please note that the ability of the depositary bank to carry out voting instructions may be limited by practical and legal limitations and the terms of the securities on deposit. We cannot assure you that you will receive voting materials in time to enable you to return voting instructions to the depositary bank in a timely manner.

Fees and Charges

As an ADR holder, you will be required to pay the following fees under the terms of the deposit agreement.

Service	Fees
Cash distributions made, or elective cash/stock dividends offered, pursuant to the Deposit Agreement	Up to $0.05 per ADR issued
Distribution or sale of securities under the Deposit Agreement	An amount equal to the fee for the execution and delivery of ADRs which would have been charged as a result of the deposit of such securities, but which securities or the net cash proceeds from the sale thereof are instead distributed by the depositary to the holders entitled thereto.
Services performed by the Depositary in administering the ADRs	Up to $0.05 per ADR per calendar year

As an ADR holder you may also be responsible to pay certain charges such as:

Reimbursement of fees, charges and expenses incurred by the Depositary and/or any of its agents in connection with the servicing of the shares or deposited securities, the delivery of deposited securities or otherwise in connection with the Depositary' s or the Custodian' s compliance with applicable law, rule or regulation;

Stock transfer or other taxes and other governmental charges;

SWIFT, cable, telex and facsimile transmission and delivery charges incurred at the request of persons depositing, or holders delivering shares, ADRs or deposited securities; and

Transfer or registration fees for the registration or transfer of deposited securities on any applicable register in connection with the deposit or withdrawal of deposited securities.

ADR fees and charges for (i) the issuance of ADRs, and (ii) the cancellation of ADRs are charged to the person for whom the ADRs are issued (in the case of ADR issuances) and to the person for whom ADRs are cancelled (in the case of ADR cancellations). In the case of ADRs issued by the depositary bank into DTC, the ADR issuance and cancellation fees and charges may be deducted from distributions made through DTC, and may be charged to the DTC participant(s) receiving the ADRs being issued or the DTC participant(s) holding the ADRs being cancelled, as the case may be, on behalf of the beneficial owner(s) and will be charged by the DTC participant(s) to the account of the applicable beneficial owner(s) in accordance with the procedures and practices of the DTC participants as in effect at the time. ADR fees and charges in respect of distributions and the ADR service fee are charged to the holders as of the applicable ADR record date. In the case of distributions of cash, the amount of the applicable ADR fees and charges is deducted from the funds being distributed. In the case of (i) distributions other than cash and (ii) the ADR service fee, holders as of the ADR record date will be invoiced for the amount of the ADR fees and charges and such ADR fees and charges may be deducted from distributions made to holders of ADRs. For ADRs held through DTC, the ADR fees and charges for distributions other than cash and the ADR service fee may be deducted from distributions made through DTC, and may be charged to the DTC participants in accordance with the procedures and practices prescribed by DTC and the DTC participants in turn charge the amount of such ADR fees and charges to the beneficial owners for whom they hold ADRs. In the case of (i) registration of ADR transfers, the ADR transfer fee will be payable by the ADR Holder whose ADRs are being transferred or by the person to whom the ADRs are transferred, and (ii) conversion of ADRs of one series for ADRs of another series, the ADR conversion fee will be payable by the Holder whose ADRs are converted or by the person to whom the converted ADRs are delivered.

In the event of refusal to pay the depositary bank fees, the depositary bank may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depositary bank fees from any distribution to be made to the ADR holder. Certain depositary fees and charges (such as the ADR services fee) may become payable shortly after the purchase of ADRs. Note that the fees and charges you may be required to pay may vary over time and may be changed by us and by the depositary bank. You will receive prior notice of such changes. The depositary bank may reimburse us for certain expenses incurred by us in respect of the ADR program, by making available a portion of the ADR fees charged in respect of the ADR program or otherwise, upon such terms and conditions as we and the depositary bank agree from time to time.

Amendments and Termination

We may agree with the depositary bank to modify the deposit agreement at any time without your consent. We undertake to give holders 30 days' prior notice of any modifications that would materially prejudice any of their substantial rights under the deposit agreement. We will not consider to be materially prejudicial to your substantial rights any modifications or supplements that are reasonably necessary for the ADRs to be registered under the Securities Act or to be eligible for book-entry settlement, in each case without imposing or increasing the fees and charges you are required to pay. In addition, we may not be able to provide you with prior notice of any modifications or supplements that are required to accommodate compliance with applicable provisions of law.

You will be bound by the modifications to the deposit agreement if you continue to hold your ADRs after the modifications to the deposit agreement become effective. The deposit agreement cannot be amended to prevent you from withdrawing the ordinary shares represented by your ADRs (except as permitted by law).

We have the right to direct the depositary bank to terminate the deposit agreement. Similarly, the depositary bank may in certain circumstances on its own initiative terminate the deposit agreement. In either case, the depositary bank must give notice to the holders at least 30 days before termination. Until termination, your rights under the deposit agreement will be unaffected.

Termination

After termination, the depositary bank will continue to collect distributions received (but will not distribute any such property until you request the cancellation of your ADRs) and may sell the securities held on deposit. After the sale, the depositary bank will hold the proceeds from such sale and any other funds then held for the holders of ADRs in a non-interest bearing account. At that point, the depositary bank will have no further obligations to holders other than to account for the funds then held for the holders of ADRs still outstanding (after deduction of applicable fees, taxes and expenses).

In connection with any termination of the deposit agreement, the depositary bank may make available to owners of ADRs a means to withdraw the ordinary shares represented by ADRs and to direct the depositary of such ordinary shares into an unsponsored American depositary share program established by the depositary bank. The ability to receive unsponsored American depositary shares upon termination of the deposit agreement would be subject to satisfaction of certain U.S. regulatory requirements applicable to the creation of unsponsored American depositary shares and the payment of applicable depositary fees.

Books of Depositary

The depositary bank will maintain ADR holder records at its depositary office. You may inspect such records at such office during regular business hours but solely for the purpose of communicating with other holders in the interest of business matters relating to the ADRs and the deposit agreement.

The depositary bank will maintain in New York facilities to record and process the issuance, cancellation, combination, split-up and transfer of ADRs. These facilities may be closed from time to time, to the extent not prohibited by law.

Limitations on Obligations and Liabilities

The deposit agreement limits our obligations and the depositary bank' s obligations to you. Please note the following:

- We and the depositary bank are obligated only to take the actions specifically stated in the deposit agreement without negligence or bad faith.
- The depositary bank disclaims any liability for any failure to carry out voting instructions, for any manner in which a vote is cast or for the effect of any vote, provided it acts in good faith and in accordance with the terms of the deposit agreement.
- The depositary bank disclaims any liability for any failure to determine the lawfulness or practicality of any action, for the content of any document forwarded to you on our behalf or for the accuracy of any translation of such a document, for the investment risks associated with investing in ordinary shares, for the validity or worth of the ordinary shares, for any tax consequences that result from the ownership of ADRs, for the credit-worthiness of any third party, for allowing any rights to lapse under the terms of the deposit agreement, for the timeliness of any of our notices or for our failure to give notice.
- We and the depositary bank will not be obligated to perform any act that is inconsistent with the terms of the deposit agreement.

We and the depositary bank disclaim any liability if we or the depositary bank are prevented or forbidden from or subject to any civil or criminal penalty or restraint on account of, or delayed in, doing or performing any act or thing required by the terms of the deposit agreement, by reason of any provision, present or future of any law or regulation, or by reason of present or future provision of any provision of our Articles of Association, or any provision of or governing the securities on deposit, or by reason of any act of God or war or other circumstances beyond our control.

We and the depositary bank disclaim any liability by reason of any exercise of, or failure to exercise, any discretion provided for in the deposit agreement or in our Articles of Association or in any provisions of or governing the securities on deposit.

We and the depositary bank further disclaim any liability for any action or inaction in reliance on the advice or information received from legal counsel, accountants, any person presenting Shares for deposit, any holder of ADRs or authorized representatives thereof, or any other person believed by either of us in good faith to be competent to give such advice or information.

We and the depositary bank also disclaim liability for the inability by a holder to benefit from any distribution, offering, right or other benefit that is made available to holders of ordinary shares but is not, under the terms of the deposit agreement, made available to you.

We and the depositary bank may rely without any liability upon any written notice, request or other document believed to be genuine and to have been signed or presented by the proper parties.

We and the depositary bank also disclaim liability for any consequential or punitive damages for any breach of the terms of the deposit agreement.

No disclaimer of any Securities Act liability is intended by any provision of the deposit agreement.

Nothing in the deposit agreement gives rise to a partnership or joint venture, or establishes a fiduciary relationship, among us, the depositary bank and you as ADR holder.

Nothing in the deposit agreement precludes the depositary bank (or its affiliates) from engaging in transactions in which parties adverse to us or the holders or beneficial owners of ADR have interests, and nothing in the deposit agreement obligates the depositary bank to disclose those transactions, or any information obtained in the course of those transactions, to us or to the holders or beneficial owners of ADR, or to account for any payment received as part of those transactions.

Taxes

You will be responsible for the taxes and other governmental charges payable on the ADRs and the securities represented by the ADRs. We, the depositary bank and the custodian may deduct from any distribution the taxes and governmental charges payable by holders and may sell any and all property on deposit to pay the taxes and governmental charges payable by holders. You will be liable for any deficiency if the sale proceeds do not cover the taxes that are due.

The depositary bank may refuse to issue ADRs, to deliver, transfer, split and combine ADRs or to release securities on deposit until all taxes and charges are paid by the applicable holder. The depositary bank and the custodian may take reasonable administrative actions to obtain tax refunds and reduced tax withholding for any distributions on your behalf. However, you may be required to provide to the depositary bank and to the custodian proof of taxpayer status and residence and such other information as the depositary bank and the custodian may require to fulfill legal obligations. You are required to indemnify us, the depositary bank and the custodian for any claims with respect to taxes based on any tax benefit obtained for you.

Foreign Currency Conversion

The depositary bank will arrange for the conversion of all foreign currency received into U.S. dollars if such conversion is practical, and it will distribute the U.S. dollars in accordance with the terms of the deposit agreement. You may have to pay fees and expenses incurred in converting foreign currency, such as fees and expenses incurred in complying with currency exchange controls and other governmental requirements.

If the conversion of foreign currency is not practical or lawful, or if any required approvals are denied or not obtainable at a reasonable cost or within a reasonable period, the depositary bank may take the following actions in its discretion:

Convert the foreign currency to the extent practicable and lawful and distribute the U.S. dollars to the holders for whom the conversion and distribution is lawful and practicable.

Distribute the foreign currency to holders for whom the distribution is lawful and practical.

Hold the foreign currency (without liability for interest) for the applicable holders.

Governing Law / Waiver of Jury Trial

The deposit agreement, the ADRs, and the ADRs will be interpreted in accordance with the laws of the State of New York. The rights of holders of ordinary shares (including ordinary shares represented by ADRs) are governed by the laws of Switzerland.

AS A PARTY TO THE DEPOSIT AGREEMENT, YOU IRREVOCABLY WAIVE, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, YOUR RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF, OR RELATING TO, THE DEPOSIT AGREEMENT OR THE ADRs, OR ANYTHING CONTAINED THEREIN AGAINST U.S. AND/OR THE DEPOSITARY.

The deposit agreement provides that, to the extent permitted by law, ADR holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our ordinary shares, the ADRs or the deposit agreement, including any claim under U.S. federal securities laws. If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable in the facts and circumstances of that case in accordance with applicable case law. However, you will not be deemed, by agreeing to the terms of the deposit agreement, to have waived our or the depositary' s compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.

PART II

ITEM 13. DEFAULTS, DIVIDEND ARREARAGES AND DELINQUENCIES

Not applicable.

ITEM 14. MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

Not applicable.

ITEM 15. CONTROLS AND PROCEDURES

Not applicable.

ITEM 16. RESERVED

ITEM 16A. AUDIT COMMITTEE FINANCIAL EXPERT

The Board of Directors has determined that Paolo Galfetti, a member of the Audit and Finance Committee, is an Audit Committee Financial Expert as defined in Regulation S-K under the Exchange Act.

ITEM 16B. CODE OF ETHICS

We have adopted a Code of Business Conduct and Ethics, which covers a broad range of matters including the handling of conflicts of interest, compliance issues and other corporate policies such as insider trading and equal opportunity and non-discrimination standards. Our Code of Business Conduct & Ethics applies to all of our directors, executive officers and employees. We have published our Code of Business Conduct and Ethics on our website, https://relieftherapeutics.com/company. The information contained on our website is not a part of this Registration Statement.

ITEM 16C. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Not applicable.

ITEM 16D. EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

ITEM 16E. PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

In 2021, no purchases of our equity securities were made by or on behalf of the Company or any affiliated purchaser.

ITEM 16F. CHANGE IN REGISTRANT' S CERTIFYING ACCOUNTANT

None.

ITEM 16G. CORPORATE GOVERNANCE

Summary of significant corporate governance differences from Nasdaq Listing Standards

We intend to seek to list our ADRs on the Nasdaq Stock Market. If we are approved for listing, we will be required to comply with certain of the Nasdaq' s corporate governance listing standards (Nasdaq Standards). As a foreign private issuer, we may follow our home country' s corporate governance practices in lieu of certain of the Nasdaq Standards. Our corporate governance practices differ in certain respects from those that U.S. companies must adopt in order to maintain a Nasdaq listing. A brief, general summary of those differences is provided as follows.

Independent directors

Swiss law does not require that a majority of our board of directors consist of independent directors. Our board of directors therefore may include fewer independent directors than would be required if we were subject to Nasdaq Listing Rule 5605(b)(1). In addition, we are not subject to Nasdaq Listing Rule 5605(b)(2), which requires that independent directors must regularly have scheduled meetings at which only independent directors are present. Notwithstanding the foregoing, however, a majority of our current Board of Directors is independent pursuant to the Nasdaq Listing Rules.

Nomination and compensation, audit and corporate governance committees

As Swiss law requires that we have a compensation committee (and we have in line with best practice installed a nomination and compensation committee as well as an audit committee and a corporate governance committee), we will follow home country requirements with respect to such committees. As a result, our practice will vary from the requirements of Nasdaq Listing Rule 5605(d), which sets forth certain requirements as to the responsibilities, composition and independence of the nomination and compensation, audit and corporate governance committees.

Quorum requirements

In accordance with Swiss law and generally accepted business practices, our articles of association do not provide quorum requirements generally applicable to general meetings of shareholders. Our practice thus varies from the requirement of Nasdaq Listing Rule 5620(c), which requires an issuer to provide in its bylaws for a generally applicable quorum, and that such quorum may not be less than one-third of the outstanding voting stock.

Solicitation of proxies

Our articles of association provide for an independent proxy holder elected by our shareholders, who may represent our shareholders at a general meeting of shareholders, and we must provide shareholders with an agenda and other relevant documents for the general meeting of shareholders. However, Swiss law does not have a regulatory regime for the solicitation of proxies, and company solicitation of proxies is prohibited for public companies in Switzerland. Thus, our practice will vary from the requirement of Nasdaq Listing Rule 5620(b), which sets forth certain requirements regarding the solicitation of proxies.

ITEM 16H. MINE SAFETY DISCLOSURE

Not applicable.

PART III

ITEM 17. FINANCIAL STATEMENTS

We have elected to furnish financial statements and related information in Item 18.

ITEM 18. FINANCIAL STATEMENTS

See pages F-1 through F-79 of this Registration Statement.

ITEM 19. EXHIBITS

The Exhibits listed in the Exhibit Index at the end of this Registration Statement are filed as Exhibits hereto.

EXHIBIT INDEX

Exhibit Number	Description of Exhibit
3.1***	Articles of Association of the Registrant
4.1*	Form of Deposit Agreement
4.2	Form of American Depositary Receipt (included in Exhibit 4.1)
4.3*	Form of Nominee Agreement
10.1**/***	Share Purchase Agreement, dated June 28, 2021, between the Company and the shareholders of APR Applied Pharma Research SA
10.2**/***	Purchase Agreement, dated July 28, 2021, between the Company and the shareholders of AdVita Lifescience GmbH
10.3**/***	Share Subscription Facility Agreement, dated as of January 20, 2021, by and among the Company, GEM Global Yield LLC SCS, and GEM Yield Bahamas Ltd.
10.4***	Binding Collaboration Agreement, dated as of September 18, 2020, between the Company and NeuroRx, Inc.
10.5**/***	Collaboration and License Agreement, dated March 19, 2021, between the Company and Acer Therapeutics, Inc.
10.6**/***	Collaboration Agreement, dated November 23, 2021, between the Company and InveniAI LLC
10.7(a)**/***	Master Service Agreement on Order to Cash Service, dated effective September 14, 2018, between APR and Arvato Services Italia S.R.L.
10.7(b)**/***	Amendment No. 1 to the Master Service Agreement on Order to Cash Service, dated effective February 1, 2021, between APR and Arvato
10.7(c)**/***	Amendment No. 2 to the Master Service Agreement on Order to Cash Service, dated July 13, 2021, between APR and Arvato.
10.8(a)**/***	Royalty Purchase Agreement, dated as of July 31, 2014, made by and between APR and SWK Funding LLC
10.8(b)**/***	Royalty Purchase Agreement, dated December 2, 2015, made by and between APR and SWK Funding LLC
21.1***	Subsidiaries of the Registrant
23.1	Consent of MAZARS SA, independent registered public accounting firm with respect to the financial statements of RELIEF Therapeutics Holding SA.
23.2	Consent of MAZARS SA, independent registered public accounting firm, with respect to the financial statements of APR Applied Pharma Research SA.

* Filed by reference to Exhibit 4.1 to the Company' s Registration Statement on Form F-6, filed with the Securities and Exchange Commission on November 3, 2021 (File No. 333-260712)

** Certain identified information has been excluded from this exhibit because it both (i) is not material and (ii) would be competitively harmful if publicly disclosed

*** Previously filed

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this registration statement on its behalf.

Date: July 1, 2022

RELIEF THERAPEUTICS HOLDING SA

By: /s/ Jack Weinstein
Jack Weinstein
Chief Financial Officer

By: /s/ Raghuram Selvaraju
Raghuram (Ram) Selvaraju
Chairman

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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Report of independent registered public accounting firm to the Board of Directors and Stockholders of RELIEF THERAPEUTICS Holding SA

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of RELIEF THERAPEUTICS Holding SA (the Company) as of December 31, 2021 and 2020, and the related consolidated statements of comprehensive loss, the consolidated cash flow statements and the consolidated statements of changes in equity for each of the years in the two-year period ended December 31, 2021, and the related notes (collectively referred to as the consolidated financial statements).

In our opinion the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2021, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Basis for Opinion

These financial statements are the responsibility of the Company' s management. Our responsibility is to express an opinion on the Company' s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company' s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ MAZARS SA - Signature

Franck Paucod
Licensed Audit Expert
(Auditor in Charge)

Yoann Bois
Licensed Audit Expert

We have served as the Company' s auditor since 2017.

Switzerland, Geneva

March 30, 2022

Consolidated balance sheet

in CHF thousands	Notes	December 31, 2021	December 31, 2020
ASSETS			
Intangible assets	9	192,299	30,800
Right-of-use assets	10	2,498	–
Property and equipment		38	–
Non-current financial assets	11	–	392
Other non-current assets		76	–
Deferred tax assets	34	1,737	–
Non-current assets		**196,648**	**31,192**
Inventories	12	391	–
Trade receivables	13	1,302	–
Other current financial assets	14	–	185
Other current assets	15	8,516	3,514
Restricted cash	16	–	5,093
Cash and cash equivalents	17	44,761	38,061
Current assets		**54,970**	**46,853**
Total assets		**251,618**	**78,045**
EQUITY AND LIABILITIES			
Share capital	18	44,133	32,467
Reserves	19	210,147	69,774
Treasury shares	18	(2,999)	–
Accumulated losses		(69,751)	(35,198)
Equity		**181,530**	**67,043**
Non-current lease liabilities	10	2,192	–
Non-current borrowings	20	396	–
Defined benefit obligations	21	2,793	–
Provisions	22	19,470	–
Deferred tax liabilities	34	25,504	4,309
Non-current liabilities		**50,355**	**4,309**
Current lease liabilities	10	331	–
Current borrowings	20	95	–
Trade payables		1,700	1,432
Financial liabilities due to third parties	23	–	891
Financial liabilities due to related parties	24	1,250	–
Provisions	22	12,083	–
Other current payables and liabilities	25	4,274	4,370
Current liabilities		**19,733**	**6,693**
Total equity and liabilities		**251,618**	**78,045**

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

Consolidated statement of comprehensive loss

in CHF thousands	Notes	2021	2020
Revenue	6	3,321	–
Other gains	26	1,171	273
Total income		**4,492**	**273**
Raw materials and consumables expense	27	(750)	–
External selling and distribution expense	27	(365)	–
External research and development expense	28	(19,024)	(13,672)
Personnel expense	29	(9,121)	(2,627)
Other administrative expense	30	(6,750)	(2,999)
Other losses	31	(752)	(1,260)
EBITDA		**(32,270)**	**(20,285)**
Reversal of impairment losses on intangible assets	9	–	11,200
Amortization and depreciation expense	32	(2,036)	–
Operating result		**(34,306)**	**(9,085)**
Gain from disposal of a subsidiary	8	–	3,382
Financial income	33	97	7
Financial expense	33	(1,316)	(565)
Net result before taxes		**(35,525)**	**(6,261)**
Income taxes	34	820	(1,567)
Net result for the period		**(34,705)**	**(7,828)**
OTHER COMPREHENSIVE INCOME			
Remeasurement of defined benefit obligation	21	152	136
Total items that will not be reclassified subsequently to profit or loss		**152**	**136**
Currency translation differences	19	255	3
Total items that may be reclassified subsequently to profit or loss		**255**	**3**
Total other comprehensive income for the year, net of tax		**407**	**139**
Total comprehensive result for the period		**(34,298)**	**(7,689)**
EARNINGS PER SHARE			
Basic and diluted loss per share (in CHF)	36	(0.010)	(0.003)

