This prospectus (the “Prospectus”) relates to a listing of (i) 35'150'961 registered shares of Spexis AG (formerly Polyphor Ltd) (the “Company” and, together with the Company’s consolidated subsidiaries, the “Group”, “we” or “us”) with a nominal value of CHF 0.02 each (the “Capital Increase Shares”) that were issued out of an ordinary capital increase (the Capital Increase Shares together with the existing shares of the Company, the “Shares”) in connection with the Company's reverse quasi merger with EnBiotix, Inc. (“EnBiotix”), which became a subsidiary of the Company and thus part of the Group (the “Transaction”) on December 29, 2021 and (ii) the formal listing of 10'191'844 registered shares of nominal value of CHF 0.02 (the “Conditional Shares”) that may be issued out of the Company's conditional share capital pursuant to the resolutions of the Company's extraordinary shareholder meeting held on October 28, 2021. At closing of the Transaction, Polyphor has been renamed to Spexis AG and begins trading under the new ticker symbol SPEX on the SIX Swiss Exchange as from the date of this Prospectus.

The respective Capital Increase Shares were issued to the holders of EnBiotix capital stock. Subscription rights of the existing shareholders were excluded. The Capital Increase Shares are fully fungible and rank pari passu in all respects with each other and with all other issued shares of the Company with a nominal value of CHF 0.02 each.

An application has been made to, and approval has been given by, the SIX Swiss Exchange Ltd (the “SIX Swiss Exchange”) to list the Capital Increase Shares and to formally list the Conditional Shares under its International Reporting Standard (the “International Reporting Standard”). The listing of the Capital Increase Shares and the formal listing of the Conditional Shares will become effective, and trading in the Capital Increase Shares on the SIX Swiss Exchange will commence, on January 3, 2022 (the “First Day of Trading”). Shares traded on the SIX Swiss Exchange according to the International Reporting Standard are traded in Swiss Francs and settle and clear through SIX SIS Ltd (the “SIS”).

Investing in Shares involves risks. For a discussion of certain factors that should be considered in connection with an investment in Shares, see Section "Risk Factors" beginning on page 12.

The Shares are not, and will not be, registered under the United States Securities Act of 1933, as amended (the “Securities Act”), or with any securities regulators of any state or other jurisdiction of the United States (the “United States” or the “U.S.”).

The Capital Increase Shares are issued as uncertificated securities (Wertrechte) within the meaning of article 973c CO, and established as intermediated securities (Bucheffekten) within the meaning of the Federal Act on Securities held with an Intermediary (Bucheffektengesetz) of October 3, 2008, as amended (the “FISA”). Since the Capital Increase Shares are issued in the form of uncertificated securities, no share certificates will be issued and no share certificates will be available for individual physical delivery.

This document is a prospectus pursuant to article 35 et seq. of the Federal Act on Financial Services (Finanzdienstleistungsgesetz) of June 15, 2018 (the “FinSA”). This Prospectus may not be used for, or in connection with, and does not constitute, an offer to sell, or a solicitation of an offer to buy, Shares. The distribution of this Prospectus may be restricted by law in certain jurisdictions. Persons in possession of this Prospectus are required to inform themselves of and observe such restrictions. The Company does not accept any responsibility for any violation by any person of any such restrictions.

Prospectus dated January 3, 2022, authorized by SIX Exchange Regulation as review body pursuant to article 52 FinSA on January 3, 2022.
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IMPORTANT INFORMATION ABOUT THE PROSPECTUS

This Prospectus has been prepared solely for use in connection with the listing of the Capital Increase Shares and the formal listing of the Conditional Shares on the SIX. This Prospectus may not be used for, or in connection with, and does not constitute, an offer to sell, or a solicitation of an offer to buy, Shares. The distribution of this Prospectus may be restricted by law in certain jurisdictions. It may not be distributed outside of Switzerland. Persons in possession of this Prospectus are required to inform themselves of and observe such restrictions. The Company does not accept any responsibility for any violation by any person of any such restrictions. Distribution of this Prospectus to any person other than an investor in the Shares, and those persons, if any, retained to advise such investor with respect thereto, is unauthorized. Except as otherwise indicated, this Prospectus speaks as of the date hereof. The delivery of this Prospectus shall, under no circumstances, imply that there has been no change in the affairs of the Company or its subsidiaries or that the information herein is correct as of any date subsequent to the earlier of the date hereof and any earlier specified date with respect to such information.