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

Consolidated cash flow statement

in CHF thousands	Notes	2021	2020
Net loss for the period		(34,705)	(7,828)
Adjustments for:			
Taxes charged	34.1	(820)	1,567
Reversal of impairment	9	–	(11,200)
Depreciation and amortisation expense	32	2,036	–
Losses on financial assets at fair value through profit or loss	14	54	1,195
Gain on disposal of subsidiary	8	–	(3,382)
Gain on loan forgiveness	26	(890)	(104)
Impairment of receivables due from third parties		470	50
Finance expenses	33	1,316	713
Finance income	33	(97)	(155)
Interest expenses paid		(260)	(143)
Loss on disposal of property and equipment		3	–
Change in defined benefit obligation	21	1,266	–
Share-based payment expenses	35	1,143	1,048
Changes in working capital:			
(Increase) in inventories		(111)	–
(Increase) in trade receivables		(208)	–
(Increase) in other assets		(2,585)	(3,874)
(Decrease)/increase in trade payables		(823)	1,160
(Decrease) in financial liabilities due to third parties		–	(654)
(Decrease) in financial liabilities due to related parties		–	(20)
(Decrease)/increase in provisions		100	(58)
(Decrease)/increase in other payables and liabilities		(1,607)	3,474
(Decrease) in liabilities associated with assets held for sale		–	(43)
Cash flow from operating activities		**(35,718)**	**(18,254)**
Payments for intangible assets	9	(13,708)	–
Proceeds on sale of right-of-use assets		11	–
Net cash out flow on acquisition of subsidiary	7	(16,681)	–
Payments to acquired other financial assets		(23)	–
Proceeds on sale of other financial assets	14	132	3,262
Payments of loans to third parties		–	(241)
Net cash out flow on disposal of subsidiary	8	–	(16)
Interest received		7	–
Cash flow from investing activities		**(30,262)**	**3,005**
Proceeds from capital increase	18	76,088	58,334
Transaction costs in relation to capital increase	19	(2,848)	(634)
Proceeds from borrowings		–	500
Repayment of borrowings		(5,551)	–
Cash flow from financing activities		**67,689**	**58,200**
Net increase in cash and cash equivalents		**1,709**	**42,951**
Cash and cash equivalents at beginning of period		43,154	137
Exchange difference on cash and cash equivalents		(102)	66
Cash and cash equivalents at end of period		**44,761**	**43,154**
included in cash and cash equivalents	17	44,761	38,061
included in restricted cash	16	–	5,093

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

Consolidated statement of changes in equity

in CHF thousands	Notes	Share capital	Treasury shares	Reserves	Accumulated loss	Total equity
Balance at January 1, 2020		**21,139**	**–**	**20,665**	**(27,506)**	**14,298**
Result for the period		–	–	–	(7,828)	(7,828)
Other comprehensive income for the period		–	–	3	136	139
Total comprehensive result for the period		**–**	**–**	**3**	**(7,692)**	**(7,689)**
Capital increase	18	2,980	–	47,959	–	50,939
Exercise of warrants	18	7,667	–	46	–	7,713
Exercise of options	18	681	–	724	–	1,405
Share-based payments	35	–	–	1,048	–	1,048
Transaction cost in relation to capital increases	18	–	–	(634)	–	(634)
Recycling of foreign currency exchange reserve		–	–	(37)	–	(37)
Balance at December 31, 2020		**32,467**	**–**	**69,774**	**(35,198)**	**67,043**
Balance at January 1, 2021		**32,467**	**–**	**69,774**	**(35,198)**	**67,043**
Result for the period		–	–	–	(34,705)	(34,705)
Other comprehensive income for the period		–	–	255	152	407
Total comprehensive result for the period		**–**	**–**	**255**	**(34,553)**	**(34,298)**
Issuance of treasury shares	18	11,535	(11,535)	–	–	–
Direct Share Placement program	18	–	3,982	46,905	–	50,887
Private placements	18	–	1,129	23,871	–	25,000
Acquisition payments	7	–	3,425	70,977	–	74,402
Exercise of options	18	131	–	70	–	201
Share-based payments	35	–	–	1,143	–	1,143
Transaction cost in relation to capital increases	18	–	–	(2,848)	–	(2,848)
Balance at December 31, 2021		**44,133**	**(2,999)**	**210,147**	**(69,751)**	**181,530**

The accompanying notes form an integral part of these consolidated 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 the OTCQB (ticker: RLFTF).

The Group historically focused on the development and commercialization of molecules with a history of clinical use and either initial human activity with efficacy data or a strong scientific rationale. On June 28, 2021, the Group acquired all outstanding shares of 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. This transaction has transformed Relief into a fully integrated commercial-stage biopharmaceutical Group employing over 50 persons. The acquisition further diversified Relief' s pipeline and portfolio with both commercial products and clinical-stage programs, offered a commercial infrastructure in Europe and strengthened internal R&D capability to i) market services to third parties, particularly in the area of difficult-to-formulate products, ii) offer in-kind services with a chance to participate in future profits and iii) advance promising drug candidates that are developed internally.

These consolidated financial statements were approved for publication by the Board of Directors on March 30, 2022.

2. Application of new and revised International Financial Reporting Standards (IFRS)

2.1 New and revised IFRS Standards and Interpretations

In the current year, the Group has applied the following new or amended Standards that became effective from January 1, 2021. The revised Standards did not have a material effect on these financial statements.

'Interest Rate Benchmark Reform' – amendment to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16.

2.2 IFRS Standards and Interpretations issued and not yet adopted

Certain new accounting Standards and Interpretations have been issued that are not mandatory for the current reporting period and have not been early adopted by the Group. These standards are not expected to have a material impact on the Group' s overall results and financial position.

Amendments to IAS 1, 'Presentation of financial statements' on classification of liabilities; and

Narrow-scope amendments to IFRS 3, IAS 16, IAS 8, IAS 12, IAS 37 and IFRS 16 and annual improvements on IFRS 9.

3. Summary of significant accounting policies

3.1 Basis of preparation

The consolidated financial statements of the Group have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB) and comply with Swiss law. They have been prepared under the historical cost convention, as modified by the revaluation of financial instruments at fair value, are presented in Swiss Francs (CHF), and all values are rounded to the nearest thousand (TCHF), except when otherwise indicated.

3.2 Basis of consolidation

The consolidated financial statements comprise the financial statements of the Group and its subsidiaries as of December 31, 2021 and 2020. Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee.

Specifically, the Group controls an investee if and only if the Group has:

power over the investee (i.e., existing rights that give it the current ability to direct the relevant activities of the investee);

exposure, or rights, to variable returns from its involvement with the investee; and

the ability to use its power over the investee to affect its returns.

When the Group has less than a majority of the voting or similar rights of an investee, the Group considers all relevant facts and circumstances in assessing whether it has power over an investee, including:

any contractual arrangement with the other vote holders of the investee;

rights arising from other contractual arrangements;

the Group' s voting rights and potential voting rights.

The Group reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control. Consolidation of a subsidiary begins when the Group obtains control over the subsidiary and ceases when the Group loses control of the subsidiary. Assets, liabilities, income and expenses of a subsidiary acquired or disposed of during the year are included in the statement of comprehensive income from the date the Group gains control until the date the Group ceases to control the subsidiary.

Profit or loss and each component of other comprehensive income are attributed to the equity holders of the parent of the Group and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. When necessary, adjustments are made to the financial statements of subsidiaries to bring their accounting policies into line with the Group' s accounting policies. Inter-company transactions, balances and unrealized gains/losses on transactions between Group companies are eliminated. The accounting policies of subsidiaries are consistent with the policies adopted by the Group.

3.3 Current versus non-current classification

The Group presents assets and liabilities in its statement of financial position based on current/non-current classification. An asset is classified as current when it is:

expected to be realized or intended to be sold or consumed in a normal operating cycle, which is twelve months;

held primarily for the purpose of trading;

expected to be realized within twelve months after the reporting period; or

cash or cash equivalents unless restricted from being exchanged or used to settle a liability for at least twelve months after the reporting period.

All other assets are classified as non-current.

A liability is current when:

it is expected to be settled in a normal operating cycle, which is twelve months;

it is held primarily for the purpose of trading;

it is due to be settled within twelve months after the reporting period; or

there is no unconditional right to defer the settlement of the liability for at least twelve months after the reporting period.

The Group classifies all other liabilities as non-current.

Deferred tax assets and liabilities are classified as non-current assets and liabilities.

3.4 Business combinations and goodwill

Business combinations are accounted for using the acquisition method. The cost of an acquisition is measured as the aggregate of the consideration transferred measured at acquisition date fair value and the amount of any non-controlling interests in the acquiree. For each business combination, the Group elects whether to measure the non-controlling interests in the acquiree at fair value or at the proportionate share of the acquiree' s identifiable net assets. Acquisition-related costs are expensed as incurred and included in other administrative expenses.

When the Group acquires a business, it assesses the financial assets and liabilities assumed for appropriate classification and designation in accordance with the contractual terms, economic circumstances and pertinent conditions as of the acquisition date. This includes the separation of embedded derivatives in host contracts by the acquiree.

If the business combination is achieved in stages, any previously held equity interest is re-measured at its acquisition date fair value and any resulting gain or loss is recognized in profit or loss. It is then considered in the determination of goodwill.

Any contingent consideration to be transferred by the acquirer will be recognized at fair value at the acquisition date. Contingent consideration classified as an asset or liability that is a financial instrument and within the scope of IFRS 9, is measured at fair value with changes in fair value recognized in profit or loss. If the contingent consideration is not within the scope of IFRS 9, it is measured in accordance with the appropriate IFRS. Contingent consideration that is classified as equity is not re-measured and subsequent settlement is accounted for within equity.

Goodwill is initially measured at cost, being the excess of the aggregate of the consideration transferred and the amount recognized for non-controlling interests and any previous interest held, over the net identifiable assets acquired and liabilities assumed. If the fair value of the net assets acquired is in excess of the aggregate consideration transferred, the Group re-assesses whether it has correctly identified all of the assets acquired and all of the liabilities assumed and reviews the procedures used to measure the amounts to be recognized at the acquisition date. If the re-assessment still results in an excess of the fair value of net assets acquired over the aggregate consideration transferred, then the gain is recognized in profit or loss.

After initial recognition, goodwill is measured at cost less any accumulated impairment losses. For the purpose of impairment testing, goodwill acquired in a business combination is, from the acquisition date, allocated to each of the Group' s cash-generating units that are expected to benefit from the combination, irrespective of whether other assets or liabilities of the acquiree are assigned to those units.

Where goodwill has been allocated to a cash-generating unit and part of the operation within that unit is disposed of, the goodwill associated with the disposed operation is included in the carrying amount of the operation when determining the gain or loss on disposal. Goodwill disposed in these circumstances is measured based on the relative values of the disposed operation and the portion of the cash-generating unit retained.

3.5 Revenue recognition

Relief may generate revenues from collaboration and license agreements under which Relief grants licenses to use, research, develop, manufacture and commercialize product candidates and products. Relief determined that those collaboration and license agreements qualify as contracts with its customers. If the grant of a license is bundled together with the rendering of services, it is assessed whether these agreements are comprised of more than one performance obligation. A performance obligation is only accounted for as the grant of a license if the grant of a license is the sole or the predominant promise of the performance obligation.

If the consideration in an agreement includes a variable amount, Relief estimates the amount of consideration to which Relief will be entitled in exchange for transferring the goods to the customer. At contract inception, the variable consideration is estimated based on the most likely amount of consideration expected from the transaction and constrained until it is highly probable that a significant revenue reversal in the amount of cumulative revenue recognized will not occur when the associated uncertainty with respect the variable consideration is subsequently resolved. The estimated revenue is updated at each reporting date to reflect the current facts and circumstances.

If a contract with a customer contains more than one performance obligation, the transaction price is allocated to each performance obligation based on relative-stand-alone selling prices.

For each separate performance obligation, it is evaluated whether control is transferred either at a point in time or over time. For performance obligations that are satisfied over time, revenue is recognized based on a measure of progress, which depicts the performance in transferring control to the customer. Under the terms of its licensing arrangements, Relief provides the licensee with a research and development license, which represents a right to access Relief' s intellectual property as it exists throughout the license period. Therefore, the promise to grant a license is accounted for as a performance obligation satisfied over time, as the licensee simultaneously receives and consumes the benefits of Relief' s performance.

Earnings based on the collaboration partners' gross profit, which is shared under the respective collaboration agreements are recognized when the underlying sales occur, which is when the performance obligation has been satisfied. Relief uses certain information from its collaboration partners, some of which is based on preliminary data shared between the partners and might vary once final data is available.

Revenue arrangements that involve two or more partners who contribute to the provision of a specific good or service to a customer are assessed in terms of principal-agent considerations in order to determine the appropriate treatment for the transactions between Relief and the collaborator and the transactions between Relief and other third parties. The classification of transactions under such arrangements is determined based on the nature and contractual terms of the arrangement along with the nature of the operations of the participants. Any consideration related to activities in which Relief is considered the principal, which includes being in control of the good or service before such good or service is transferred to the customer, are accounted for as gross revenue. Any consideration related to activities in which Relief is considered the agent, are accounted for as net revenue.

Revenue from the sale of products is recognized when Relief transfers control of the product to the customer. Control of the product normally transfers when the customer gains physical possession and Relief has not retained any significant risks of ownership or future obligations with respect to the product. A receivable is recognized, as the consideration is unconditional and only the passage of time is required before payment is due. The transaction price is quoted in the relevant price lists in force at the date of customer placing the respective order for such products.

Revenue from research and development services provided by the Company is recorded as earned based on the performance requirements of the underlying contracts. Where agreements include milestones that are determined to be substantive and at risk at the inception of the agreement, revenue is recognized upon confirmation by the counterparty that the milestone has been achieved.

3.6 Foreign currency translation

Functional and presentation currency

Items included in the financial statements of each of the Group' s entities are measured using the currency of the primary economic environment in which the entity operates (i.e., the functional currency). The consolidated financial statements are presented in CHF, which is the presentation currency of the Company.

Transactions and balances

In preparing the financial statements of each individual group entity, transactions in currencies other than the entity' s functional currency are recognized at the rates of exchange prevailing at the dates of the transactions. At the end of each reporting period, monetary items denominated in foreign currencies are re-translated at the rates prevailing at that date. Non-monetary items that are measured at historical cost in a foreign currency are not re-translated. Exchange differences on monetary items are recognized in profit or loss in the period in which they arise.

Group companies

Assets and liabilities of Group entities using a functional currency different from the presentation currency are translated into the presentation currency using year-end rates of exchange. Income and expenses and cash flows are translated at average exchange rates. All resulting translation differences are recognized directly in other comprehensive income. On the divestment of a foreign entity, the identified cumulative currency translation difference relating to that foreign entity is recognized in profit or loss as part of the gain or loss on divestment.

3.7 Intangible assets

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is their fair value at the date of acquisition. Following initial recognition, intangible assets are carried at cost less any accumulated amortization and accumulated impairment losses.

Internally generated intangibles, excluding capitalized development costs, are not capitalized and the related expenditure is reflected in profit or loss in the period in which the expenditure is incurred.

The useful lives of intangible assets are assessed as either finite or indefinite. 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. The amortization period and the amortization method for an intangible asset with a finite useful life are reviewed at least at the end of each reporting period. Changes in the expected useful life or the expected pattern of consumption of future economic benefits embodied in the asset are considered to modify the amortization period or method, as appropriate, and are treated as changes in accounting estimates. The amortization expense on intangible assets with finite lives is recognized in the statement of profit or loss in the expense category that is consistent with the function of the intangible assets.

Amortization of capitalized in process research & development ("IPR&D") starts once the asset is available for use, which is usually the point in time at which marketing approval is granted by the relevant authority. Before that date, capitalized IPR&D that is not available for use is tested at least annually for impairment, irrespective of whether any indication of impairment exists.

Intangible assets with indefinite useful lives are not amortized, but are tested for impairment annually, either individually or at the cash-generating unit level. The assessment of indefinite life is reviewed annually to determine whether the indefinite life continues to be supportable. If not, the change in useful life from indefinite to finite is made on a prospective basis.

Gains or losses arising from de-recognition of an intangible asset are measured as the difference between the net disposal proceeds and the carrying amount of the asset and are recognized in the statement of profit or loss when the asset is derecognized.

3.8 Leases

The Group assesses whether a contract is or contains a lease at inception of the contract. The Group recognizes a right-of-use asset and a corresponding lease liability with respect to all lease arrangements in which it is the lessee, except for short-term leases (defined as leases with a lease term of twelve months or less) and leases of low value assets. For these leases, the Company recognizes the lease payments as an operating expense on a straight-line basis over the term of the lease unless another systematic basis is more representative of the time pattern in which economic benefits from the leased assets are consumed.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted by using the rate implicit in the lease. If this rate cannot be readily determined, the Group uses its incremental borrowing rate for such liabilities.

Lease payments included in the measurement of the lease liability comprise:

fixed lease payments (including in-substance fixed payments), less any lease incentives;

variable lease payments that depend on an index or rate, initially measured using the index or rate at the commencement date;

the amount expected to be payable by the lessee under residual value guarantees;

the exercise price of purchase options, if the lessee is reasonably certain to exercise the options; and

payments of penalties for terminating the lease if the lease term reflects the exercise of an option to terminate.

The lease liability is subsequently measured by increasing the carrying amount to reflect interest on the lease liability (using the effective interest method) and by reducing the carrying amount to reflect the lease payments made.

The right-of-use assets comprise the initial measurement of the corresponding lease liability, lease payments made at or before the commencement day and any initial direct costs. They are subsequently measured at cost less accumulated depreciation and impairment losses.

Right-of use assets are depreciated over the shorter period of lease term and useful life of the underlying asset. If a lease transfers ownership of the underlying asset or the cost of the right-of-use asset reflects that the Group expects to exercise a purchase option, the related right-of-use asset is depreciated over the useful life of the underlying asset. The depreciation starts at the commencement date of the lease.

The Group has elected not to recognize right-of-use assets and lease liabilities for short-term leases that have a lease term of 12 months or less, or leases of low-value assets. The Group recognizes the lease payments associated with these leases as an expense in the consolidated statements of operations on a straight-line basis over the lease term.

3.9 Financial assets

Classification

The Group has only financial assets classified within the categories, “financial assets at fair value through profit or loss (FVTPL)” and “financial assets at amortized cost.” The classification at initial recognition depends on the financial asset’ s contractual cash flow characteristics and the Group’ s business model for managing them. The Group’ s financial assets at amortized cost include other current assets and other receivables that are non-derivative financial assets with fixed or determinable payments that are not quoted in an active market. The Group’ s financial assets at fair value through profit or loss include publicly traded securities.

Recognition and measurement

Financial assets at amortized cost are measured initially at their fair value and are subsequently measured at amortized cost using the effective interest rate method and are subject to impairment.

A financial asset is derecognized when:

the contractual rights to the cash flows from the asset have expired; or

the Group has transferred its rights to receive cash flows from the asset or has assumed an obligation to pay the received cash flows in full without material delay to a third party under a 'pass-through' arrangement; and either (a) the Group has transferred substantially all the risks and rewards of the asset, or (b) the Group has neither transferred nor retained substantially all the risks and rewards of the asset but has transferred control of the asset.

Financial assets at FVTPL are measured at fair value at the end of each reporting period, with any fair value gains or losses recognized in profit or loss. Fair value is determined in the manner described in note 37.3.

Impairment of financial assets

The Group recognizes an allowance for expected credit losses ("ECL") for all debt instruments not held at fair value through profit or loss. ECL are based on the difference between the contractual cash flows due in accordance with the contract and all the cash flows that the Group expects to receive, discounted at an approximation of the original effective interest rate. The expected cash flows will include cash flows from the sale of collateral held or other credit enhancements that are integral to the contractual terms.

ECLs are recognized in two stages. For credit exposures for which there has not been a significant increase in credit risk since initial recognition, ECLs are provided for credit losses that result from default events that are possible within the next twelve months (a twelve-month ECL). For those credit exposures for which there has been a significant increase in credit risk since initial recognition, a loss allowance is required for credit losses expected over the remaining life of the exposure, irrespective of the timing of the default (a lifetime ECL).

The Group considers a financial asset in default when contractual payments are 90 days past due. However, in certain cases, the Group may also consider a financial asset to be in default when internal or external information indicates that the Group is unlikely to receive the outstanding contractual amounts in full before taking into account any credit enhancements held by the Group. A financial asset is written off when there is no reasonable expectation of recovering the contractual cash flows.

3.10 Inventories

Raw materials and merchandise purchased are recognized at cost; semi-finished and finished goods at their production cost. Discounts are recognized as a reduction in the purchase price. Manufacturing costs include the associated direct production costs and production overheads, where applicable. If the acquisition or manufacturing costs are higher than the net market value, an impairment loss is recorded on the income statement in the current period to write the inventories down to the net market value (lower of cost or market principle). Net market value is equivalent to the current market price less the usual sales deductions, marketing costs and administrative costs yet to be incurred. Inventories that cannot be sold are written off in full. The costs of inventories are determined by using the FIFO method.

Inventory related to drug products that have not yet obtained regulatory approval are immediately written down to zero. The write-down is charged to research and development expenses. If regulatory approval is subsequently obtained, the recorded expenses are not reversed.

3.11 Cash and cash equivalents

Cash and cash equivalents include cash in hand, deposits held at call with banks and other short-term highly liquid investments with original maturities of three months or less. Bank overdrafts are shown within financial debts in current liabilities on the balance sheet. This definition is also used for the purposes of the cash flow statement.

3.12 Financial liabilities

The Group' s financial liabilities include trade and other payables as well as borrowings.

Financial liabilities are recognized initially at fair value and are subsequently measured at amortized cost using the effective interest rate method, with interest expense recognized on an effective yield basis.

The Group derecognizes financial liabilities when, and only when, the Group' s obligations are discharged, cancelled or expired.

3.13 Current and deferred income tax

The tax expense for the period comprises current and deferred tax. Tax is recognized in the income statement, except to the extent that it relates to items recognized in other comprehensive income or directly in equity. In this case, the tax is also recognized in other comprehensive income or directly in equity, respectively.

Deferred income tax is recognized, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. However, the deferred income tax is not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that, at the time of the transaction, affects neither accounting nor taxable profit or loss. Deferred income tax is determined using tax rates (and laws) that have been enacted or substantively enacted by the balance sheet date and are expected to apply when the related deferred income tax asset is realized or the deferred income tax liability is settled.

Deferred income tax assets are recognized to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilized.

Deferred income tax is provided on temporary differences arising on investments in subsidiaries and associates, except for deferred income tax liability where the timing of the reversal of the temporary difference is controlled by the Group and it is probable that the temporary difference will not reverse in the foreseeable future.

3.14 Fair values

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either:

in the principal market for the asset or liability, or

in the absence of a principal market, in the most advantageous market for the asset or liability.

The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data are available to measure fair value, maximizing the use of relevant observable inputs and minimizing the use of unobservable inputs.

The fair values of financial assets and liabilities at the balance sheet date are not materially different from their reported carrying values unless specifically mentioned in the notes to the consolidated financial statements.

3.15 Research and development costs

Research and development costs consist primarily of remuneration and other expenses related to research and development personnel, costs associated with preclinical testing and clinical trials of product candidates, expenses for research and development services under collaboration agreements and outsourced research and development expenses. Furthermore, the Group may acquire in-process research and development assets, either through business combinations or through purchases of specific assets. In-process research and development assets acquired either through business combinations or separate purchases are capitalized as intangible assets and reviewed for impairment at each reporting date. Once available for use, such intangible assets are amortized on a straight-line basis over the period of the expected benefit.

Internal development costs are capitalized as intangible assets only when there is an identifiable asset that can be completed and that will generate probable future economic benefits and when the cost of such an asset can be measured reliably.

3.16 Employee benefits

General

Wages, salaries, social security contributions, paid annual leave and sick leave, bonuses, and non-monetary benefits are accrued in the year in which the associated services are rendered by employees of the Group.

Pension obligations

The cost of providing benefits under the defined benefit plan is determined using the projected unit credit method.

Re-measurements, including actuarial gains and losses, the effect of the asset ceiling, and the return on plan assets (excluding net interest), are recognized immediately in the statement of financial position with a corresponding debit or credit to retained earnings through other comprehensive income (“OCI”) in the period in which they occur. Re-measurements are not reclassified to profit or loss in subsequent periods.

Past service costs are recognized in profit or loss on the earlier of:

- the date of the plan amendment or curtailment, or
- the date that the Group recognizes restructuring-related costs.

Net interest is calculated by applying the discount rate to the net defined benefit liability or asset. The Group recognizes the following changes in the net defined benefit obligation under 'personnel expense' in the consolidated statement of comprehensive income:

- service costs comprising current service costs, past-service costs, gains and losses on curtailments and non-routine settlements; and
- net interest expense or income.

3.17 Share-based payments

The cost of equity-settled transactions is determined by the fair value at the date when the grant is made using an appropriate valuation model.

That cost is recognized, together with a corresponding increase in other capital reserves in equity, over the period in which the performance and/or service conditions are fulfilled in employee benefits expense. The cumulative expense recognized for equity-settled transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired and the Group' s best estimate of the number of equity instruments that will ultimately vest. The statement of profit or loss expense or credit for a period represents the movement in cumulative expense recognized at the beginning and end of that period and is recognized in employee benefits expense.

No expense is recognized for awards that do not ultimately vest, except for equity-settled transactions for which vesting is conditional upon a market or non-vesting condition. These are treated as vested, irrespective of whether or not the market or non-vesting condition is satisfied, provided that all other performance and/or service conditions are satisfied.

When the terms of an equity-settled award are modified, the minimum expense recognized is the expense as if the terms had not been modified if the original terms of the award have been met. An additional expense is recognized for any modification that increases the total fair value of the share-based payment transaction or is otherwise beneficial to the employee as measured at the date of modification.

The dilutive effect of outstanding options is reflected as additional share dilution in the computation of diluted earnings per share.

4. Summary of critical accounting judgements 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. The estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year are described below.

4.1 Critical judgements in applying accounting policies

Collaboration and license agreement with Acer

In March 2021, Relief and Acer Therapeutics Inc. ("Acer") entered into a collaboration and license agreement for worldwide development and commercialization of ACER-001.

The management has assessed the payment of USD 15 million (CHF 13.7 million), comprised of USD 14 million as initial payment due upon signing of the agreement plus USD 1 million paid in exchange of an exclusivity period to negotiate the agreement, is in substance the acquisition cost of the development project. Hence, the license and the price paid for its acquisition meet the requirements of an intangible asset and are capitalized as an intangible asset (note 9).

Amortization of the intangible asset will begin when the license is available for use, i.e., when it is in the condition necessary to operate in the manner intended by the management. The amortization will therefore begin when the regulatory and marketing approvals are obtained. Until then, the intangible asset will be tested for impairment at least annually, irrespective of whether any indication of impairment exists.

With regards to the possible future milestone payments, the Group, in accordance with industry practice, is following the cost accumulation approach. Hence, the milestone payments are not considered on initial recognition of the asset but will be added to the cost of the asset if and when incurred.

The upfront development payments paid and to be paid by Relief to Acer for further development activities do not yet meet the capitalization criteria for intangible assets. Hence, they are recognized as a prepayment in the balance sheet upon payment (note 15) and released to the income statement over the period of the development activity as incurred. Development expenses occurred under the collaboration agreement, which are incurred by the Acer and subsequently reported to Relief, are recorded as external research and development expense.

Revenue recognition

Revenue is primarily from fees related to licenses, milestones and royalties as well as product sales. Given the complexity of the relevant agreements, judgement is required to identify distinct performance obligations, allocate the transaction price to these performance obligations and determine when the performance obligations are met.

Going concern

These consolidated financial statements are prepared on a going concern basis. The Group maintains liquidity forecasts and monitors its ability to continue as a going concern. The viability of the Group is dependent on its ability to start generating recurring positive cash flows to adequately support its operations. The Group may never achieve sustainable profitability and is exposed to all the risks inherent in establishing a business. Since its inception, the Group has primarily relied on share issuances to finance its cash needs. The ability of the Group to raise money and fund its long-term operations is uncertain. If the Group is unable to obtain the required financing, it may be unable to continue its operations, realize its assets and discharge its liabilities.

4.2 Key sources of estimation uncertainty

Business combination

The allocation of the purchase price for business acquisitions to the identifiable assets acquired and liabilities assumed based on their respective fair values, requires use of accounting estimates and judgment. Acquired intangible assets are valued using valuation models under which fair values are derived from future net cash flows, which are discounted to the acquisition date using an appropriate discount factor. Relief has estimated fair values of assets acquired, liabilities assumed, and contingent considerations based on reasonable assumptions.

Valuation and impairment of intangible assets

Determining whether intangible assets are impaired requires management to estimate the recoverable value of the cash-generating unit to which the intangible assets are attributable. If the recoverable value of the cash-generating unit is lower than the carrying amount of the cash-generating unit to which the intangible assets have been allocated, impairment is recorded. Changes to the assumptions may result in impairment losses or impairment reversals in subsequent periods.

Share-based compensation

The fair values of the options at the grant date have been assessed using the Black-Scholes valuation model and spread over the vesting period. The significant inputs into the model were share price, exercise price, expected life of the options, volatility and risk-free interest rate.

Deferred income taxes

The determination of the recoverability of deferred income tax assets is based on the judgment of management. Deferred income tax assets are recognized only if it is probable that they can be used in the future. Whether or not they can be used depends on whether the tax-deductible temporary difference can be offset against future taxable profits. In order to assess the probability of their future use, management considers the scheduled reversal of deferred tax liabilities, projected future taxable income and tax planning strategies. Such deferred tax assets are only recorded when sufficient future taxable profits are probable.

Defined benefit obligation

The retirement benefit obligation is calculated on the basis of various financial and actuarial assumptions. The key assumptions for assessing these obligations are the discount rate, future salary increases, future pension increases as well as the probability of the employee reaching retirement. The obligation was calculated using a discount rate of 0.30 %. The calculations were done by an external expert and the principal assumptions used are summarized in note 21. As of December 31, 2021, the underfunding amounted to TCHF 1,550. Using another basis for the calculations could have led to a different result.

5. Group companies

The following table lists the subsidiaries controlled by Relief at the end of the reporting period.

			Equity interest	
Name	**Country**	**City**	**31.12.21**	**31.12.20**
Relief Therapeutics International SA	Switzerland	Geneva	100 %	100 %
Relief Therapeutics US, Inc.	United States	New York	100 %	100 %
Relief Therapeutics, Inc.	United States	New York	100 %	100 %
APR Applied Pharma Research SA	Switzerland	Balerna	100 %	–
APR Applied Pharma Research Holding SA	Switzerland	Balerna	100 %	–
APR Applied Pharma Research - Italy s.r.l.	Italy	Rome	100 %	–
APR Applied Pharma Research Deutschland GmbH	Germany	Offenbach am Main	100 %	–
AdVita Lifescience GmbH	Germany	Freiburg im Breisgau	100 %	–
AdVita Lifescience AG	Switzerland	Basel	100 %	–
AdVita Lifescience, Inc.	United States	New York	100 %	–

The equity interest percentage shown in the table also represents the share in voting rights in those entities.

6. Segment information

6.1 Description of segment

The Group operates in one segment, namely research, development and commercialization of biopharmaceutical products. The Board of Directors and the Executive Committee, being together the chief operating decision maker, allocate resources and assess the performance of the Group at a consolidated level. The accounting policies used for segment reporting are the same as those used for the preparation of these financial statements.

6.2 Information on revenue

Relief generates revenue from out-licensing transactions and sales of products. In 2021, the primary source of revenue was the portfolio of marketed products acquired in the business combination with APR at the end of June 2021. As a result, sales reported in the Group' s income statement represent revenue realized during the 6-month period from July 1, 2021, to December 31, 2021. Revenue is reported by geographical location based on the location of the customer or licensee and, for services, based on the location where the services were performed.

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

TCHF	2021*	2020
Revenue streams		
Royalties	1,268	–
Product sales	1,305	–
License fees, upfront fees and milestones	289	–
Revenue from research & development services	459	–
Total revenue	**3,321**	–
Geographical area		
Switzerland	527	
Europe (excluding Switzerland)	1,115	–
North America	835	–
Rest of the world	844	–
Total revenue	**3,321**	–
Timing of revenue recognition		
Point in time	3,321	–
Over time	–	–
Total revenue	**3,321**	–

* Revenue recognized since the acquisition of APR, i.e., from July 1, 2021, to December 31, 2021.

In 2021, each of the three largest customers of the Group represented 19.1%, 13.6% and 13.3%, respectively, of the total net sales.

6.3 Geographical location of non-current assets

TCHF	December 31, 2021	December 31, 2020
Switzerland	194,935	30,800
Rest of the world	183	–
Total non-current assets *	**195,118**	**30,800**

* Without financial assets and deferred tax assets.

7. Business combinations

7.1 Acquisition of APR

On June 28, 2021, the Group acquired all outstanding shares and voting rights of APR Applied Pharma Research SA (Ticino, Switzerland). The APR subgroup is constituted by its parent company APR Applied Pharma Research SA and three fully owned subsidiaries: APR Applied Pharma Research Holding SA (Ticino, Switzerland), APR Applied Pharma Research Deutschland GmbH (Offenbach am Main, Germany), and APR Applied Pharma Research - Italy S.r.l. (Rome, Italy).

The main corporate purpose of APR is the research and development of new technologies and methods in the chemical, pharmaceutical and food sectors, the registration of patents, as well as the registration of dietetic products, cosmetics and medical-surgical aids; it also manufactures and trades medical products on an international scale and acquire, hold, use or sell patents, trademarks and other intangible rights as well as licenses.

The acquisition of APR provided Relief with a platform for future growth, including established commercial infrastructure that will facilitate future therapeutic product launches in key European markets and in the U.S., as well as commercial revenues and qualified human resources. Under the terms of the agreement, APR' s former shareholders have received from Relief a cash payment of CHF 21.5 million and CHF 42.9 million in Relief common registered shares. APR' s former shareholders are also eligible to receive additional contingent payments in a combination of cash and Relief common shares upon achievement of pre-agreed milestones.

Consideration transferred

	TCHF
Cash	21,500
Non-cash (Relief shares)	42,912
Contingent consideration	20,157
Total consideration transferred	**84,569**

Under IFRS 3, the cost of the acquisition is based on the market value of Relief s listed shares at the acquisition date. Therefore, the fair value of the consideration transferred is calculated as follows: 206,786,784 shares at a fair value of CHF 0.20752 per share resulting to TCHF 42,912. The fair value of the shares based on the share price at the date of the transaction differs from the contractual value of CHF 45 million.

The acquisition agreement includes contingent considerations to the previous owners in the aggregate maximum amount of up to CHF 35 million upon achievement of pre-agreed milestones involving (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, (iii) the launch of Golike in the U.S., and (iv) the launch of APR-TD011 in the first of France, Germany, Spain, Italy and the United Kingdom. Depending on the milestone payment, 60% to 75% will be payable in Relief shares and the rest in cash.

At the acquisition date, the fair value of the contingent consideration was TCHF 20,157, based on the estimated probability of occurrence as of the date of acquisition and the time factor. The contingent liability is presented in current and non-current provisions (note 22).

Acquisition-related costs of TCHF 775 have been excluded from the consideration transferred and recognized in 'other administrative expense' in the statement of comprehensive loss for the current period and are included in cash flows used in operating activities in the consolidated statement of cash flows.

Assets acquired and liabilities recognized at the date of acquisition

The fair values of the assets and liabilities of APR as at the date of acquisition were as follows:

	TCHF
Non-current assets	
Right-of-use assets	2,599
Property and equipment	34
Intangible assets	90,236
Deferred tax assets	1,239
Other non-current assets	55
Current assets	
Inventories	192
Trade receivables	1,107
Other current assets and other receivables	851
Cash and cash equivalents	5,710
Non-current liabilities	
Non-current lease liabilities	(2,248)
Defined benefit obligation	(1,707)
Deferred tax liabilities	(14,402)
Current liabilities	
Current lease liabilities	(371)
Current borrowings	(5,170)
Trade payables	(952)
Other current liabilities	(1,262)
Net assets acquired	**75,911**

Goodwill arising from the acquisition

	TCHF
Consideration transferred	84,569
Fair value of identifiable net assets	(75,911)
Goodwill	**8,658**

The purchase price allocation includes the recognition of intangible assets of TCHF 90,236 and a related deferred tax liability of TCHF 14,402. As no other individual identifiable assets meeting the recognition criteria were identified, the residual amount paid of TCHF 8,658 was allocated to goodwill. The goodwill is attributable to APR' s established organization, history of successful partnerships and developments, and expected synergies with the Group' s development and intended commercialization of aviptadil and ACER-001 in Europe. This goodwill is not expected to be deductible for income tax purposes. Intangible assets acquired in the business combination are described in note 9.

Net cash outflow from the acquisition

	TCHF
Cash and cash equivalent balance acquired	5,710
Consideration paid in cash and cash equivalents	(21,500)
Total net cash outflow	**(15,790)**

7.2 Acquisition of AdVita

On July 27, 2021, the Company closed the definitive agreement to acquire all outstanding shares of AdVita Lifescience GmbH ("AdVita").

Under the terms of the agreement, AdVita' s former shareholders have received from Relief 135,741,063 Relief common listed shares. AdVita' s sellers are also eligible to receive additional contingent payments of up to EUR 20 million (CHF 20.7 million) in cash upon achievement of pre-agreed milestones.

Consideration transferred

	TCHF
Cash	–
Non-cash (Relief shares)	31,490
Contingent consideration	10,465
Total consideration transferred	**41,955**

Under IFRS 3, the cost of the acquisition is based on the market value of Relief` s listed shares at the acquisition date. Therefore, the fair value of the consideration transferred is calculated as follows: 135,741,063 shares at a fair value of CHF 0.232 (share price on transaction date) resulting to TCHF 31,490.

The acquisition agreement with AdVita includes contingent considerations to the previous owners in the aggregate maximum amount of up to EUR 20 million (CHF 20.7 million) in cash upon achievement of pre-agreed milestones involving (i) the issuance of one of AdVita' s pending patents, (ii) upon the first regulatory approval in the U.S. or Europe for the inhaled form of aviptadil for the prevention or therapy of acute respiratory distress system or acute lung injury, (iii) upon regulatory approval in the U.S. or Europe for the inhaled form of aviptadil for the treatment of sarcoidosis or berylliosis, and (iv) the identification of a partner for co-development or the start of a phase II clinical trial for checkpoint inhibitor-induced pneumonitis.

At the acquisition date, the fair value of the contingent consideration was TCHF 10,465, based on the estimated probability of occurrence and the time factor. The contingent liability is presented in current and non-current provisions (note 22).

Acquisition-related costs amounting to TCHF 325 have been excluded from the consideration transferred and recognized in 'other administrative expense' in the statement of comprehensive loss for the current period and are included in cash flows used in operating activities in the consolidated statement of cash flows.

Assets acquired and liabilities recognized at the date of acquisition

The fair values of the assets and liabilities of AdVita as at the date of acquisition were as follows:

	TCHF
Non-current assets	
Tangible assets	14
Right-of-use assets	98
Intangible assets	50,716
Current assets	
Trade receivables	64
Inventory	88
Other current assets	717
Cash and cash equivalents	1,302
Non-current liabilities	
Non-current lease liabilities	(76)
Other non-current borrowings	(2,900)
Deferred tax liabilities	(7,086)
Current liabilities	
Current lease liabilities	(22)
Other current borrowings	–
Trade payables	(63)
Provisions	(649)
Other current liabilities	(248)
Net assets acquired	**41,955**

The purchase price allocation includes the recognition of intangible assets of TCHF 50,716 and a related deferred tax liability of TCHF 7,086. The activity, expertise and pending intellectual property rights of AdVita are centered exclusively on the medical compound aviptadil. The Group has identified one intangible asset constituted by in-process research and development expenses, which was recorded with the existing asset of Relief (note 9). The acquisition did not result in the recognition of a goodwill.

Net cash outflow from the acquisition

	TCHF
Cash and cash equivalent balance acquired	1,302
./. Loan due to Relief by the acquired subsidiary	(2,193)
./. Consideration paid in cash and cash equivalents	–
Total net cash outflow	**(891)**

7.3 Impact of the acquisitions on the results of the Group

From the dates of acquisition through December 31, 2021, APR and AdVita contributed, respectively, TCHF 3,207 and TCHF 113 revenue, and TCHF 2,169 and TCHF 1,200 operating loss, to the respective results of the Group, excluding amortization of intangible assets and related income tax effect.

If APR and AdVita were consolidated since the beginning of the financial year, the consolidated loss and the consolidated revenue of the Group for the year 2021 would have been TCHF 37,117 and TCHF 7,007, respectively.

8. Disposal of subsidiary

In 2020, the Group divested its former subsidiary Relief Therapeutics SA to Sonnet Biotherapeutics, Inc. in exchange for an equity consideration valued at TCHF 4,642. The transaction does not impact the consolidated balance sheet as of December 31, 2021 and 2020. A disposal gain of TCHF 3,382 was recognized in the consolidated statement of comprehensive loss for the year 2020. The contribution of the disposed subsidiary to the result of the Group for the year 2020 was a loss of TCHF 63.

Comprehensive disclosures are provided in note 14 of the consolidated financial statements for the year ended December 31, 2020.

9. Intangible assets

TCHF	Aviptadil project	APR product portfolio	ACER-001 license	Goodwill	Total
COST					
Balance at January 1, 2020	**30,800**	–		–	**30,800**
Balance at December 31, 2020	**30,800**	–		–	**30,800**
Addition	–	–	13,729	–	**13,729**
Acquired in business combination	50,716	90,236	–	8,658	**149,610**
Balance at December 31, 2021	**81,516**	**90,236**	**13,729**	**8,658**	**194,139**
ACCUMULATED AMORTISATION					
Balance at 1 January 2020	**(11,200)**	–	–	–	**(11,200)**
Reversal of impairment loss	11,200	–	–	–	**11,200**
Balance at December 31, 2020	–	–	–	–	–
Amortisation expense	–	(1,840)	–	–	**(1,840)**
Balance at December 31, 2021	–	**(1,840)**	–	–	**(1,840)**
CARRYING AMOUNT					
at December 31, 2020	30,800	–	–	–	**30,800**
at December 31, 2021	**81,516**	**88,396**	**13,729**	**8,658**	**192,299**

Intangible assets include acquired trademarks, patents, licenses, technologies and other assets without physical substance. These items are measured at cost less accumulated amortization and impairment. The cost of an intangible asset acquired in a business combination corresponds to its fair value at the date of the acquisition. The intangible assets consist of in-progress research and development projects and products in marketing phase.

9.1 Aviptadil project

The intangible asset is the medicinal product candidate RLF-100® constituted by intellectual property rights and clinical knowledge. It was initially acquired in 2016 in the business combination between Relief Therapeutics SA and THERAMetrics Holding AG. With the acquisition of AdVita in 2021, the Group gained additional expertise and potential intellectual property rights around the inhaled formulation of aviptadil.

RLF-100 is currently in clinical testing for acute respiratory distress syndrome (ARDS) and acute lung injury (ALI) associated with the SARS-CoV-2 virus (COVID-19). Relief also plans to develop RLF-100 for less severe form of COVID-19 and other acute and chronic lung diseases, including pulmonary sarcoidosis. The asset is not yet available for use in the meaning of IAS 38.

9.2 ACER-001 license

The intangible asset is the acquisition cost of licensing and royalty rights under the collaboration and license agreement with Acer. The agreement provides for the development, regulatory approval and worldwide commercialization of ACER-001 by Relief and Acer. ACER-001 is a proprietary powder formulation of sodium phenylbutyrate for the potential treatment of Urea Cycle Disorders and Maple Syrup Urine Disease.

Acer will retain development and commercialization rights in the U.S., Canada, Brazil, Turkey, and Japan. The companies will split net profits from Acer' s territories 60%:40% in favor of Relief. In addition, Relief has licensed the rights for the rest of the world, where Acer will receive from Relief a 15% royalty on all revenues received in Relief' s territories. The asset is not yet available for use in the meaning of IAS 38. Refer to notes 4.1 and 41 for further details.

9.3 APR product portfolio

The intangible assets acquired from the acquisition of APR are comprised of patents, trademarks, licenses, sub-licenses, technologies, in-process research and development projects, and other assets without physical substance.

Products that have reached marketing phase consist primarily of PKU GOLIKE® as well as of a portfolio of a dozen of medicinal products that are currently licensed or marketed. The corresponding intangible assets will be amortized over their estimated remaining useful lives. Amortization is charged on a straight-line basis over the estimated economic or legal useful life, whichever is shorter. The amortization period ranges from 3 to 15 years.

Products that are in development phase consist primarily of APR-TD011, a clinical-stage drug candidate for the treatment of epidermolysis bullosa, and APR-AOS2020 (Sentinox), a near-to-market product reducing the risk of infections caused by bacteria and viruses. Amortization of the assets will commence when they are available for use.

The carrying amounts of in-process research and development asset and marketed products at acquisition date were TCHF 50,878 and TCHF 39,358, respectively.

9.4 Goodwill and intangible assets with indefinite useful lives

Intangible assets with indefinite useful lives, those not yet ready for use, and goodwill are not amortized but tested for impairment annually or more frequently if there are indications of impairment. If the recoverable amount (higher of fair value less costs of disposal and value in use) is lower than the carrying amount, the carrying amount is reduced to the recoverable amount by recording an impairment charge.

Goodwill is recognized at cost on the acquisition date and corresponds to the difference between the consideration transferred and the fair value of assets, liabilities and contingent liabilities identified in the purchase price allocation. Goodwill is capitalized and included in intangible assets. After initial measurement, goodwill is recognized at cost less any accumulated impairment. For impairment testing purpose, the goodwill acquired through the business combination with APR is allocated to the “APR product portfolio’ ” as a single cash-generating unit (CGU).

For impairment testing models of in-process research and development assets, cash flows are projected over a period greater than five years to reflect the cycle of development and commercialization of the products.

9.4.1 Impairment testing Aviptadil project

The impairment test was performed by determining the recoverable amount of the asset as the risk-adjusted net present value of future cashflows (value in use) as of December 31, 2021. The analysis took into consideration the current plans of the Company to develop RLF-100 for the treatment of COVID-induced indications and other pulmonary indications.

Impairment testing involves judgmental assumptions that may change over time. Management has adopted conservative estimates as follows:

- revenue forecasts were derived from internal market analyses and external sources of information. Amounts and timing of these forecasts were based on the expected patient populations who could benefit from RLF-100 treatment over the product life cycle, as well as on the expected development milestones for each indication. Year of obtention of market approval was based on management’ s best estimate given the current stage of development of each indication;
- probability of success to reach market approval was defined on a per indication basis and ranged from 21% to 35%, depending on the development stage. The probabilities were based on empirical success rate analysis of phase 2 and phase 3 studies for comparable indications;
- patent protection period lasts at least until 2029 in the U.S. and 2026 in European main markets, excluding extension possibilities the Group will seek to obtain and provisional patents acquired with AdVita that would be, if granted, valid until 2041. Cash flows were projected on a period from 2021 to up to 2034; and
- pre-tax discount rate of 17% (December 31, 2020: 17%) used for the valuation reflects the risk profile of such program and the current development stage.

The Group performed a sensitivity analysis considering reasonably possible changes in the assumptions used to calculate the discounted cash flows. Main assumptions tested for changes on a per indication basis were the discount rate, the time to market, the probabilities of success and the number of patients who will benefit from RLF-100. The sensitivity analysis did not reveal situations where the carrying amount of the asset would exceed its recoverable amount.

9.4.2 Impairment testing APR product portfolio

The valuation of the identifiable net asset of APR and goodwill arising from the acquisition was performed in the purchase price allocation for the consolidation of APR within these consolidated financial statements. The acquisition value of the intangible assets has been derived from commercial forecasts (value in use) covering a nine-year period. The discount rate applied to cash flow projections was 14%. 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.

The valuation analysis was finalized in early 2022 and was based on assumptions prevailing at the date of acquisition. No events have occurred since the acquisition date that would have led to a decrease of the net present value of projected cash flows. As a result, changes in assumptions as part of the impairment test result in a reallocation of the purchase price among the acquired intangible assets instead of a possible impairment.

9.4.3 Impairment testing ACER-001 license

The recoverable amount of the ACER-001 licenses has been derived from commercial forecasts (value in use) covering a fourteen-year period. The discount rate applied to cash flow projections was 17% and cash flows beyond the forecast period were not considered. As a result of the analysis, management did not identify an impairment for this asset. The sensitivity analysis did not reveal situations where the carrying amount of the license would exceed its recoverable amount.

10. Leases

10.1 Right-of-use assets

TCHF	Office Building	Equipment	Total
COST			
Balance at January 1, 2020	–	–	–
Balance at December 31, 2020	–	–	–
Acquired in business combination	2,548	151	2,699
Disposal	–	(11)	(11)
Foreign exchange difference	(10)	(1)	(11)
Balance at December 31, 2021	**2,538**	**139**	**2,677**
ACCUMULATED DEPRECIATION			
Balance at 1 January 2020	–	–	–
Balance at December 31, 2020	–	–	–
Depreciation expense	(147)	(33)	(180)
Foreign exchange difference	–	1	1
Balance at December 31, 2021	**(147)**	**(32)**	**(179)**
CARRYING AMOUNT			
at December 31, 2020	–	–	–
at December 31, 2021	**2,391**	**107**	**2,498**

The Group leases office equipment, laboratory equipment and cars as well as office buildings in Switzerland, Italy and Germany. The remaining expected lease terms are between 2 years and 10 years. Except for the laboratory and office equipment, the Group does not have an option to purchase the asset at the end of the lease term.

10.2 Maturity analysis of lease liabilities

TCHF	December 31, 2021	December 31, 2020
< 1 year	331	–
1-5 years	1,161	–
> 5 years	1,031	–
Total	**2,523**	**–**

10.3 Amounts recognized in profit or loss

TCHF	December 31, 2021	December 31, 2020
Lease expense for short-term and low value leases	27	15
Depreciation expense on right-of use assets (note 32)	180	–
Interest expense on lease liabilities (note 33)	17	–

10.4 Further information on leases

The Group had non-cancellable commitments of TCHF 10 for short-term leases as of December 31, 2021. In 2021, the total cash-outflow for leases amounts to TCHF 201.

11. Non-current financial assets

In 2020, the Group had provided a loan of TUSD 500 (TCHF 460) to NeuroRx, Inc. ("NeuroRx") for the development of RLF-100 in COVID-19 induced ARDS, as part of the collaboration agreement. The loan carries an interest rate of 2% per annum and is due in April 2022. Considering the ongoing dispute between the parties (note 41.3), the Group reassessed the recoverability risk of the loan and fully impaired the loan and accrued interests as at December 31, 2021.

12. Inventories

TCHF	December 31, 2021	December 31, 2020
Raw material	2,742	181
Finished goods	366	–
Gross inventories	3,108	181
Valuation allowance	(2,717)	(181)
Total	**391**	**–**

The Company holds in inventory aviptadil active ingredient valued at acquisition cost of TCHF 2,717. As the aviptadil was manufactured prior to obtaining regulatory approval, the inventory is fully impaired and the impairment charge is recognized in research and development expenses.

13. Trade receivables

TCHF	December 31, 2021	December 31, 2020
Current receivables	1,506	–
Expected credit loss allowance	(204)	–
Total	**1,302**	**–**

Trade receivables are non-interest bearing and generally have maturities between 30 and 90 days.

The Group uses a provision matrix to calculate expected credit losses from trade receivables. The provision rates are based on days past due of customer invoices. The provision is initially based on the Group' s historical observed default rates. The Group calibrates the matrix to adjust the historical credit losses with forecasts on economic conditions or similar forecast data for the various geographical areas. At each reporting date, the historical observed default rates are updated and changes in the various forecasts are analysed.

TCHF	2021	2020
Opening balance of the expected credit loss allowance	–	–
Acquired through business combination	(126)	–
Impairment losses recognised	(78)	–
Closing balance	**(204)**	–

14. Other current financial assets

In April 2020, the Group received 757,933 common shares of the publicly listed Sonnet BioTherapeutics, Inc. as consideration for the sale of its subsidiary Relief Therapeutics SA. During 2020, the Group sold 663,960 of these shares in various tranches. During the first semester of 2021, the Group sold the remaining 93,973 shares resulting in proceeds of TCHF 132 and valuation losses of TCHF 54 which are recognized in 'other losses' within the consolidated statement of comprehensive loss (note 31).

15. Other current assets

TCHF	December 31, 2021	December 31, 2020
Prepaid expenses	6,422	3,442
Accrued revenue	313	–
VAT receivable	115	63
Deposits with others	28	–
Indemnification asset (note 22)	622	–
Other current receivables	1,016	9
Total	**8,516**	**3,514**

The increase in prepaid expenses is mainly attributable to the upfront development payments made to Acer under the collaboration and license agreement. Over the reporting period, these payments amount to USD 15 million of which USD 9.3 million were expensed, thus resulting in a prepayment of USD 5.7 million (CHF 5.3 million) as of December 31, 2021. Other current receivables mainly consist of advance payments issued by the Group and to be reimbursed by the vendors.

16. Restricted cash

As of December 31, 2020, TCHF 5,093 was held in an escrow account as a security deposit under a pledge agreement signed with the Company' s bank. The escrow account was set up for a commitment issued by the Company for the acquisition of clinical material produced, delivered, and paid for in 2021. As of December 31, 2021, the Group did not hold any restricted cash position.

17. Cash and cash equivalents

As of December 31, 2021 and 2020, cash and cash equivalents are consituted by cash at bank and on hand.

18. Share capital

	Number of shares		
	Common shares	Treasury shares	Total
Balance at January 1, 2020	**2,113,919,272**	**–**	**2,113,919,272**
Share Subscription Facility	240,000,000	–	240,000,000
Debt to Equity conversion	58,023,584	–	58,023,584
Exercises of warrants	766,658,667	–	766,658,667
Exercises of options	68,125,725	–	68,125,725
Balance at December 31, 2020	**3,246,727,248**	**–**	**3,246,727,248**
Balance at January 1, 2021	**3,246,727,248**	**–**	**3,246,727,248**
Issuance of treasury shares	1,153,502,908	(1,153,502,908)	–
Direct Share Placement program	–	398,219,762	398,219,762
Private placements	–	112,887,942	112,887,942
Acquisition payments	–	342,527,847	342,527,847
Exercises of options	13,104,461	–	13,104,461
Balance at December 31, 2021	**4,413,334,617**	**(299,867,357)**	**4,113,467,260**

18.1 Issued share capital

As of December 31, 2021, the share capital consisted of 4,413,334,617 issued shares with a par value of CHF 0.01 each. The Company has issued a total of 1,166,607,369 shares during the reporting period and held 299,867,357 shares in treasury as of December 31, 2021.

Equity transactions in 2021

The Company initiated in 2021 its Direct Share Placement ("DSP") program in order to diversify its funding sources and raise capital in a cost-efficient and flexible manner. Under such program, the Company is able to issue shares out of its authorized capital to constitute and monetize its treasury shares reserve. Newly issued shares can be sold on the open market at the share price prevailing at the date of the settlement without incurring significant transaction costs or granting any discount, as is the case with private or public offerings.

In 2021, the following capital increase transactions provided the Group with cumulated gross proceeds of TCHF 76,088, before deducting transaction costs of TCHF 2,848. Transactions costs are mostly constituted by issuance stamp taxes and placement agent fees.

Issuances of shares: the Company issued during the period 1,153,502,908 shares from its authorized capital. The shares were entirely subscribed at par value by its wholly owned subsidiary Relief Therapeutics International SA. The transactions provided the Group with shares to be held in treasury until subsequent placements.

Private placement in March 2021: sale of 41,459,370 shares at CHF 0.2412 per share to an institutional investor for total gross proceeds of TCHF 10,000.

Private placement in July 2021: sale of 71,428,572 shares at CHF 0.2100 per share to two institutional investors for total gross proceeds of TCHF 15,000.

DSP program: sale of 398,219,762 shares at an average price of CHF 0.1278 for total gross proceeds of TCHF 50,887.

Exercises of options: issuance upon exercise of 13,104,461 shares at prices between CHF 0.01 and 0.02 per share, resulting in gross proceeds of TCHF 201.

As further detailed in note 7, Relief transferred 342,527,847 shares to APR' s and AdVita' s sellers as equity payments for the acquisition of APR and AdVita. The two non-cash transactions resulted in an increase of equity of TCHF 74,402.

Equity transactions in 2020

Capital increase transactions in 2020 provided the Group with total gross proceeds of TCHF 60' 691 before deducting transactions costs of TCHF 634. Details of these transactions are as follows:

Share Subscription Facility ("SSF") financing: the Company drew down a total of 240,000,000 shares from its SSF in place with GEM Global Yield LLC SCS at an average price of CHF 0.205 per share. Cumulated net proceeds amounted to CHF 49,215,600.

Debt to Equity conversion: issuance of 58,023,584 shares at CHF 0.0297 per share through conversion of loans for total gross proceeds of CHF 1,723,301.

Exercises of warrants: issuance upon exercises of warrants of 766,658,667 shares at prices between CHF 0.01 and 0.0146 per share, resulting in gross proceeds of CHF 7,712,587.

Exercises of options: issuance upon exercises of stock options of 68,125,725 shares at prices between CHF 0.01 and 0.04 per share, resulting in gross proceeds of CHF 1,405,507.

18.2 Authorized share capital

As of December 31, 2021, the Company had an authorized nominal share capital of TCHF 6,565, consisting of 656,497,092 registered shares with a par value of CHF 0.01 each, which the Board of Directors is authorized to issue at any time until June 17, 2023.

18.3 Conditional share capital

The conditional share capital of the Company as of December 31, 2021 was TCHF 16,849, consisting of 1,684,874,275 shares with a par value of CHF 0.01 each, of which 121,874,275 to be used for stock options for members of the Board of Directors, Executive Committee, employees and consultants, as well as 1,563,000,000 shares to be used for the exercise of option rights granted in connection with bonds, notes or similar debt instruments issued by the Company.

19. Reserves

TCHF	December 31, 2021	December 31, 2020
Share premium (note 19.1)	207,521	68,546
Share-based payment reserve (note 19.2)	2,371	1,228
Foreign currency translation reserve (note 19.3)	255	–
Total	**210,147**	**69,774**

19.1 Share premium

TCHF	2021	2020
Balance at beginning of year	68,546	20,451
Additional paid-in capital from capital increases	141,823	48,729
Transaction cost in relation to capital increases	(2,848)	(634)
Balance at end of year	**207,521**	**68,546**

19.2 Share-based payment reserve

TCHF	2021	2020
Balance at beginning of year	1,228	180
Share-based payments (note 35)	1,143	1,048
Balance at end of year	**2,371**	**1,228**

19.3 Foreign currency translation reserve

TCHF	2021	2020
Balance at beginning of year	–	34
Exchange differences arising on translating foreign operations	255	3
Recycled to profit or loss upon liquidation of the subsidiaries	–	(37)
Balance at end of year	**255**	–

20. Borrowings

	December 31, 2021		December 31, 2020	
TCHF	Non-current	Current	Non-current	Current
Bank loans	396	28	–	–
Other financial liability	–	67	–	–
Total	**396**	**95**	**–**	**–**

Bank loans

As of December 31, 2021, a bank loan of TCHF 398 was owed to a German bank. The loan has an interest of 2.7% per annum and is granted until December 30, 2023, with an extension option. Monthly installments due in the next twelve months are classified as current for TCHF 25.

Another loan of TCHF 26 does not bear interest and is repaid in monthly installments until 2026. TCHF 3 is classified as current.

Other financial liability

This consists in an interest-bearing loan acquired in the business combination with AdVita. The interest rate is 3.5% per annum and the loan is repayable on June 30, 2022.

Credit facilities

During 2021, the Group had, through its subsidiary APR, a credit line from a Swiss bank. The amount drawn was fully repaid as of December 31, 2021, and the unsecured credit line was renewed in January 2022 for an amount of CHF 2 million. The Group would pay interest on the drawn amounts, if any, at a rate to be defined at the dates of the drawdowns.

21. Defined benefit obligations

The following table provides information on the amounts recognized in the balance sheet:

TCHF	December 31, 2021	December 31, 2020
Present value of pension benefit obligation	4,496	–
Fair value of pension plan assets	(2,946)	–
Net pension defined benefit obligation	1,550	–
Present value of other benefit obligations	1,243	–
Total defined benefit obligations	**2,793**	**–**

21.1 Defined benefit plan

Swiss pension plans need to be administered by a separate pension fund that is legally separated from the entity. The law prescribes certain minimum benefits. The pension plans of the employees of the parent entity and its Swiss subsidiaries are carried out by collective funds with Swiss Life Collective Foundation and Caisse Inter-Entreprises de Prévoyance Professionelle. Under the pension plans, the employees are entitled to retirement benefits and risk insurance for death and disability.

In accordance with IAS 19, the above-mentioned pension plans are classified as defined benefit plans. The pension plans are described in detail in the corresponding statues and regulations. The contributions of employers and employees, in general, are defined in percentages of the insured salary. The retirement pension is calculated based on the old-age credit balance on retirement multiplied by the fixed conversion rate. The employee has the option to withdraw the capital at once. The death and disability pensions are defined as percentage of the insured salary. The assets are invested directly with the corresponding pension funds.

The pension funds can change their financing system (contributions and future payments) at any time. Also, when there is a deficit which cannot be eliminated through other measures, the pension funds can oblige the entity to pay a restructuring contribution. For the pension funds of the Group such a deficit currently cannot occur as the plans are fully reinsured. However, the pension funds could cancel the contracts and the entities of the Group would have to join another pension fund.

In the current and comparative periods no plan amendments, curtailments or settlements occurred.

The fully reinsured pension funds have concluded insurance contracts to cover the biometric and investment risk. The board of each pension fund is responsible for the investment of assets and the investment strategies are defined in a way that the benefits can be paid out on due date.

The actuarial valuations of plan assets and the present value of the defined benefit obligation were carried out on December 31, 2021. The present value of the defined benefit obligation, and the related current service cost and past service cost, were measured using the "projected unit credit" method.

Amounts recognized in profit or loss in respect of these defined benefit plans were as follows:

TCHF	2021	2020
Current service cost	132	–
Net interest expense	2	–
Administration cost excl. cost for managing plan assets	11	–
Expense recognised in profit or loss	**145**	**–**

Amounts recognized in other comprehensive income in respect of these defined benefit plans were as follows:

TCHF	2021	2020
Remeasurement (gain)/loss on defined benefit obligation		
due to changes in demographic assumptions	–	–
due to changes in financial assumptions	(39)	–
due to changes in experience adjustments	(166)	–
Return on plan assets excl. interest income	24	–
Derecognition of defined benefit obligation (note 8)	–	(136)
(Income) recognised in other comprehensive income	**(181)**	**(136)**

Movements in the present value of the defined benefit obligation were as follows:

TCHF	2021	2020
Opening defined benefit obligation	–	–
Current service cost	132	–
Interest expense on defined benefit obligation	6	–
Contributions from plan participants	54	–
Benefits (paid)/deposited	(640)	–
Remeasurement (gain)/loss due to changes in financial assumptions	(39)	–
Remeasurement (gain)/loss due to changes in experience adjustments	(166)	–
Acquired through business combinations	5,149	–
Closing defined benefit obligation	**4,496**	**–**

Movements in the present value of the plan assets in the current period were as follows:

TCHF	2021	2020
Opening fair value of plan assets	–	–
Interest income on plan assets	4	–
Return on plan assets excluding interest income	(24)	–
Contributions from the employer	121	–
Contributions from plan participants	54	–
Benefits (paid)/deposited	(640)	–
Administration cost	(11)	–
Acquisition through business combination	3,442	–
Closing fair value of plan assets	**2,946**	**–**

The respective insurance companies are providing reinsurance of these assets and bear all market risk on these assets.

The actual return on plan assets was TCHF (20).

Principal assumptions used for the purposes of the actuarial valuations were as follows:

TCHF	2021	2020
Discount rates	0.30%	n.a.
Expected rates of salary increase	1.50%	n.a.

The following sensitivity analyses based on the principal assumptions have been undertaken based on reasonably possible changes to the assumptions occurring at the end of the reporting period:

If the discount rate would be 25 basis points (0.25 percent) higher (lower), the defined benefit obligation would decrease by 4.1% (increase by 4.1%) if all other assumptions were held constant.

If the expected salary growth would increase (decrease) by 0.25%, the defined benefit obligation would increase by 0.6% (decrease by 0.6%) if all other assumptions were held constant.

The average duration of the defined benefit obligation at the end of the reporting period was 17.5 years.

The Group expects to make contributions of TCHF 244 to the defined benefit plans during the next financial year.

21.2 Other employee benefits

The obligations for other employee benefits mainly consist of end of service indemnities, which do not have the character of pensions, and are classified as a defined benefit plan in accordance with IAS 19.

22. Provisions

TCHF	Contingent liabilities (i)	Legal and regulatory (ii)	Total
At the beginning of the year	–	–	–
Additional provisions recognized	–	100	100
Acquired through business combination	30,622	649	31,271
Change in fair value due to passage of time	653	–	653
Unrealized foreign exchange loss	(444)	(27)	(471)
At the end of the year	**30,831**	**722**	**31,553**
thereof current	11,461	622	12,083
thereof non-current	19,370	100	19,470

(i) Contingent liabilities

The Group has recognized contingent settlement provisions of TCHF 30,622 for the probability-weighted present value of payments, as at the date of the business combination, that may become due to the former shareholders of APR and AdVita upon completion of pre-agreed milestones (note 7). The provisions are classified within current and non-current liabilities based on estimated possible due dates of milestone payments.

Until the related liabilities are settled, cancelled or expired, the provisions are measured at fair value at balance sheet date and changes are recognized in the income statement.

Acquisition milestone payments related to APR will be payable in Relief shares, from 60% to 75% of the total amount, and the rest in cash. Acquisition milestone payments related to AdVita are entirely payable in cash.

(ii) Legal and regulatory proceedings

On June 10, 2021, SIX Exchange Regulation initiated an investigation against the Company due to a potential violation of the rules on ad-hoc publicity. As part of the investigation, SIX Exchange Regulation AG is examining whether there has been an actual violation of the regulations. The provision of TCHF 100 reflects the management' s best estimate of the most likely outcome and is subject to uncertainty. It is expected to be paid within the next twelve months and is therefore classified as current.

A subsidiary of the Group is party to a legal proceeding for the payment to a third party of TCHF 622. The claim was acquired in a business combination in 2021 and is entirely provisioned as of December 31, 2021. Should the Group settle part or whole of the claim, the former shareholders of the acquired company have contractually agreed to fully indemnify Relief. An indemnification asset of the same amount was recorded on the balance sheet as of December 31, 2021 (note 15).

23. Financial liabilities due to third parties

As of December 31, 2020, financial liabilities of TCHF 891 were due to a former subsidiary of the Group. In 2021, the claim was entirely waived by the counterparty and was therefore written-off and recognized as income in the current reporting period (note 26).

24. Financial liabilities due to related parties

The Company signed in January 2021 a financing agreement with the Company' s main shareholder, Gem Global Yield LLC ("GEM"), for the implementation of a new Share Subscription Facility ("SSF") in the amount of up to CHF 50 million until January 20, 2024. The Company agreed to pay GEM a commitment fee of TCHF 1' 250, payable upon proceeds from the first drawdowns or on January 20, 2022. The Company did not draw on the SSF during the reporting period. The liability did not bear interest in 2021. From January 21, 2022, the liability bears interest at 1% per annum above the base rate of Barclays Bank PLC and is repayable on demand.

As the obligation to pay the commitment fee arose with the execution of the agreement, the Company immediately recorded the commitment fee as a liability. The corresponding expense is recognized as financial expense (note 33) over the SSF commitment period of three years ending January 20, 2024.

25. Other current payables and liabilities

TCHF	December 31, 2021	December 31, 2020
Accrued expenses	2,143	2,634
Payable to social security institutions	720	816
Withholding tax liability for personnel	853	–
Stamp duty and capital tax liabilities	486	433
VAT payable	19	–
Other current liabilities	53	487
Total	**4,274**	**4,370**

26. Other gains

TCHF	2021	2020
Write-off of liabilities due to former subsidiaries (note 23)	891	146
Gain on settlement of a financial liability	–	104
Write-off of old liabilities	168	–
Income from sublease agreements	87	–
Various others	25	23
Total other gains	**1,171**	**273**

27. Cost of sales

Expenses incurred with third parties in relation with advertising, marketing, shipping, distribution and commission on sales, are classified in 'external selling and distribution expense' . Expenses incurred with third parties in relation with the purchase and manufacturing of drug products for sale are classified in 'raw materials and consumables expense' .

The consolidated statement of comprehensive loss aggregates transactions according to their nature. The overall cost of sales, which include expenses of different natures, is therefore not presented in a distinct line.

28. External research and development expense

External research and development expense includes costs associated with outsourced clinical research organization activities, sponsored research studies, clinical trial costs, process development, product manufacturing expenses, license fees, and investigator-sponsored trials, including licensing fees and milestone payments charged by licensors or collaboration partners. In 2021, external research and development expenses primarily related to the development expenses incurred by Acer under the license and collaboration agreement and to the clinical development of aviptadil.

29. Personnel expense

TCHF	2021	2020
Salaries including social security expense	4,485	76
Independent contractors fees	2,220	761
Share-based payment expense (note 35)	1,143	1,048
Social security expense in relation to share-based payments	30	742
Service cost for other benefit obligation	1,243	–
Total personnel expense	**9,121**	**2,627**

In 2021, personnel and administrative expenses of the Group increased mainly as result of the addition of APR and AdVita, the building up of a group organization, and the growth of operations.

30. Other administrative expense

TCHF	2021	2020
Professional services	6,022	2,774
Capital tax	180	161
Other administrative expense	548	64
Total other administrative expense	**6,750**	**2,999**

Professional services include expenses incurred in relation with legal and tax advisory, consulting, corporate communication, accounting and audit. Other administrative expense comprises IT, leases and various other expenses. The increase in 2021 was primarily attributable to the expanded activities of the Group with the addition of APR and AdVita, as well as to legal and consulting service needs to support the operations and development plans of the Group at a corporate level.

31. Other losses

TCHF	2021	2020
Losses on financial assets at fair value through profit or loss (note 14)	54	1,195
Impairment losses on loans to third parties	692	50
Various others	6	15
Total other losses	**752**	**1,260**

32. Amortization and depreciation expense

TCHF	2021	2020
Amortization of intangible assets (note 9)	1,840	–
Depreciation of rights-of-use assets (note 10)	180	–
Depreciation of property and equipment	16	–
Total amortization and depreciation expense	**2,036**	**–**

33. Financial income and expense

TCHF	2021	2020
Interest income	40	7
Foreign exchange gain, net	57	–
Total finance income	**97**	**7**
Interest expense related to leases	(17)	–
Negative interest on cash deposits	(127)	(100)
Other interest expenses	(50)	–
Bank charges	(74)	(69)
Change in fair value of provisions for milestone payments (note 22)	(653)	–
Foreign exchange loss, net	–	(396)
SSF commitment fee (note 24)	(395)	–
Total finance expense	**(1,316)**	**(565)**

34. Income taxes

34.1 Income tax recognized in profit or loss

TCHF	2021	2020
CURRENT TAX		
Current tax expense for the current year	–	–
Adjustments in relation to the current tax of prior years	–	–
	–	–
DEFERRED TAX		
Deferred tax (income)/expense recognized in the current year	(820)	1,567
Adjustment to deferred tax attributable to changes in income tax rate	–	–
	(820)	**1,567**
Total income tax expense/(income) recognized in the current year	**(820)**	**1,567**

The following table provides a reconciliation between the income tax expense recognized for the year and the tax calculated by applying the applicable tax rates on the net result before income taxes.

TCHF	2021	2020
Loss before tax	(35,525)	(6,261)
Income tax expense calculated at 13.99% (2020: 13.99%)	(4,970)	(876)
Unrecognized deferred tax assets during the year	4,392	4,920
Previously unrecognized tax losses used	–	(163)
Effect of deferred tax balances due to difference in applicable tax rates	(178)	–
Effect of net (income)/expenses that are not added/(deductible) in determining taxable profit	(64)	(2,314)
Total income tax expense/(income) recognized in the current year	**(820)**	**1,567**

The applicable tax rate of the Group is 13.99% (2020: 13.99%), which is equal to the statutory tax rate of the holding company.

34.2 Income tax recognized in other comprehensive income

The remeasurement of the defined benefit obligation by TCHF 181 (note 21) led to a credit in the corresponding tax asset of TCHF 29 recognized in the statement of other comprehensive income.

34.3 Deferred tax balance

The following table sets out the changes in deferred tax assets and liabilities.

2021 TCHF	Opening balance	Business combination	Recognized in OCI	Recognized in profit or loss	Closing balance
Tax losses	–	615	–	591	1,206
Defined benefit obligation	–	272	(29)	4	247
Intangible assets	–	309	–	(29)	280
Financial instruments	–	40	–	(40)	–
Leases	–	3	–	1	4
Total deferred tax assets	**–**	**1,239**	**(29)**	**527**	**1,737**
Intangible assets	4,309	21,488	–	(293)	25,504
Total deferred tax liabilities	**4,309**	**21,488**	**–**	**(293)**	**25,504**

2020 TCHF	Opening balance	Recognized in profit or loss	Closing balance
Total deferred tax assets	–	–	–
Intangible assets	2,742	1,567	4,309
Total deferred tax liabilities	**2,742**	**1,567**	**4,309**

34.4 Unrecognized deferred tax assets

The Group did not capitalize deferred tax assets from carryforward tax losses located in companies of the Group for which the availability of future taxable profits is uncertain. The cumulated tax losses on which no deferred tax assets have been capitalized will expire as follows:

TCHF	2021	2020
Within one year	33,389	17,954
Later than one year and not later than five years	53,506	50,497
More than five years	49,466	56,036
Total tax losses carry forward	**136,361**	**124,487**

The deferred tax assets not recognized as of December 31, 2021, amounted to CHF 19 million (2020: CHF 17 million).

35. Share-based payments

The Company maintains a stock option plan established in 2021 (the "Stock Option Plan 2021"), as well as a legacy stock option plan (the "Equity Awards Program 2015") for which certain options remain outstanding. Stock option plans were established for the Company' s employees, directors, and consultants whereby each option gives its holder the right to purchase one share of the Company at a pre-determined price. As of December 31, 2021, 121,874,275 shares were available for issuance of shares from the Company,s conditional capital under the stock option plans. Stock options granted are subject to certain vesting conditions based on service period defined on an individual basis at grant date.

As of December 31, 2021, the Company had 68,650,697 options outstanding. The following table reconciles the stock options outstanding at the beginning and end of the year:

	2021	2020
At beginning of the year	**24,367,658**	**70,530,000**
Granted	62,200,000	21,963,383
Exercised[1]	(13,104,461)	(68,125,725)
Forfeited	(4,812,500)	–
At end of the year	**68,650,697**	**24,367,658**

[1] In 2021, the weighted average exercise price was CHF 0.015 (2020: CHF 0.021).

Share options outstanding at the end of the year 2021 and 2020 had the following expiry dates:

Expiration year	December 31, 2021	December 31, 2020
2021	–	6,854,461
2022	3,187,500	10,000,000
2023	100,000	100,000
2024	100,000	100,000
2025	100,000	250,000
2026	7,063,197	7,063,197
2027	22,300,000	–
2028	19,300,000	–
2029	16,500,000	–
	68,650,697	**24,367,658**
Weighted average remaining contractual life in months	76	32

Of the 68,650,697 share options at year end, 7,550,697 were exercisable as of December 31, 2021. The exercise prices ranged from CHF 0.01 to CHF 0.495.

The fair values of the options at the grant date have been assessed using the Black-Scholes valuation model and recognized over their vesting period. For options that vested upon grant, the fair value of the options was recognized at grant date. The weighted average fair value of options granted in 2021 was CHF 0.09 per option. Significant inputs into the model were share price at grant date between CHF 0.061 and CHF 0.269, exercise price between CHF 0.01 and 0.269, volatility of returns between 83% and 122% and a risk-free interest rate of 0%.

The expected life of the options is based on historical data and current expectations and is not necessarily indicative of exercise patterns that may occur. The expected volatility reflects the assumption that the historical volatility over a period similar to the life of the options is indicative of future trends, which may not necessarily be the actual outcome.

In 2021, TCHF 1,143 (2020: TCHF 1,048) was recorded in personnel expense with a corresponding credit to the share-based payment reserve (note 19).

36. Earnings per share

	2021	2020
Loss attributable to shareholders (in TCHF)	(34,705)	(7,828)
Weighted average number of shares	3,593,069,451	2,413,222,815
Basic and diluted loss per share (in CHF)	**(0.010)**	**(0.003)**

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 2021 and 2020, the number of shares outstanding varied as a result of different transactions on the share capital structure of the Company.

Neither outstanding options nor effects from the contingent consideration of APR acquisition (note 7) have not been considered in the calculation of the diluted loss per share as their effect is anti-dilutive.

The 2020 earnings per share amounts to CHF (0.005) when excluding the one-time disposal gain of TCHF 3,382 recognized in the statement of comprehensive loss for the comparative reporting period (note 8).

37. Financial instruments

37.1. Categories of financial instruments

December 31, 2021 TCHF	Financial assets at amortized cost	Financial liabilities at amortized cost	Financial liabilities at FVTPL	Total
Other non-current assets	76	–	–	**76**
Trade receivables	1,302	–	–	**1,302**
Other current assets and receivables	2,094	–	–	**2,094**
Cash and cash equivalents	44,761	–	–	**44,761**
Total financial assets	**48,233**	**–**	**–**	**48,233**
Non-current lease liabilities	–	2,192	–	**2,192**
Non-current borrowings	–	396	–	**396**
Current lease liabilities	–	331	–	**331**
Current borrowings	–	95	–	**95**
Provisions for milestone payments	–	–	30,831	**30,831**
Trade payables	–	1,700	–	**1,700**
Financial liabilities due to related parties	–	1,250	–	**1,250**
Other current payables and liabilities	–	2,024	–	**2,024**
Total financial liabilities	**–**	**7,988**	**30,831**	**38,819**

December 31, 2020 TCHF	Financial assets at FVTPL	Financial assets at amortised cost	Financial liabilities at amortised cost	Total
Financial assets	185	–	–	**185**
Third party loan	–	399	–	**399**
Other current assets and receivables	–	65	–	**65**
Cash and cash equivalents	–	43,154	–	**43,154**
Total financial assets	**185**	**43,618**	**–**	**43,803**
Trade payables		–	1,432	**1,432**
Financial liabilities due to third parties		–	892	**892**
Other current payables and liabilities		–	1,860	**1,860**
Total financial liabilities		**–**	**4,184**	**4,184**

37.2 Reconciliation of liabilities arising from financing activities

			Non-cash changes				
2021 TCHF	Opening balance	Financing cash flows	Gain on settlement	Business Combination	Accrued interest	FX	Closing balance
Lease liabilities	–	(185)	–	2,719	–	(11)	**2,523**
Borrowings (note 20)	–	(5,366)	–	5,886	3	(32)	**491**
Due to third parties (note 23)	891	–	(891)	–	–	–	**–**
Due to related parties (note 24)	–	–	–	–	1,250	–	**1,250**
Total	**891**	**(5,551)**	**(891)**	**8,605**	**1,253**	**(43)**	**4,264**

			Non-cash changes					
2020 TCHF	Opening balance	Financing cash flows	Gain on settlement	Debt-Equity swap	Disposal of subsidiary	Accrued interest	FX	Closing balance
Financial liabilities due to third parties (note 23)	757	(648)	(104)	–	892	–	(6)	**891**
Financial liabilities due to related parties (note 24)	982	723	–	(1,723)	–	26	(8)	–
Total	**1,739**	**75**	**(104)**	**(1,723)**	**892**	**26**	**(14)**	**891**

37.3 Fair value measurement

Financial liabilities at fair value through profit and loss ("FVTPL") consist of contingent considerations resulting from business combinations. The fair value is measured based on the expected cash flows, the probability of occurrence and the current market interest rates. Refer to notes 7 and 22 for further details.

As of December 31, 2020, the Group held TCHF 185 of financial assets at fair value through profit or loss. These financial assets were quoted on the Nasdaq, and fair value was determined with reference to the market price in accordance with IFRS 9. They were considered level 1 financial instruments. As of December 31, 2021, the Group did not hold financial assets at fair value through profit or loss.

37.4 Amortized cost measurement

For all other financial assets and liabilities, their carrying amount at amortized cost approximates their fair value.

38. Financial risk management

The Group is exposed to various financial risks such as credit risk, liquidity risk and market risk (including interest rate and currency risk). The following sections provide an overview of the extent of the individual risks and the goals, principles and processes employed to handle these risks.

Credit risk

Credit risk refers to the risk that a counterparty will default on its contractual obligations towards the Group, resulting in financial loss to the Group. For product sales and trade account receivables, Relief may conduct selective analysis of the creditworthiness of distributors and other customers. Other financial assets mainly consist of cash for which the counterparty risk is minimized by deposits at well-known banks in Switzerland with an A rating as per Standard & Poor' s so that any expected credit loss is considered immaterial.

The carrying amounts of financial assets recorded in the financial statements represent the Group' s maximum exposure to credit risk without taking into account the value of any collateral obtained.

Capital and liquidity risk

The Group' s objectives when managing capital are to safeguard its ability to fund development and marketing activities in order to provide returns for shareholders and benefits for other stakeholders. The funds raised in various private financing rounds and public placements executed since the listing of the Company have been the principal source of liquidity, to date. Equity financing through placement of shares remains the expected main source of liquidity in the near-term.

Liquidity risk management implies maintaining sufficient cash and cash equivalents to meet the financial obligations of the Group. Management monitors the Group' s net liquidity position through rolling forecasts of projected cash flows. Maintaining adequate cash reserves is dependent on the Group' s ability to raise funds or generate profits; therefore, the liquidity risk is significant (see note 4.1 'going concern').

Interest rate risk

The Group is exposed to interest risk in respect of its cash deposits, bank loans and other interest-bearing liabilities. Cash deposits held in Swiss francs and Euros are subject to negative interest rates above certain thresholds defined by bank counterparties. The Group deems the interest rate risk as low on its performance and its equity.

Currency risk

The Group is exposed to foreign currency risk primarily through short-term cash deposits held in foreign currencies intended to fund operational expenditures in such currencies. To a lesser extent, the Group is also exposed to foreign currency risk through trade account receivables, other financial assets and trade payables, held or due in foreign currencies. The Group monitors its exposure by periodically assessing future spending needs in foreign currencies.

In light of the Group' s foreign currency positions and assuming that all other variables remain unchanged, any change in the foreign exchange rates of USD/CHF and EUR/CHF resulting from a 5% increase/decrease in these foreign currencies against CHF would have an impact of TCHF 1,000/(1,000) on the Group' s result for 2021 (2020: TCHF 652).

Based on the above sensitivity analysis and due to the fact that the cash balances in foreign currencies are held for settlement of expected invoices in these currencies, they are naturally hedged. The foreign currency risk is therefore limited to estimates' uncertainties.

During the years ended December 31, 2021 and 2020, the Group did not enter into any forward currency transactions. No derivative currency contracts were outstanding as of December 31, 2021 and 2020.

39. Related party transactions

Balances and transactions between the Group and its subsidiaries have been eliminated on consolidation and are not disclosed in this note. Details of transactions between the Group and other related parties are disclosed below.

39.1 Related party transactions

Related parties included members of the Board of Directors and the Executive Committee. The following transactions were carried out with related parties and recorded in the consolidated statement of comprehensive loss:

TCHF	2021	2020
Short-term employee benefits (including base and variable cash compensation)	2,759	570
Post-employment benefits	30	–
Share-based compensation	814	1,006
Total compensation for key management	**3,603**	**1,576**

There were no other related party transactions in the financial periods 2021 and 2020.

Further disclosures on Board and Executive committee compensation are provided in the compensation report.

39.2 Related party balances

As of December 31, 2021, the liability of TCHF 1,250 due to GEM (note 24) was the only material related party balance. As of December 31, 2020, there were no related party balances.

40. Non-cash transactions

In 2021 and 2020, the Group entered into the following significant non-cash investing or financing activities which are not reflected in the consolidated statement of cash flow:

In January 2021, recognition of the SSF commitment fee as a financial liability (note 24). In March 2021, payment of USD 14 million for the ACER-001 license partially settled by offsetting a loan of USD 4 million previously granted to Acer in January 2021 (note 4.1). In June 2021, acquisition of APR partially financed through a payment in shares (note 7). In July 2021, acquisition of AdVita entirely financed through a payment in shares (note 7).

In August 2020, conversion of GEM' s loans into equity. In April 2020, the payment of the loan of TUSD 250 provided by GEM to Relief was directly wired to NeuroRx as payment of 50% of the loan granted by Relief. Relief wired an additional TUSD 250 to NeuroRx. Relief, therefore, recorded a receivable from NeuroRx of TUSD 500 (TCHF 482) and a liability due to GEM of TUSD 250 (TCHF 241).

41. Contingent liabilities

41.1 License and collaboration agreement with Acer

Under the license and collaboration agreement with Acer, the Group has committed to make remaining milestone payments of up to USD 11 million (CHF 10 million) in cash upon the achievement of development and commercial milestones. The last development milestone payment was made in January 2022 for USD 5 million (CHF 4.6 million). USD 6 million (CHF 5.5 million) may become due upon certain regulatory approvals of ACER-001 in Europe. Further, Relief has agreed to pay royalties of 15% on future net revenue of ACER-001 in Relief' s territories.

41.2 Business combination with APR

The acquisition contract of APR contains possible future contingent milestone payments in the aggregate maximum amount of up to CHF 35 million in a combination of cash and Relief common registered share, upon achievement of pre-agreed objectives. A provision of CHF 20.7 million was recognized to account for the probability-weighted present value at balance sheet date of these contingent payments (note 22).

41.3 Business combination with AdVita

The acquisition contract of AdVita contains possible future contingent milestone payments in the aggregate maximum amount of up to EUR 20 million (CHF 21.6 million) in cash upon achievement of pre-agreed objectives. A provision of CHF 10.2 million was recognized to account for the probability-weighted present value at balance sheet date of these contingent payments (note 22).

41.3 NeuroRx claim

In October 2021, Relief filed a lawsuit against NeuroRx for multiple breaches by NeuroRx of the collaboration agreement relating to the development and commercialization of RLF-100. In January 2022, NeuroRx filed a distinct lawsuit against Relief. Among other claims, NeuroRx claims Relief has not paid USD 13.8 million (CHF 12.6 million) for costs associated with clinical and formulation development of aviptadil in the U.S. and claims damages in excess of USD 185 million (CHF 168.6 million).

Relief believes that it has previously paid NeuroRx all that it is obligated to pay under the collaboration agreement and that it will prevail before the court. Since the entire amount claimed by NeuroRx is in dispute, no provision for any liability has been recognized as of December 31, 2021. The amount due to NeuroRx, if any, will depend on the resolution of the ongoing litigation, and there can be no assurance as to the amount, if any, that the Company might ultimately be obligated to pay to NeuroRx.

The Company' s business and financial condition may be adversely affected by an adverse outcome in the litigation between the Company and NeuroRx.

42. Events after the reporting period

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

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Independent Auditor' s Report

APR Applied Pharma Research SA
Via Corti 5
6828 Balerna
Switzerland

Report on the Consolidated Financial Statements

We have audited the accompanying consolidated financial statements of APR Applied Pharma Research SA, which comprise the consolidated statements of financial position at December 31, 2020 and January 1, 2020 and the related consolidated statement of comprehensive income, the consolidated statements of changes in equity and the consolidated statements of cash flows for the year then ended, and the related notes to the consolidated financial statements.

Management' s Responsibility for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB); this includes the design, implementation, and maintenance of internal control relevant to the preparation and fair presentation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

Auditor' s responsibility

Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on the auditor' s judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, the auditor considers internal control relevant to the entity' s preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the entity' s internal control. Accordingly, we express no such opinion. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of significant accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our qualified audit opinion.

Basis for Qualified Opinion

As disclosed in Note 2.1 to the consolidated financial statements, International Financial Reporting Standards as issued by the IASB require that consolidated financial statements be presented with comparative financial information. The accompanying consolidated financial statements have been prepared as of and for the year ended December 31, 2020 solely for the purpose of meeting the requirements of Rule 3-05 of Regulation S-X of the US Securities and Exchange Commission ("Rule 3.05"). Accordingly no comparative financial information is presented.

Qualified Opinion

In our opinion, except for the omission of the information described in the Basis for Qualified Opinion paragraph, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of APR Applied Pharma Research SA as of January 1, 2020 and December 31, 2020, and the results of its operations and its cash flows for the year then ended in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB).

MAZARS SA

Franck Paucod
Licensed Audit Expert
(Auditor in Charge)

Yoann Bois
US Certified Public Accountant

Switzerland, Geneva, December 15, 2021

APR Applied Pharma Research SA

Consolidated statements of financial position

In thousands of Swiss Francs ("CHF")	Notes	As of December 31, 2020	January 1, 2020
ASSETS			
NON-CURRENT ASSETS			
Property, plant and equipment	7	48	79
Right-of-use assets	29.1	2,731	3,097
Intangible assets	8	1,853	2,706
Financial assets	9	75	568
Deferred tax assets	25.3	1,296	1,675
Total non-current assets		**6,003**	**8,125**
CURRENT ASSETS			
Inventory	10	226	364
Trade receivables	18.3	1,708	2,097
Other current assets	11	342	736
Cash and cash equivalents	12	6,381	3,116
Total current assets		**8,657**	**6,313**
Total assets		**14,660**	**14,438**
EQUITY AND LIABILITIES			
EQUITY			
Share capital	13	617	617
Reserves		4,707	4,709
Accumulated losses		(2,946)	(3,534)
Total Equity		**2,378**	**1,792**
NON-CURRENT LIABILITIES			
Lease liabilities	29.2	2,379	2,727
Net pension liabilities	14	2,379	3,274
Total non-current liabilities		**4,758**	**6,001**
CURRENT LIABILITIES			
Borrowings	15	5,262	4,000
Lease liabilities	29.2	366	370
Trade payables	16	1,265	1,429
Other current liabilities	17	631	846
Total current liabilities		**7,524**	**6,645**
Total liabilities		**12,282**	**12,646**
Total equity and liabilities		**14,660**	**14,438**

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

APR Applied Pharma Research SA

Consolidated statement of comprehensive income

In thousands of CHF	Notes	For the year ended December 31, 2020
CONSOLIDATED STATEMENT OF PROFIT OR LOSS		
Revenue	18	10,100
Other gains	19	3,943
Total income		**14,043**
Goods and service expense	20	(6,069)
Personnel expense	21	(4,809)
Net impairment losses on financial and contract assets	22	(657)
General and administrative expense	23	(1,019)
Operating result		**1,489**
Depreciation and amortization expense	7/8/29.1	(1,053)
Profit before interest and taxes		**436**
Financial income and expense, net	24	(327)
Profit before income taxes		**109**
Income taxes	25.1	(315)
Loss for the year		**(206)**
OTHER CONSOLIDATED COMPREHENSIVE INCOME		
Gain on remeasurement of defined benefit plan	14/25.2	794
Total items that will not be reclassified subsequently to profit or loss		**794**
Exchange differences arising on translation of foreign operations		(2)
Total items that may be reclassified subsequently to profit or loss		**(2)**
Total other comprehensive income for the year, net of income tax		**792**
Total comprehensive income for the year		**586**

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

APR Applied Pharma Research SA

Consolidated statements of changes in equity

In thousands of CHF	Share capital	Capital Contribution (Reserves)	Foreign exchange (FX) translation (Reserves)	Accumulated losses	Total
Balance as of January 1, 2020	**617**	**4,659**	**50**	**(3,534)**	**1,792**
Loss for the year	–	–	–	(206)	(206)
Other comprehensive income for the year	–	–	(2)	794	792
Total comprehensive income for the year	**–**	**–**	**(2)**	**588**	**586**
Balance as of December 31, 2020	**617**	**4,659**	**48**	**(2,946)**	**2,378**

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

APR Applied Pharma Research SA

Consolidated statements of cash flows

In thousands of CHF	Notes	For the year ended December 31, 2020
Loss for the year		(206)
Adjustments for:		
Income tax expense	25.1	315
Finance expense	24	123
Net foreign exchange (gain)/loss	24	203
Gain from disposal of intangible assets	19	(3,880)
Depreciation and amortization expense	7/8/29.1	1,053
Impairment financial assets	22	487
Impairment receivables	22	170
Changes in net pension liabilities		79
Changes in net working capital:		
- (Increase)/decrease in inventory		138
- (Increase)/decrease in trade receivables		216
- (Increase)/decrease in other current assets		394
- Increase/(decrease) in trade payables		(164)
- Increase/(decrease) in other current liabilities		(215)
Income tax paid		(117)
Interest paid		(123)
Cash flow used in operating activities		**(1,527)**
Payments for property, plant and equipment	7	(2)
Proceeds from disposal of intangible assets	19	4,103
Proceeds from disposal of financial assets		5
Cash flow used in investing activities		**4,106**
Proceeds from borrowings	27.4	1,262
Payments for lease liabilities	27.4	(375)
Cash flow generated from financing activities		**887**
Net increase in cash and cash equivalents		3,466
Cash and cash equivalents at beginning of the year		3,116
Net effect of exchange rate changes on cash and cash equivalents		(201)
Cash and cash equivalents at end of the year	**12**	**6,381**

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

APR Applied Pharma Research SA

Notes to the consolidated financial statements

1 General information

APR Applied Pharma Research SA ("APR" or the "Company") is a Swiss stock corporation whose registered office is at Via Corti 5, Balerna, Switzerland. The Company was incorporated on March 31, 1993 in Switzerland. It is subject to provisions of the articles of incorporation and to article 620 et seq. of the Swiss Code of Obligations ("SCO"), which describes the legal requirements for limited companies. These consolidated financial statements comprise the financial statements of APR Applied Pharma Research SA (Switzerland), as well its subsidiaries (collectively, the "Group").

APR is an international pharma group focused on the development and commercialization of science driven, patent protected products engineered with proprietary Drug Delivery Technologies (DDS) intended to improve quality of life of patients and caregivers having and dealing with diseases with still high medical need.

2 Application of new and revised International Financial Reporting Standards ("IFRS")

2.1 First-time adoption of IFRS

These consolidated financial statements comply with IFRS as issued by the International Accounting Standards Board ("IASB"), except that no comparative period was presented.

The Group adopted IFRS as of January 1, 2020, and as such qualifies as a first-time adopter under IFRS 1 "First-time Adoption of International Financial Reporting Standards" ("IFRS 1").

This note explains the principal adjustments made by the Group in restating its SCO consolidated financial statements, including the consolidated statement of financial position as at January 1, 2020, and the consolidated financial statements as at and for the year ended December 31, 2020.

IFRS 1 allows first-time adopters certain exemptions from the retrospective application of certain requirements under IFRS. The following two exemptions have been applied:

- exemption under IFRS 2 "Share-based payment", which allows to not apply IFRS 2 to equity-settled share-based payments that vested before the date of transition to IFRS;
- exemption under IFRS 16 "Leases", which allows to measure a lease liability at the date of transition to IFRS and recognize the related lease asset at an amount equal to the lease liability.

The estimates at January 1, 2020, and December 31, 2020, are consistent with those made for the same dates in accordance with SCO (after adjustments to reflect any differences in accounting policies) apart from the pension benefits and the share-based payments where application of SCO did not require the same estimation. The estimates used by the Group to present these amounts in accordance with IFRS reflect conditions at January 1, 2020, and December 31, 2020.

Reconciliation of equity

In thousands of CHF	Notes	As of December 31, 2020	As of January 1, 2020
Equity in accordance with SCO		**3,475**	**3,391**
Adjustments due to defined benefit plans (IAS 19)	A	(1,939)	(2,669)
Adjustment due to leases (IFRS 16)	B	(12)	–
Adjustment due to deferred tax assets (IAS 12)	C	854	1,070
Equity in accordance with IFRS		**2,378**	**1,792**

Reconciliation of comprehensive income for the year

In thousands of CHF	Notes	For the year ended December 31, 2020
Profit for the year in accordance with SCO		84
Adjustments due to defined benefit plans (IAS 19)	A	895
Adjustment due to leases (IFRS 16)	B	(14)
Adjustment due to deferred tax assets (IAS 12)	C	(379)
Comprehensive income for the year in accordance with IFRS		**586**

Notes to the reconciliations

The following notes explain the reconciliation-adjustments at January 1, 2020, and at and for the year ended December 31, 2020.

A Net pension liabilities

Under SCO, the Group recognized costs related to its pension plan on a contribution basis. Under IFRS, pension liabilities are recognized on an actuarial basis. At transition date, the pension liability has been recognized in full against retained earnings. This led to net pension liabilities of CHF 3' 274 thousand. For the year ended December 31, 2020, the actuarial gains of CHF 974 thousand were recognized in other comprehensive income and any other additional expense of CHF 79 thousand in profit or loss within personnel expense. Net pension liabilities as of December 31, 2020, comprised CHF 2' 379 thousand.

B Leases

Under SCO, the Group recognizes payments for office and car leases as lease expense within other operating expenses as incurred. Under IFRS, such leases with an estimated lease term of more than 12 months are capitalized within the balance sheet. At transition date, this led to the recognition of right-of-use asset of CHF 2' 906 thousand (December 31, 2020: CHF 2' 627 thousand) as well as non-current lease liabilities of CHF 2' 624 thousand (December 31, 2020: CHF 2' 344 thousand) and current lease liabilities of CHF 282 thousand (December 31, 2020: CHF 298 thousand). In the statement of comprehensive income for the year ended December 31, 2020, the rental expense recognized within other operating expenses of CHF 319 thousand is replaced by depreciation expense of CHF 302 thousand as well as finance expense of CHF 31 thousand.

C Deferred tax assets

Under SCO, no deferred taxes are recognized for tax losses carry-forwards. Under IFRS, the tax losses carry-forwards as well as the adjustments mentioned in notes A and B result in deferred tax assets. At transition date, deferred tax assets in the total amount of CHF 1' 675 thousand (December 31, 2020: CHF 1' 296 thousand) were recognized. For the year ended December 31, 2020, income tax expense of CHF 199 thousand was recognized in profit or loss and tax losses of TCHF 180 were recognized within other comprehensive income in relation to the adjustments for leases and pension plans as well as the use of tax losses carried forward.

Statement of cash flows

No statement of cash flows has been prepared in accordance with SCO and therefore no reconciliations are presented in these financial statements.

2.2 Standards and Interpretations in issue but not yet effective

Certain new and amended accounting Standards have been issued that are not mandatory for the current reporting period and have not been early adopted by the Group. These standards are not expected to have a material impact on the Group' s overall results and financial position.

3 Summary of significant accounting policies

Basis of preparation

The consolidated financial statements of the Group have been prepared in accordance with IFRS as issued by IASB, except as described in note 2.1, and comply with Swiss law. The consolidated financial statements have been prepared on a historical cost basis and are presented in Swiss Francs ("CHF"), which is also the functional currency of the Company. All values are rounded to the nearest thousand ("CHF thousand"), except when otherwise indicated.

The preparation of the consolidated financial statements in conformity with IFRS requires management to make estimates and assumptions that affect the reported amounts of income, expenses, assets and liabilities, and the disclosures of contingent liabilities, among others, at the date of the financial statements. The actual outcome may differ from the assumptions and estimates made. If such estimates and assumptions, which are based on management' s best judgment at the date of the financial statements, deviate from the actual circumstances, the original estimates and assumptions will be modified as appropriate in the year in which the circumstances change. The areas involving higher degrees of judgment or complexity or where assumptions and estimates are significant to the financial statements are disclosed in Note 4.

Consolidation

The Group' s consolidated financial statements include the assets, liabilities, income and expenses and cash flows of the subsidiaries which the Group controls (see Note 6 for further details). Control is achieved when the Group is exposed, or has rights, to variable returns from its involvement with the investee and has the ability to affect those returns through its power over the investee.

Specifically, the Group controls an investee if and only if the Group has:

Power over the investee (i.e. existing rights that give it the current ability to direct the relevant activities of the investee),

Exposure, or rights, to variable returns from its involvement with the investee, and

The ability to use its power over the investee to affect its returns.

When the Group has less than a majority of the voting or similar rights of an investee, the Group considers all relevant facts and circumstances in assessing whether it has power over an investee, for example:

Any contractual arrangement with the other vote holders of the investee,

Rights arising from other contractual arrangements,

The Group' s voting rights, or potential voting rights.

The Group reassesses whether or not it controls an investee if facts and circumstances indicate that there are changes to one or more of the three elements of control. Consolidation of a subsidiary begins when the Group obtains control over the subsidiary and ceases when the Group loses control of the subsidiary. Assets, liabilities, income and expenses and cash flows of a subsidiary acquired or disposed of during the year are included in the consolidated financial statements from the date the Group gains control until the date the Group ceases to control the subsidiary.

Profit or loss and each component of other comprehensive income ("OCI") are attributed to the equity holders of the parent of the Group and to the non-controlling interests, even if this results in the non-controlling interests having a deficit balance. When necessary, adjustments are made to the financial statements of the subsidiaries to bring their accounting policies in line with the Group' s accounting policies. Intercompany transactions, balances and unrealized gains/losses on transactions between Group companies are eliminated upon consolidation.

Current versus non-current classification

The Group presents assets and liabilities in the statement of financial position based on current/non-current classification. An asset is current when it is:

Expected to be realized or intended to be sold or consumed in normal operating cycle which is 12 months,

Held primarily for the purpose of trading,

Expected to be realized within 12 months after the reporting period, or

Cash or cash equivalent unless restricted from being exchanged or used to settle a liability for at least 12 months after the reporting period.

All other assets are classified as non-current.

A liability is current when:

It is expected to be settled in normal operating cycle which is 12 months,

It is held primarily for the purpose of trading,

It is due to be settled within 12 months after the reporting period, or

There is no unconditional right to defer the settlement of the liability for at least 12 months after the reporting period.

The Group classifies all other liabilities as non-current.

Foreign currency translation

(a) Functional and presentation currency

Items included in the consolidated financial statements of the Group are measured using the currency of the primary economic environment in which the individual company operates (the "functional currency"). The presentation currency of the Group is CHF.

(b) Transactions and balances

Foreign currency transactions are translated into the functional currency using the exchange rate prevailing at the date the transaction first qualifies for recognition. Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency spot rates of exchange at the reporting date. Foreign exchange gains and losses resulting from the settlement or translation of monetary assets and liabilities denominated in foreign currencies are recognized through profit or loss. Non-monetary items that are measured in terms of historical cost in a foreign currency are translated using the exchange rates at the dates of the initial transaction.

(c) Group companies

Assets and liabilities of Group entities using a functional currency different from the presentation currency of the Group are translated into the presentation currency using year-end exchange rates. Income and expenses and cash flows are translated at average exchange rates. All resulting translation differences are recognized directly in OCI. Upon divestment of a foreign entity, the identified cumulative currency translation difference related to that foreign entity is recognized through profit or loss as part of the gain or loss on divestment.

The exchange rates for the major foreign currencies against CHF relevant to the consolidated financial statements are presented below:

	2020	
	Year end	Average
EUR/CHF	1.0815	1.0705
USD/CHF	0.8839	0.9381

Property, plant and equipment

Property, plant and equipment is stated at historical cost less depreciation. Historical cost includes expenditures that are directly attributable to the acquisition of an asset. Subsequent costs are included in the assets' carrying amount or recognized as a separate asset, as appropriate, only when it is probable that future economic benefits associated with the item will flow to the Group and the cost can be reliably measured. All other repairs and maintenance costs are charged through profit or loss during the financial period in which they are incurred. Gain or loss on disposals is determined by comparing proceeds from disposal with the carrying amount and is included in profit or loss.

Depreciation of property, plant and equipment is calculated using the straight-line method to allocate costs less residual values over the assets' estimated useful lives, as follows:

Plant and equipment: 5 years

Furniture and fixtures: 8 years

The assets' residual values, useful lives and methods of depreciation are reviewed at each reporting date.

Intangible assets

Intangible assets acquired separately are measured on initial recognition at cost. The cost of intangible assets acquired in a business combination is the fair value at the date of acquisition. Following initial recognition, intangible assets are carried at cost less any accumulated amortization and accumulated impairment losses.

Internally developed intangibles, excluding capitalized development costs, are not capitalized and the related expenditure is reflected through profit or loss in the period in which the expenditure is incurred.

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. The amortization period and the amortization method for an intangible asset with a finite useful life are reviewed at least at the end of each reporting period. Changes in the expected useful life or the expected pattern of consumption of future economic benefits provided by the asset are considered to modify the amortization period or method, as appropriate, and are treated as changes in accounting estimates. The amortization expense on intangible assets with finite useful lives is recognized through profit or loss.

Inventories

Inventories are stated at the lower of cost and net realizable value. Cost comprises direct materials and, where applicable, direct labour costs and those overheads that have been incurred in bringing the inventories to their present location and condition. Cost is calculated using the weighted average cost method. Net realizable value represents the estimated selling price less all estimated costs of completion and costs to be incurred in marketing, selling and distribution.

Financial assets

The Group has financial assets classified within the category 'financial assets at amortized cost' . The classification depends on the purpose for which the financial assets were acquired. Management determines the classification of its financial assets at initial recognition and re-evaluates this designation at every reporting date. Financial assets at amortized cost are held within a business model with the objective to hold financial assets in order to collect contractual cash flows and the contractual terms of the financial asset give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

Financial assets are derecognized when the contractual rights to the cash flows of the assets expire or when the Group sells or otherwise disposes of the contractual rights to the cash flows, including situations where the Group retains the contractual rights, but assumes a contractual obligation to pay the cash flows to a third party.

Impairment of non-financial assets

Assets that are subject to depreciation and amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for the amount by which the asset' s carrying amount exceeds its recoverable amount. The recoverable amount is the higher of an asset' s fair value less costs to sell and value in use. For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows (cash-generating units). Non-financial assets that suffered impairment are reviewed for possible reversal of the impairment at each reporting date.

Cash and cash equivalents

Cash and cash equivalents include cash on hand, deposits held at call with banks and other short-term highly liquid investments with original maturities of three months or less. This definition is also used for the purposes of the statement of cash flows.

Current and deferred income tax

Income tax expense for the period comprises current and deferred tax. Tax is recognized in the consolidated statement of profit or loss, except to the extent that it relates to items recognized in other comprehensive income or directly in equity. In this case the tax is also recognized in other comprehensive income or directly in equity, respectively.

Deferred income tax is recognized, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. However, the deferred income tax is not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss. Deferred income tax is determined using tax rates (and laws) that have been enacted or substantively enacted by the balance sheet date and are expected to apply when the related deferred income tax asset is realized or the deferred income tax liability is settled.

Deferred income tax assets are recognized to the extent that it is probable that future taxable profit will be available against which the temporary differences can be utilized.

Financial liabilities

Financial liabilities, other than derivative financial instruments, are recognized initially at fair value and subsequently measured at amortized cost using the effective interests' method. If payment is due within one year or less, they are classified as current liabilities. If not, they are represented as non-current liabilities.

The Group derecognizes financial liabilities when, and only when, the Group' s obligations are discharged, cancelled or expired.

Share capital

Financial instruments issued by the Group are classified as equity only to the extent that they do not meet the definition of a financial liability or financial asset.

Fair values

Fair value is the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The fair value measurement is based on the presumption that the transaction to sell the asset or transfer the liability takes place either:

In the principal market for the asset or liability, or

In the absence of a principal market, in the most advantageous market for the asset or liability.

The Group uses valuation techniques that are appropriate in the circumstances and for which sufficient data is available to measure fair value, maximising the use of relevant observable inputs and minimising the use of unobservable inputs.

All assets and liabilities for which fair value is measured or disclosed in the consolidated financial statements are categorized within the fair value hierarchy, described as follows, based on the lowest level of input that is significant to the fair value measurement as a whole:

Level 1 - Quoted (unadjusted) market prices in active markets for identical assets or liabilities,

Level 2 - Valuation techniques for which the lowest level of input that is significant to the fair value measurement is directly or indirectly observable, or

Level 3 - Valuation techniques for which the lowest level of input that is significant to the fair value measurement is unobservable.

For assets and liabilities that are recognized in the consolidated financial statements on a recurring basis, the Group determines whether transfers have occurred between Levels in the hierarchy by re-assessing categorisation (based on the lowest level input that is significant to the fair value measurement as a whole) at the end of each reporting period.

The fair values of financial assets and liabilities at the reporting date are not materially different from their reported carrying values unless specifically mentioned in the notes to the consolidated financial statements.

Revenue

The Group recognizes revenue from the following major sources:

Service revenue from sub-licencing including upfront payments, milestone payments as well as royalties

Product sales from sub-licensing

Contract development

In general, the Group recognizes revenue when it transfers control of a product or service to a customer.

Service revenue from sub-licensing is generated on the basis of licensing agreements under which third parties are granted rights to products and technologies. Non-refundable payments received, or expected to be received, that relate to the sale or out-licensing of technologies or technological expertise are recognized in income as of the effective date of the respective agreement if all obligations resulting from them have been relinquished under the contract terms. However, if payments are refundable under certain circumstances or obligations resulting from agreements have yet to be fulfilled, the payments received are deferred accordingly. Payments received under these agreements are recorded as deferred income and recognized in income when they become not-refundable respectively over the estimated performance period.

Revenue from product sales is recognized when risk and rewards are transferred to the client. Revenue from services is recognized in the accounting period in which the services are rendered.

Research and development expenses

Research and development costs, which are included in service expense, consist primarily of costs associated with preclinical testing and clinical trials of product candidates, expenses for research and development services under license agreements and outsourced research and development expenses. Expected but not yet invoiced research and development expenses are accrued if they relate to the current financial period.

Research costs are expensed as incurred, as these expenses do not meet the criteria for capitalization. Development expenditures on an individual project are recognized as an intangible asset when the Group can demonstrate:

The technical feasibility of completing the intangible asset so that the asset will be available for use or sale

Its intention to complete and its ability and intention to use or sell the asset

How the asset will generate future economic benefits

The availability of resources to complete the asset

The ability to measure reliably the expenditure during development

Amortization of capitalized intellectual property research and development (“IPR&D”) starts once the development is complete and the asset is available for use, which is usually the point in time at which marketing approval is granted by the relevant authority. Before that date, capitalized IPR&D is tested at least annually for impairment, irrespective of whether any indication of impairment exists.

Employee benefits

(a) General

Wages, salaries, social security contributions, paid annual leave and sick leave, bonuses, and non-monetary benefits are accrued in the year in which the associated services are rendered by employees of the Group.

(b) Pension obligations

The cost of providing benefits under the defined benefit plan is determined using the Projected Unit Credit method.

Re-measurements, comprising of actuarial gains and losses, the effect of the asset ceiling, excluding net interest (not applicable to the Group) and the return on plan assets (excluding net interest), are recognized immediately in the statement of financial position with a corresponding debit or credit to retained earnings through OCI in the period in which they occur. Re-measurements are not reclassified to profit or loss in subsequent periods.

Past service costs are recognized through profit or loss on the earlier of:

The date of the plan amendment or curtailment, or

The date on which the Group recognizes related restructuring costs.

Net interest is calculated by applying the discount rate to the net defined benefit liability or asset. The Group recognizes the following changes in the net defined benefit obligation under "employee benefits expense" through profit or loss:

Service costs comprised of current service costs, past service costs, gains and losses on curtailments and non-routine settlements, and

Net interest expense or income.

Leases

The group as lessee

The Group assesses whether a contract is or contains a lease, at inception of the contract. The Group recognizes a right-of-use asset and a corresponding lease liability with respect to all lease arrangements in which it is the lessee, except for short-term leases (defined as leases with a lease term of 12 months or less) and leases of low value assets. For these leases, the Group recognizes the lease payments as an operating expense within general and administrative expense on a straight-line basis over the term of the lease unless another systematic basis is more representative of the time pattern in which economic benefits from the leased assets are consumed.

The lease liability is initially measured at the present value of the lease payments that are not paid at the commencement date, discounted by using the rate implicit in the lease. If this rate cannot be readily determined, the Group uses its incremental borrowing rate for such liabilities.

Lease payments included in the measurement of the lease liability comprise:

fixed lease payments (including in substance fixed payments), less any lease incentives;

variable lease payments that depend on an index or rate, initially measured using the index or rate at the commencement date;

the amount expected to be payable by the lessee under residual value guarantees;

the exercise price of purchase options, if the lessee is reasonably certain to exercise the options; and

payments of penalties for terminating the lease, if the lease term reflects the exercise of an option to terminate the lease.

The lease liability is subsequently measured by increasing the carrying amount to reflect interest on the lease liability (using the effective interest method) and by reducing the carrying amount to reflect the lease payments made.

The Group remeasures the lease liability (and makes a corresponding adjustment to the related right-of-use asset) whenever:

the lease term has changed or there is a change in the assessment of exercise of a purchase option, in which case the lease liability is remeasured by discounting the revised lease payments using a revised discount rate.

the lease payments change due to changes in an index or rate or a change in expected payment under a guaranteed residual value, in which cases the lease liability is remeasured by discounting the revised lease payments using the initial discount rate (unless the lease payments change is due to a change in a floating interest rate, in which case a revised discount rate is used).

a lease contract is modified and the lease modification is not accounted for as a separate lease, in which case the lease liability is remeasured by discounting the revised lease payments using a revised discount rate.

The right-of-use assets comprise the initial measurement of the corresponding lease liability, lease payments made at or before the commencement day and any initial direct costs. They are subsequently measured at cost less accumulated depreciation and impairment losses.

Right-of-use assets are depreciated over the shorter period of lease term and useful life of the underlying asset. If a lease transfers ownership of the underlying asset or the cost of the right-of-use asset reflects that the Group expects to exercise a purchase option, the related right-of-use asset is depreciated over the useful life of the underlying asset. The depreciation starts at the commencement date of the lease.

The Group applies IAS 36 Impairment of Assets to determine whether a right-of-use asset is impaired and accounts for any identified impairment loss as described in the impairment of non-financial assets policy.

Variable rents that do not depend on an index or rate are not included in the measurement the lease liability and the right-of-use asset. The related payments are recognized as an expense in the period in which the event or condition that triggers those payments occurs and are included in the line "general and administrative expense" in the consolidated statement of profit or loss.

Equity-settled share-based payments

Employees, members of the board and certain external advisors (providing services similar to those rendered by employees) of the Group receive remuneration in the form of share-based payments, whereby they render services in consideration for equity instruments (equity-settled transactions).

All the options granted vested prior to the date of transition to IFRS and, therefore, the Group applied IFRS 1 exemption to not apply IFRS 2 to such options.

4 Summary of 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. The estimates and assumptions that have the most significant effect on the amounts recognized in the financial statements are described below.

4.1 Critical judgements in applying accounting policies

Going concern

The Group has not yet demonstrated sustainable profitability and may generate losses in the foreseeable future. Under the current development plan, investments required to develop and market clinical-stage products may exceed the income generated from its portfolio of marketed products and the current liquidity reserves. APR' s ability to continue on a going concern basis is uncertain and dependent on (i) the financial support of its shareholder, Relief Therapeutics Holding SA, which acquired all outstanding shares of APR in June 2021, or (ii) the generation of positive cash flows from its own operations. Management has a reasonable expectation that the Group has and will have adequate resources to fund its operations and repay its liabilities. These consolidated financial statements have been prepared on a going concern basis.

Revenue recognition

Revenue is primarily from fees related to licenses, milestones and royalties as well as product sales. Given the complexity of the relevant agreements, judgement is required to identify distinct performance obligations, allocate the transaction price to these performance obligations and determine when the performance obligations are met.

4.2 Key sources of estimation uncertainty

Intangible assets

The recoverable amount of intangible assets is based on various financial assumptions. As there was no indication for impairment based on the defined financial assumptions, no impairment review was necessary.

Net pension liabilities

The retirement benefit obligation is calculated based on various financial and actuarial assumptions. The key assumptions for assessing these obligations are the discount rate, future salary and pension increases and the probability of the employee reaching retirement. The calculations were performed by external actuaries and the principal assumptions used are summarized in Note 14. As of December 31, 2020, the underfunding amounted to CHF 2' 379 thousand. Using other basis for the calculations could have led to different results.

5 Impact due to Covid-19 pandemic

Covid-19, confirmed as a pandemic by the World Health Organization on March 11, 2020, has led to a global health crisis. The Group has assessed the impact of the uncertainties created by the pandemic. The Board of Directors and management of the Group have been following the developments in relation to the Covid-19 pandemic as well as possible impacts on the Group closely. So far, the Group was able to continue to work on its development programs without any major delays. Further, all key suppliers were able to deliver in time.

The Group is closely monitoring the global evolution of the pandemic but does not anticipate any negative impacts on the going concern of the Group over the next months.

6 Subsidiaries

Details of the Group' s subsidiaries as of each reporting date are as follows:

Subsidiary	Domicile	Proportion of ownership interest and voting power as of			
		December 31, 2020		January 1, 2020	
APR Applied Pharma Research Holding SA	Switzerland	100.00	%	100.00	%
APR Applied Pharma Research Italy Srl	Italy	100.00	%	100.00	%
APR Applied Pharma Research Deutschland GmbH	Germany	100.00	%	100.00	%

7 Property, plant and equipment

In thousands of CHF	Plant and Equipment	Furniture and Fixtures	Total
COST			
Balance as of January 1, 2020	**120**	**154**	**274**
Additions	2	–	2
Disposals	(6)	–	(6)
Foreign exchange difference	(1)	2	1
Balance as of December 31, 2020	**115**	**156**	**271**
ACCUMULATED DEPRECIATION			
Balance as of January 1, 2020	**(84)**	**(111)**	**(195)**
Disposals	6	–	6
Depreciation expense	(14)	(20)	(34)
Foreign exchange difference	–	–	–
Balance as of December 31, 2020	**(92)**	**(131)**	**(223)**
CARRYING AMOUNT			
as of January 1, 2020	36	43	79
as of December 31, 2020	**23**	**25**	**48**

8 Intangible assets

In thousands of CHF	Patents	Trademarks	Technology	Others	Total
COST					
Balance as of January 1, 2020	**2,563**	**270**	**516**	**1,731**	**5,080**
Additions	–	–	–	–	–
Disposals	–	(12)	–	(443)	(455)
Balance as of December 31, 2020	**2,563**	**258**	**516**	**1,288**	**4,625**
ACCUMULATED AMORTIZATION					
Balance as of January 1, 2020	**(1,537)**	**(108)**	**(122)**	**(607)**	**(2,374)**
Disposals	–	–	–	233	233
Amortization expense	(292)	(24)	(79)	(236)	(631)
Balance as of December 31, 2020	**(1,829)**	**(132)**	**(201)**	**(610)**	**(2,772)**
CARRYING AMOUNT					
as of January 1, 2020	1,026	162	394	1,124	2,706
as of December 31, 2020	**734**	**126**	**315**	**678**	**1,853**

Other intangible assets mainly include internally generated capitalized assets.

9 Financial assets

	As of	
In thousands of CHF	December 31, 2020	January 1, 2020
Loans due from third parties (i)	–	487
Deposits	75	81
Total	**75**	**568**

(i) In 2017, the Group has granted two interest free loans to third parties which are both due in 2022. As at December 31, 2020, these loans were fully written-off leading to a loss of CHF 487 thousand which is recognized as net impairment losses on financial and contract assets in the statement of comprehensive income (note 22).

10 Inventory

	As of	
In thousands of CHF	December 31, 2020	January 1, 2020
Raw material	11	21
Finished goods	215	343
Total	**226**	**364**

As at December 31, 2020, none of the inventory is impaired.

11 Other current assets

In thousands of CHF	As of December 31, 2020	As of January 1, 2020
VAT receivables	166	140
Prepaid expenses	76	572
Accrued revenue (i)	13	7
Other current receivables (i)	87	17
Total	**342**	**736**

(i) These other current assets qualify as financial instruments. Refer to Note 27.2.

Other current assets are neither impaired nor overdue.

12 Cash and cash equivalents

In thousands of CHF	As of December 31, 2020	As of January 1, 2020
Bank deposits in CHF	3,481	289
Bank deposits in EUR	1,602	1,553
Bank deposits in USD	1,289	1,265
Cash on hand	9	9
Total	**6,381**	**3,116**

13 Share capital

	Number of issued and outstanding shares 2020	Nominal value of share capital (in thousands of CHF) 2020
Balance at beginning of year	616,596	617
Issuance of ordinary shares	–	–
Balance at end of the year	**616,596**	**617**

13.1 Issued share capital

As of December 31, 2020, the issued share capital amounted to CHF 617 thousand, consisting of 616’ 596 ordinary shares (fully paid registered shares) with a nominal value of CHF 1.00 per share. All of these shares have the same voting rights.

Since January 1, 2020, the issued share capital has been unchanged.

13.2 Authorized share capital

As of December 31, 2020, there was no unissued authorized share capital.

13.3 Conditional share capital

As of December 31, 2020, the conditional share capital amounted to CHF 50 thousand, consisting of 50’ 000 ordinary shares with a par value of CHF 1.00 per share to be used for stock options to members of the Board of Directors, employees and consultants.

14 Net pension liabilities

14.1 Swiss pension plans

Swiss pension plans are required to be administered by a separate pension fund that is legally separated from the entity. The law prescribes certain minimum benefits to be provided to the beneficiaries.

The pension plan of the employees of the Swiss company, APR Applied Pharma Research SA, is carried out by a collective fund with Swiss Life Collective BVG Foundation. Under the pension plan, the employees are entitled to retirement benefits and risk insurance for death and disability. The board of the pension fund is composed of an equal number of representatives from both employers and employees.

In accordance with IAS 19, the above-mentioned pension plan is classified as defined benefit plan. The pension plan is described in detail in the corresponding statutes and regulations. The contributions of employers and employees in general are defined in percentages of the insured salary. The retirement pension is calculated based on the old-age credit balance on retirement multiplied by the fixed conversion rate. The employee has the option to withdraw the capital on demand. The death and disability pensions are defined as percentage of the insured salary. The assets are invested directly with the corresponding pension funds.

The pension fund can change their financing system, such as contributions and future payments, at any time. Also, when there is a deficit which cannot be eliminated through other measures, the pension fund can oblige the entity to pay a restructuring contribution. For the pension fund of APR, such a deficit cannot occur as the plan is fully reinsured. However, the pension fund could cancel the contract and APR would have to join another pension fund.

During 2020, changes to the future conversion factors (for 2022 and later), used to convert a participant' s account balance into a pension at retirement, were approved. This plan change resulted in a decrease in the defined benefit obligation of CHF 85 thousand, which was immediately recognized as a gain in profit and loss for the financial year ended December 31, 2020. No further curtailment or settlement occurred during the year ended December 31, 2020.

The most recent actuarial valuations of plan assets and the present value of the defined benefit obligation were carried out as of December 31, 2020, by an independent third party. The present value of the defined benefit obligation, and the related current service cost and past service cost, were measured using the Projected Unit Credit method.

The amounts recognized through profit or loss within employee benefits expenses with respect to the defined benefit plans are as follows:

In thousands of CHF	For the year ended December 31, 2020
Current service cost	400
Past service cost	(85)
Interest cost	5
Administration costs	30
Expense recognised in profit or loss	**350**

The amounts recognized in OCI with respect to the defined benefit plans are as follows:

In thousands of CHF	For the year ended December 31, 2020
Remeasurement (gain)/loss on defined benefit obligation actuarial (gains)/losses arising from plan experience (i)	(1,119)
actuarial (gains)/losses arising from demographic assumptions	–
actuarial (gains)/losses arising from financial assumptions	110
Return on plan assets excl. interest income	35
(Gains) / Expenses recognised in other comprehensive income	**(974)**

(i) Actuarial gains arising from plan experience mainly relates to the turnover rate of employees which was higher than expected

The amount included in the consolidated statement of financial position arising from the Group' s obligation in respect to its defined benefit plans is as follows:

In thousands of CHF	As of December 31, 2020	As of January 1, 2020
Present value of defined benefit obligation	5,722	7,900
Fair value of plan assets	(3,343)	(4,626)
Net liability arising from defined benefit obligation	**2,379**	**3,274**

Movements in the present value of the defined benefit obligation in the reporting period were as follows:

In thousands of CHF	For the year ended December 31, 2020
Beginning defined benefit obligation as of January 1	7,900
Current service cost	400
Past service cost (plan amendment)	(85)
Interest expense on defined benefit obligation	12
Contributions paid by employees	116
Benefits (paid)/deposited	(1,612)
Remeasurement (gain)/loss on defined benefit obligation	(1,009)
Ending defined benefit obligation as of December 31	**5,722**

Movements in the fair value of the plan assets in the reporting period were as follows:

In thousands of CHF	For the year ended December 31, 2020
Beginning fair value of plan assets as of January 1	4,626
Interest income on plan assets	7
Contributions paid by employer	271
Contributions paid by employees	116
Benefits (paid)/deposited	(1,612)
Return on plan assets excluding amount included in interest income	(35)
Administration expense	(30)
Ending fair value of plan assets as of December 31	**3,343**

The insurance company is providing reinsurance of these assets and bears all market risk on these assets.

Principal assumptions used for the purposes of the actuarial valuations were as follows:

	For the year ended December 31, 2020
Discount rates	0.05 %
Expected rates of salary increase	1.50 %
Mortality rates	BVG 2015

The following sensitivity analyses - based on the principal assumptions - have been performed based on reasonably possible changes to the assumptions occurring at the end of the reporting period:

If the discount rate would increase (decrease) by 25 basis points, the defined benefit obligation would decrease by CHF 263 thousand (increase by CHF 286 thousand) if all other assumptions were held constant.

If the expected salary growth would increase (decrease) by 25 basis points, the defined benefit obligation would increase by CHF 40 thousand (decrease by CHF 40 thousand) if all other assumptions were held constant.

The average duration of the defined benefit obligation at the end of the reporting period is 19.2 years.

The Group expects to make contributions of CHF 251 thousand to the defined benefit plan during 2021.

15 Borrowings

In thousands of CHF	As of December 31, 2020	As of January 1, 2020
Bank loans (i)	4,000	4,000
Covid-19 loans (ii)	1,262	–
Total	**5,262**	**4,000**

(i) The Group has a current account limit of CHF 4' 000 thousand which they have fully drawn down. For the entire reporting period the interest rate was fixed at 2.30%. The loan is granted for 12 months with extension option.

(ii) To cover the liquidity needs during the Covid-19 pandemic, the Group requested and obtained government-supported loans of CHF 1' 262 thousand in 2020. For the duration of the Covid-19 loans, the Group may not distribute dividends and may not repay capital contributions. There are also further restrictions regarding the granting and repayment of loans to group companies and owners. These loans were classified as current as they were paid back in the financial year 2021.

16 Trade payables

In thousands of CHF	As of December 31, 2020	As of January 1, 2020
Related to goods and services	1,144	1,291
Related to general and administrative expense	121	138
Total	**1,265**	**1,429**

17 Other current liabilities

In thousands of CHF	As of December 31, 2020	As of January 1, 2020
Payables related to social security institutions	265	265
Payables related to employee benefits	3	2
Payables due to VAT	26	2
Accrued royalty revenue (ii)	67	226
Accrued expenses (i)	139	322
Tax payable (other than income tax)	121	9
Other current payables (i)	10	20
Total	**631**	**846**

(i) These other current liabilities qualify as financial instruments. Refer to Note 27.2.

(ii) Accrued royalty revenue relates to royalties which were received from a third party in excess of the actual amount due. They were accrued and returned in 2020 and 2021.

18 Revenue

18.1 Disaggregated revenue information

In thousands of CHF	For the year ended December 31, 2020
Revenue from Licensing - Upfront and milestones (i)	1,767
Revenue from Licensing - Royalties (i)	2,945
Revenues from Licensing - Product sales (i)	5,349
Revenues from Contract Development	39
Total	**10,100**

(i) Revenue from Licensing includes realized revenue in relation to the various licensing agreements with third parties.

Regarding the upfront and licensing agreement, the Group determined that the transaction price at contract inception is only consisting of the upfront, non-refundable amount. Those agreements included variable consideration which were constraint. None of the future milestones in the total amount of CHF 6.7 million (January 1, 2020: CHF 6.3 million) were included in the transaction price upon inception as they are contingent upon achieving uncertain, future development stages and net sales. Any consideration related to royalties will be recognized when the related sales occur, and therefore have also been excluded from the transaction price. Hence, as at December 31, 2020 and January 1, 2020 the Group does not have any unsatisfied performance obligations.

With the exception of the royalty income from the sale of Diclofenac, which is recognized on a net basis as the Company acts as an agent (Note 31), all the revenue are presented on a gross basis

18.2 Contract assets and liabilities

	As of	
In thousands of CHF	December 31, 2020	January 1, 2020
Trade receivables (note 18.3)	1,708	2,097
Accrued revenue (note 11)	13	7
Accrued royalties (note 17)	(67)	(226)

18.3 Trade receivables

	As of	
In thousands of CHF	December 31, 2020	January 1, 2020
Trade receivables	2,096	2,321
Allowance for doubtful debts	(388)	(224)
Total	**1,708**	**2,097**

Trade receivables are non-interest bearing and generally have maturities between 30 and 90 days.

The Group uses a provision matrix to calculate ECLs for trade receivables from third parties. The provision rates are based on days past due of customer invoices. The provision is initially based on the Group' s historical observed default rates. The Group calibrates the matrix to adjust the historical credit losses with forecasts on economic conditions or similar forecast data for the various geographical areas. At each reporting date, the historical observed default rates are updated and changes in the various forecasts are analysed.

19 Other gains

Other gains of TCHF 3' 880 relate to the sale of licenses for specific territories of one of the products capitalized within intangible assets for the total net amount of CHF 4' 103 thousand to a third party. Further, income from sublease contracts of CHF 62 thousand were also recognized within other gains.

20 Goods and service expense

In thousands of CHF	For the year ended December 31, 2020
Third party research and development expense	741
Service expense	26
License expense	813
Expense directly related to goods sold (i)	3,704
Other goods and service expense	785
Total	**6,069**

(i) Expense directly related to goods sold includes the amount of inventory cost.

21 Personnel expense

In thousands of CHF	For the year ended December 31, 2020
Salary expense	3,869
Social security expense	895
Other personnel expense	45
Total	**4,809**

22 Net impairment losses on financial and contract assets

In thousands of CHF	For the year ended December 31, 2020
Impairment of trade receivables (note 18.3)	170
Impairment of financial assets (note 9)	487
Total	**657**

23 General and administrative expense

In thousands of CHF	For the year ended December 31, 2020
Corporate expense	464
Travel expense	111
Other operating expense	444
Total	**1,019**

24 Financial income and expense, net

In thousands of CHF	For the year ended December 31, 2020
Interest expense on lease liabilities	(37)
Interest expense on borrowings	(79)
Bank charges	(7)
Total financial expenses	**(123)**
Foreign currency exchange losses	(204)
Foreign exchange differences, net	**(204)**
Total	**(327)**

25 Income taxes

25.1 Income tax recognized through profit or loss

In thousands of CHF	For the year ended December 31, 2020
Current tax	
Current tax expense	(117)
	(117)
Deferred tax	
Deferred tax expense recognized in the current year	(198)
	(198)
Total	**(315)**

The following table provides a reconciliation between income tax expense recognized for the year and the tax calculated by applying the applicable tax rates on accounting profit:

In thousands of CHF	For the year ended December 31, 2020
Profit before income taxes	110
Income tax expense calculated at 18.47%	(20)
Adjustments due to different tax rates applicable within subsidiaries	102
Adjustments due to withholding tax on royalty revenue	(117)
Previously unrecognized tax losses used	127
Unrecognized deferred tax assets during the year	(209)
Adjustments in respect of current income tax of previous years	(198)
Income tax expense	**(315)**

The applicable tax rate of the Group is 18.47%, which is the applicable domestic tax rate of the Company.

25.2 Income tax recognized in other comprehensive loss

Income tax benefits of CHF 180 thousand were recognized in other comprehensive income due to deferred tax assets on net defined benefit obligations.

25.3 Deferred tax balances

In thousands of CHF	Opening balance	Recognized in profit or loss	Recognized in OCI	Closing balance
Tax losses carried forward	559	(256)	–	303
Defined benefit obligation	605	14	(180)	439
Right-of-use assets	–	3	–	3
Intangible assets	470	(77)	–	393
Receivables	41	117	–	158
Total deferred tax assets	**1,675**	**(199)**	**(180)**	**1,296**

25.4 Unrecognized deferred tax assets

For the tax losses carry-forwards as well as deductible temporary differences related to the defined benefit pension plans, the criteria for recognition (i.e. the probability of future taxable profits) were not met. The gross value of unused tax losses, which has not been capitalized as a deferred tax asset, will expire as follows:

	As of	
In thousands of CHF	December 31, 2020	January 1, 2020
Later than one year and not later than five years	224	224
More than five years	1,250	626
Total tax losses carryforwards	**1,474**	**850**

26 Share-based payments

Starting in 2010, the Company has set up a stock option plan for its employees, members of the board of directors as well as external advisors for their services provided to the Group. The exercise price for the options is set at each grant date which is indicated by the different exercise price The options either vested immediately or the vesting period was spread over 2-3 years depending on the vesting periods of the individual agreements. The expiry date of these options, which was originally set to ten years from grant date, was extended to 15 years during the financial period ended December 31, 2020. Early exercise is possible if certain criteria are met.

As all outstanding options were granted between 2010 and 2012, they had already fully vested before January 1, 2020. Therefore, the outstanding options did not have an impact on profit or loss for any of the financial periods presented in these consolidated financial statements.

The total amount of options outstanding is 24’ 000 with a weighted average exercise price of CHF 18.67. 2’ 500 options expired during the financial period ended December 31, 2020.

Share options outstanding as of December 31, 2020 and January 1, 2020 were as follows:

	As of	
Number of options	December 31, 2020	January 1, 2020
Expiry date		
August 29, 2020	–	2,500
November 26, 2022	–	7,000
December 20, 2020	–	17,000
December 20, 2025	17,000	–
November 26, 2027	7,000	–
Total	**24,000**	**26,500**

27 Financial instruments

27.1 Capital management

The Group' s objectives when managing capital (equity including any preferred shares) are to safeguard its ability to continue as a going concern in order to provide returns for shareholders and benefits for other stakeholders.

27.2 Categories of financial instruments

As of December 31, 2020 In thousands of CHF	Financial assets at amortized cost (incl. cash and cash equivalents)	Financial liabilities at amortized cost	Total
Financial assets	75	–	**75**
Trade receivables	1,708	–	**1,708**
Other current assets	100	–	**100**
Cash and cash equivalents	6,381	–	**6,381**
Total financial assets	**8,264**	**–**	**8,264**
Borrowings	–	5,262	**5,262**
Lease liabilities	–	2,745	**2,745**
Trade payables	–	1,265	**1,265**
Other current liabilities	–	149	**149**
Total financial liabilities	**–**	**9,421**	**9,421**

As of January 1, 2020 In thousands of CHF	Financial assets at amortized cost (incl. cash and cash equivalents)	Financial liabilities at amortized cost	Total
Financial assets	568	–	**568**
Trade receivables	2,097	–	**2,097**
Other current assets	24	–	**24**
Cash and cash equivalents	3,116	–	**3,116**
Total financial assets	**5,805**	**–**	**5,805**
Borrowings	–	4,000	**4,000**
Lease liabilities	–	3,097	**3,097**
Trade payables	–	1,429	**1,429**
Other current liabilities	–	342	**342**
Total financial liabilities	**–**	**8,868**	**8,868**

The carrying amounts of financial assets and financial liabilities recognized in the consolidated financial statements approximate their fair values.

27.3 Financial risk management

The Group is exposed to various financial risks such as credit risk, liquidity risk and market risk (including interest-rate and currency risk). The following sections provide an overview of the extent of the individual risks and the goals, principles and processes employed to handle these risks.

Credit risk

Credit risk refers to the risk that a counter party will default on its contractual obligations resulting in financial loss to the Group. Counterparty risk is minimized by ensuring that the majority of cash and cash equivalents are held with major Swiss, Italian and German banks.

The carrying amount of financial assets recorded in the consolidated financial statements represents the Group' s maximum exposure to credit risk without taking into account of the value of any collateral obtained.

Liquidity risk

Liquidity risk management implies maintaining sufficient cash and cash equivalents to meet the financial obligations of the Group. Currently the major liquidity sources are represented by shareholders and investors who systematically made up for major liquidity requirements. Management monitors the Group' s net liquidity position through rolling forecasts on the basis of expected cash flows.

Interest rate risk

With the exception of short-term cash deposits as well as the outstanding borrowings, the Group has no other interest-bearing assets or liabilities and the interest rate risk exposure is therefore minimized.

Currency risk

With the exception of certain short-term cash deposits, which are held in foreign currencies (for details refer to Note 12), as well as trade receivables and payables in foreign currencies, the Group is not exposed to any foreign currency risk. As the cash balances in foreign currencies are held for settlement of expected invoices in these currencies, they are naturally hedged. The Group' s exposure to foreign currency risk based on year end amounts was:

As of December 31, 2020 In thousands of CHF	EUR	USD	GBP
Financial assets	7	–	–
Trade receivables	1,437	656	–
Other current assets	1	12	–
Cash and cash equivalents	1,602	1,289	–
Borrowings	(28)	–	–
Lease liabilities	(147)	–	–
Trade payables	(1,111)	(72)	(16)
Other current liabilities	(115)	(50)	–
Net exposure	**1,646**	**1,835**	**(16)**

As at December 31, 2020, a 5% strengthening of the CHF against the following currencies would have increased/(decreased) unrestricted funds and results by the amounts shown below. This analysis assumes that all other variables, in particular interest rates, remain constant.

In thousands of CHF	For the year ended December 31, 2020
EUR	82
USD	92
GBP	(1)

A 5% weakening of the CHF against the above currencies as at December 31, 2020, would have had the equal but opposite effects on the above currencies to the amounts shown above, on the basis that all other variables remain constant.

During the year ended December 31, 2020 the Group did not enter into any forward currency transactions.

27.4 Reconciliation of liabilities arising from financing activities

In thousands of CHF	January 1, 2020	Financing Cash flows	New leases	FX	December 31, 2020
Borrowings	4,000	1,262	–	–	5,262
Lease liabilities	3,097	(375)	24	(1)	2,745
Total	**7,097**	**887**	**24**	**(1)**	**8,007**

28 Related party transactions

28.1 Compensation for Executive Management and Board of Directors ("BOD")

In thousands of CHF	For the year ended December 31, 2020
Fees, salaries and other short-term employee benefits	813
Post-employment benefits	104
Total compensation for Executive Management and BOD	**917**

28.2 Related party balances and transactions

There were no significant related party balance and transactions as at December 31, 2020 and for the year ended December 31, 2020.

29 Leases (the Group as lessee)

29.1 Right-of-use assets

In thousands of CHF	Office Building	Equipment	Total
COST			
Balance as of January 1, 2020	**2,856**	**512**	**3,368**
Additions	–	24	24
Disposals	–	(78)	(78)
Foreign exchange difference	(1)	–	(1)
Balance as of December 31, 2020	**2,855**	**458**	**3,313**
ACCUMULATED DEPRECIATION			
Balance as of January 1, 2020	–	**(271)**	**(271)**
Disposals	–	78	78
Depreciation expense	(272)	(117)	(389)
Foreign exchange difference	–	–	–
Balance as of December 31, 2020	**(272)**	**(310)**	**(582)**
CARRYING AMOUNT			
as of January 1, 2020	2,856	241	3,097
as of December 31, 2020	**2,583**	**148**	**2,731**

The Group leases office equipment, laboratory equipment and cars as well as office buildings in Switzerland, Italy and Germany. The remaining expected lease terms are between 2 years and 10 years. Except for the office and laboratory equipment, the Group does not have an option to purchase the asset at the end of the lease term.

29.2 Maturity analysis of lease liabilities

	As of	
In thousands of CHF	December 31, 2020	January 1, 2020
< 1 year	366	370
1-5 years	1,118	1,216
> 5 years	1,261	1,511
Total	**2,745**	**3,097**

29.3 Amounts recognized in profit or loss

In thousands of CHF	For the year ended December 31, 2020
Lease expense for short-term and low value leases	79
Depreciation expense on right-of-use assets (note 29.1)	389
Interest expense on lease liabilities (note 24)	37

29.4 Further information on leases

At December 31, 2020 the Group does have commitments of CHF 4 thousand for short-term leases.

The total cash-outflow for leases amounts to CHF 491 thousand.

30 Non-cash transactions

During 2020, there were no significant non-cash investing and financing transactions.

31 Commitments and contingent liabilities

The Company has committed to pay to a third party 50% of the royalties received from a commercialization partner for the sale of Diclofenac in certain territories. The royalty payments are deducted from the corresponding royalty income stream and therefore only the net amount is accounted as revenue in the income statement. As of December 31, 2020, the Company has no unrecognized liabilities or contingent commitments with regards to this arrangement.

As at December 31, 2020, there were no other commitments or contingent liabilities.

32 Events after the reporting period

On June 28, 2021, all outstanding shares and voting rights of the Company were acquired by Relief Therapeutics Holding SA. Under the terms of the agreement, the Company’ s shareholders have received a cash payment of CHF 21.5 million in June 2021 and further received 206’ 786’ 784 common registered shares of Relief Therapeutics Holding SA in July 2021. The Company’ s shareholders are also eligible to receive additional contingent payments in a combination of cash and Relief Therapeutics Holding SA common shares upon achievement of pre-agreed milestones.

33 Approval of financial statements

These consolidated financial statements were approved by the Board of Directors on December 15, 2021

APR Applied Pharma Research SA

Consolidated statements of financial position

In thousands of Swiss Francs ("CHF")	Notes	As of June 30, 2021 (unaudited)	As of December 31, 2020
ASSETS			
NON-CURRENT ASSETS			
Property, plant and equipment	6	34	48
Right-of-use assets	7	2,599	2,731
Intangible assets	8	1,513	1,853
Financial assets	9	55	75
Deferred tax assets		1,239	1,296
Total non-current assets		**5,440**	**6,003**
CURRENT ASSETS			
Inventory		192	226
Trade receivables	16.2	1,107	1,708
Other current assets	10	851	342
Cash and cash equivalents	11	5,710	6,381
Total current assets		**7,860**	**8,657**
Total assets		**13,300**	**14,660**
EQUITY AND LIABILITIES			
EQUITY			
Share capital	12	641	617
Reserves		5,217	4,707
Accumulated losses		(4,160)	(2,946)
Total Equity		**1,698**	**2,378**
NON-CURRENT LIABILITIES			
Lease liabilities		2,248	2,379
Net pension liabilities		1,707	2,379
Total non-current liabilities		**3,955**	**4,758**
CURRENT LIABILITIES			
Borrowings	13	5,170	5,262
Lease liabilities		371	366
Trade payables	14	952	1,265
Other current liabilities	15	1,154	631
Total current liabilities		**7,647**	**7,524**
Total liabilities		**11,602**	**12,282**
Total equity and liabilities		**13,300**	**14,660**

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

APR Applied Pharma Research SA

Consolidated unaudited statement of comprehensive income

In thousands of CHF	Notes	For the period ended June 30, 2021
CONSOLIDATED STATEMENT OF PROFIT OR LOSS		
Net revenues	16.1	3,590
Other gains	7	12
Total income		**3,602**
Goods and service expense	17	(1,686)
Personnel expense	18	(2,932)
Net impairment reversal gains on financial and contract assets		117
General and administrative expense	19	(314)
EBITDA		**(1,213)**
Depreciation and amortization expense		(547)
EBIT		**(1,760)**
Financial income and expense, net	20	(26)
Loss before income taxes		**(1,786)**
Income taxes	21.1	67
Loss for the period		**(1,719)**
OTHER CONSOLIDATED COMPREHENSIVE INCOME		
Gain on remeasurement of defined benefit plan		505
Total items that will not be reclassified subsequently to profit or loss		**505**
Exchange differences arising on translation of foreign operations		88
Total items that may be reclassified subsequently to profit or loss		**88**
Total other comprehensive income for the period, net of income tax		**593**
Total comprehensive loss for the period		**(1,126)**

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

APR Applied Pharma Research SA

Consolidated unaudited statements of changes in equity

In thousands of CHF	Share capital	Capital Contribution (Reserves)	Foreign exchange (FX) translation (Reserves)	Accumulated losses	Total
Balance as of January 1, 2021	**617**	**4,659**	**48**	**(2,946)**	**2,378**
Loss for the period	–	–	–	(1,719)	(1,719)
Other comprehensive income for the period	–	–	88	505	593
Total comprehensive income for the period	**–**	**–**	**88**	**(1,214)**	**(1,126)**
Capital increase through exercise of options	24	424	–	–	448
Expense in relation to capital increase		(2)	–	–	(2)
Balance as of June 30, 2021	**641**	**5,081**	**136**	**(4,160)**	**1,698**

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

APR Applied Pharma Research SA

Consolidated unaudited statements of cash flows

In thousands of CHF	Notes	For the period ended June 30, 2021
Loss for the period		(1,719)
Adjustments for:		
Income tax benefit	21.1	(67)
Finance expense	20	95
Net foreign exchange (gain)/loss	20	(69)
Gain from disposal of right-of-use assets	7	(12)
Depreciation and amortization expense		547
Impairment of receivables		7
Reversal of impairment of receivables		(124)
Changes in net working capital:		
- Decrease in inventory		34
- Decrease in trade receivables		718
- (Increase) in other current assets		(509)
- (Decrease) in trade payables		(313)
- Increase in other current liabilities		523
Income tax paid		(43)
Interest paid		(72)
Cash flow used in operating activities		**(1,004)**
Proceeds from disposal of right-of-use assets		12
Cash flow generated from investing activities		**12**
Proceeds from exercise of share options	12.1	448
Expense in relation to capital increase		(2)
Payments for borrowings		(92)
Payments for lease liabilities		(179)
Cash flow generated from financing activities		**175**
Net decrease in cash and cash equivalents		(817)
Cash and cash equivalents at beginning of the period		6,381
Net effect of exchange rate changes on cash and cash equivalents		146
Cash and cash equivalents at end of the period	**11**	**5,710**

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

APR Applied Pharma Research SA

Notes to the consolidated unaudited interim financial statements

1 General information

APR Applied Pharma Research SA ("APR" or the "Company") is a Swiss stock corporation whose registered office is at Via Corti 5, Balerna, Switzerland. The Company was incorporated on March 31, 1993, in Switzerland. It is subject to provisions of the articles of incorporation and to article 620 et seq. of the Swiss Code of Obligations ("SCO"), which describes the legal requirements for limited companies. These consolidated financial statements comprise the financial statements of APR Applied Pharma Research SA (Switzerland), as well its subsidiaries (collectively, the "Group").

APR is an international pharma group focused on the development and commercialization of science driven, patent protected products engineered with proprietary Drug Delivery Technologies (DDS) intended to improve quality of life of patients and caregivers having and dealing with diseases with still high medical need.

On June 28, 2021, all outstanding shares and voting rights of the Company were acquired by Relief Therapeutics Holding SA. Under the terms of the agreement, the Company' s shareholders have received a cash payment of CHF 21.5 million in June 2021 and further received 206' 786' 784 common registered shares of Relief Therapeutics Holding SA in July 2021. The Company' s shareholders are also eligible to receive additional contingent payments in a combination of cash and Relief Therapeutics Holding SA common shares upon achievement of pre-agreed milestones.

2 Application of new and revised International Financial Reporting Standards ("IFRS")

2.1 Amendments to IFRS that are mandatorily effective in the current year

In the current period, the Group has applied the following amended Standard that became effective from January 1, 2021. The amended Standard did not have a material effect on these consolidated financial statements:

Interest Rate Benchmark Reform – amendment to IFRS 9, IAS 39, IFRS 7, IFRS 4 and IFRS 16

2.2 Standards and Interpretations in issue but not yet effective

Certain new and amended accounting Standards have been issued that are not mandatory for the current reporting period and have not been early adopted by the Group. These standards are not expected to have a material impact on the Group' s overall results and financial position.

3 Summary of significant accounting policies

3.1 Basis of preparation

These condensed consolidated financial statements have been 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 consolidated financial statements and should therefore be read in conjunction with the Group' s last annual consolidated financial statements for the year ended December 31, 2020. They have been prepared under the historical cost convention, as modified by the revaluation of financial instruments at fair value, are presented in Swiss Francs ("CHF"), and all values are rounded to the nearest thousand ("CHF thousands"), except when otherwise indicated.

These condensed consolidated financial statements do not fully comply with IFRS as no comparative period was presented.

3.2 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, 2020.

3.3 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 expenditures.

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 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.

Key sources of estimation uncertainty were the same as those applied to the consolidated financial statements for the year ended December 31, 2020.

5 Impact due to Covid-19 pandemic

Covid-19, confirmed as a pandemic by the World Health Organization on March 11, 2020, has led to a global health crisis. The Group has assessed the impact of the uncertainties created by the pandemic. The Board of Directors and management of the Group have been following the developments in relation to the Covid-19 pandemic as well as possible impacts on the Group closely. So far, the Group was able to continue to work on its development programs without any major delays. Further, all key suppliers were able to deliver in time.

The Group is closely monitoring the global evolution of the pandemic but does not anticipate any negative impacts on the going concern of the Group over the next months.

6 Property, plant and equipment

There were no additions or disposals to property, plant and equipment. The decrease is due to depreciation expense recognized for the six-months period.

7 Right-of-use assets

There were additions in the total amount of CHF 51 thousand and disposals of fully depreciated laboratory equipment. The disposals led to a profit of CHF 12 thousand which is recognized as other gains in the statement of comprehensive income. The decrease is due to depreciation expense recognized for the six-month period.

8 Intangible assets

There were no additions or disposals to intangible assets. The decrease is due to amortization expense recognized for the six-month period.

9 Financial assets

Financial assets mainly consist of deposits related to office leases.

10 Other current assets

In thousands of CHF	As of June 30, 2021	As of January 1, 2021
VAT receivables	169	166
Prepaid expenses	42	76
Accrued revenue (i)	640	13
Other current receivables	–	87
Total	**851**	**342**

(i) The increase in accrued revenue is mainly due to accrued licensing revenue.

Other current assets are neither impaired nor overdue.

11 Cash and cash equivalents

In thousands of CHF	As of June 30, 2021	As of January 1, 2021
Bank deposits in CHF	1,747	3,481
Bank deposits in EUR	1,652	1,602
Bank deposits in USD	2,302	1,289
Cash on hand	9	9
Total	**5,710**	**6,381**

12 Share capital

	Number of issued and outstanding shares 2021	Nominal value of share capital (in thousands of CHF) 2021
Balance at beginning of the period	616,596	617
Exercise of share options	24,000	24
Balance at end of the period	**640,596**	**641**

12.1 Issued share capital

As of June 30, 2021, the issued share capital amounted to CHF 641 thousand, consisting of 640’ 596 ordinary shares (fully paid registered shares) with a nominal value of CHF 1.00 per share. All of these shares have the same voting rights.

Since January 1, 2021, the issued share capital has been increased as follows:

Issuance of 24’ 000 shares with a nominal value of CHF 1.00 per share through exercise of share options at an average exercise price of CHF 18.67 resulting in an increase of nominal share capital of CHF 24 thousand and an increase in capital contribution reserve of CHF 424 thousand.

12.2 Authorized share capital

As of June 30, 2021, there was no unissued authorized share capital.

12.3 Conditional share capital

As of June 30, 2021, the conditional share capital amounted to CHF 26 thousand, consisting of 26’ 000 ordinary shares with a par value of CHF 1.00 per share to be used for stock options to members of the Board of Directors, employees and consultants.

13 Borrowings

In thousands of CHF	As of June 30, 2021	As of December 31, 2020
Bank loans (i)	4,000	4,000
Covid-19 loans (ii)	1,170	1,262
Total	**5,170**	**5,262**

(i) The Group has a current account limit of CHF 4' 000 thousand which they have fully drawn down. For the entire reporting period the interest rate was fixed at 2.30%. The loan is granted for 12 months with extension option.

(ii) To cover the liquidity needs during the Covid-19 pandemic, the Group requested and obtained government-supported loans of CHF 1' 262 thousand in 2020. For the duration of the Covid-19 loans, the Group may not distribute dividends and may not repay capital contributions. There are also further restrictions regarding the granting and repayment of loans to group companies and owners. These loans were reclassified as current as they were paid back subsequent to the reporting period.

14 Trade payables

Trade payables mainly decreased due to a decrease in payables related to goods and services.

15 Other current liabilities

In thousands of CHF	As of June 30, 2021	As of January 1, 2021
Accruals related to employee benefits (i)	765	3
Accruals related to social security	169	265
Accrued expenses	133	139
Accrued royalty revenue	65	67
Payables due to VAT	–	26
Tax payable (other than income tax)	22	121
Other current payables	–	10
Total	**1,154**	**631**

(i) The increase in accruals related to employee benefits is mainly in relation to unpaid bonuses.

16 Revenue

16.1 Disaggregated revenue information

In thousands of CHF	For the period ended June 30, 2021
Revenue from Licensing - Upfront and milestones (i)	640
Revenue from Licensing - Royalties (i)	1,283
Revenues from Licensing - Product sales (i)	1,327
Revenues from Contract Development	340
Total	**3,590**

(i) Revenue from Licensing includes realized revenue in relation to the various licensing agreements with third parties.

With the exception of the royalty income from the sale of Diclofenac, which is recognized on a net basis as the Company acts as an agent, all the revenue are presented on a gross basis

16.2 Trade receivables

In thousands of CHF	As of June 30, 2021	As of January 1, 2021
Trade receivables	1,468	2,096
Allowance for doubtful debts	(361)	(388)
Total	**1,107**	**1,708**

Trade receivables are non-interest bearing and generally have maturities between 30 and 90 days.

The Group uses a provision matrix to calculate ECLs for trade receivables from third parties. The provision rates are based on days past due of customer invoices. The provision is initially based on the Group' s historical observed default rates. The Group calibrates the matrix to adjust the historical credit losses with forecasts on economic conditions or similar forecast data for the various geographical areas. At each reporting date, the historical observed default rates are updated and changes in the various forecasts are analysed.

17 Goods and service expense

In thousands of CHF	For the period ended June 30, 2021
Third party research and development expense	725
Service expense	52
License expense	16
Expense directly related to goods sold	751
Other goods and service expense	142
Total	**1,686**

18 Personnel expense

In thousands of CHF	For the period ended June 30, 2021
Salary expense	2,388
Social security expense	530
Other personnel expense	14
Total	**2,932**

19 General and administrative expense

In thousands of CHF	For the period ended June 30, 2021
Corporate expense	173
Travel expense	58
Other operating expense	83
Total	**314**

20 Financial income and expense, net

In thousands of CHF	For the period ended June 30, 2021
Write-off of third-party loans	(24)
Interest expense on lease liabilities	(15)
Interest expense on borrowings	(51)
Bank charges	(5)
Total financial expenses	**(95)**
Foreign currency exchange gains	69
Foreign exchange differences, net	**69**
Total	**(26)**

21 Income taxes

21.1 Income tax recognized through profit or loss

In thousands of CHF	For the period ended June 30, 2021
Current tax	
Current tax expense	(43)
	(43)
Deferred tax	
Deferred tax income recognized in the current year	110
	110
Total	**67**

21.2 Income tax recognized in other comprehensive loss

Income tax expense of CHF 167 thousand were recognized in other comprehensive income due to deferred tax assets on net defined benefit obligations.

22 Related party transactions

There were no significant related party balances and transactions as at June 30, 2021, and for the period ended June 30, 2021.

23 Non-cash transactions

During the six-month period 2021, there were no significant non-cash investing and financing activities.

24 Commitments and contingent liabilities

The Company has committed to pay to a third party 50% of the royalties received from a commercialization partner for the sale of Diclofenac in certain territories. The royalty payments are deducted from the corresponding royalty income stream and therefore only the net amount is accounted as revenue in the income statement. As of June 30, 2021, the Company has no unrecognized liabilities or contingent commitments with regards to this arrangement.

As at June 30, 2021, there were no other commitment or contingent liabilities.

25 Events after the reporting period

There were no significant events between June 30, 2021 and the date of approval of these financial statements.

26 Approval of financial statements

These consolidated financial statements were approved by the Board of Directors on December 15, 2021.

Exhibit 23.1

Consent of Independent Public Accounting Firm

We hereby consent to the inclusion in this Registration Statement on Form 20-F (File Number 001-41174) of RELIEF THERAPEUTICS Holding SA of our report dated March 30, 2022, on the consolidated financial statements of RELIEF THERAPEUTICS Holding SA as of December 31, 2021 and 2020 and for the years then ended.

/s/ Mazars SA

Franck Paucod	Yoann Bois
Licensed Audit Expert	Licensed Audit Expert

Geneva
July 1, 2022

Exhibit 23.2

Consent of Independent Public Accounting Firm

We hereby consent to the inclusion in this Registration Statement on Form 20-F (File Number 001-41174) of RELIEF THERAPEUTICS Holding SA of our report dated December 15, 2021, on the consolidated financial statements of APR Applied Pharma Research SA as of January 1, 2020 and December 31, 2020 for the year then ended. Our report on the consolidated financial statements of APR Applied Pharma Research SA includes a "Basis for Qualified Opinion" paragraph to highlight that no comparative financial information is presented.

/s/ Mazars SA

Franck Paucod	Yoann Bois
Licensed Audit Expert	Licensed Audit Expert

Geneva
July 1, 2022