Each potential investor in Shares should consider the merits and risks involved in making such an investment decision. Investors in Shares are not to construe the contents of this Prospectus as legal, business or tax advice, and they should inform themselves inter alia as to (i) the risk factors described in detail in the Section "Risk Factors" beginning on page 12, (ii) the possible tax consequences, (iii) the legal requirements and (iv) any foreign exchange restrictions or exchange control requirements that they might encounter under the laws of the countries of their citizenship, residence or domicile and that might be relevant to the purchase, holding or disposal of Shares. The Company does not make any representation to any purchaser of the Shares hereby regarding the legality of an investment by such purchaser under appropriate legal investment or similar laws.

The information presented herein was prepared by the Company or obtained from sources deemed reliable by the Company. The Company (i) cannot guarantee the accuracy of such information, (ii) has not assumed any responsibility for independent verification of such information or information otherwise made available in connection with the listing of the Capital Increase Shares or the formal listing of the Conditional Shares or (iii) makes no representations or warranties as to the accuracy or completeness of such information. In making a decision to invest in the Shares, investors must rely on their own evaluation of the Company and the Shares, including the merits and risks involved. Nothing contained herein is, or shall be relied on as, a promise or representation as to the future performance of the Company. Such information necessarily incorporates significant assumptions and estimates as well as factual matters.

No person, other than the officers and directors of the Company, has been authorized to give any information other than that contained in this Prospectus, or to make any representations in connection with the listing of the Capital Increase Shares or the formal listing of the Conditional Shares on the SIX Swiss Exchange, and, if given or made, such other information or representations must not be relied upon as having been authorized by the Company.

Information on the Company's website, any website directly or indirectly linked to the Company's website or any website mentioned in this Prospectus does not constitute in any way part of, and is not incorporated by reference into, this Prospectus except where expressly provided otherwise, and investors should not rely on any such information in making their decision to invest in the Shares.

A. Notice to Prospective Investor in the United States

THE SHARES ARE NOT, AND WILL NOT BE, REGISTERED UNDER THE U.S. SECURITIES ACT, OR WITH ANY SECURITIES REGULATORS OF ANY STATE OR OTHER JURISDICTION OF THE UNITED STATES NOR OF ANY OTHER JURISDICTION, EXCEPT SWITZERLAND. THE SHARES MAY NOT BE OFFERED, SOLD, PLEDGED OR OTHERWISE TRANSFERRED WITHIN THE UNITED STATES OR TO, OR FOR THE ACCOUNT OR BENEFIT OF, U.S. PERSONS EXCEPT PURSUANT TO AN EXEMPTION FROM OR TRANSACTION NOT SUBJECT TO, REGISTRATION UNDER THE U.S. SECURITIES ACT, IN EACH CASE IN ACCORDANCE WITH ANY APPLICABLE SECURITIES LAWS OF ANY STATE OR OTHER JURISDICTION OF THE UNITED STATES.

THE SHARES HAVE NOT BEEN APPROVED OR DISAPPROVED BY THE U.S. SECURITIES AND EXCHANGE COMMISSION OR ANY STATE SECURITIES COMMISSION IN THE UNITED STATES OR ANY OTHER U.S. REGULATORY AUTHORITY, NOR HAVE ANY OF THE FOREGOING AUTHORITIES PASSED UPON OR ENDORSED THE MERITS OF THE TRANSACTION OR THE CAPITAL INCREASE OR THE ACCURACY OR ADEQUACY OF THIS PROSPECTUS. ANY REPRESENTATION TO THE CONTRARY MAY BE A CRIMINAL OFFENCE IN THE UNITED STATES.
THE SHARES ARE SUBJECT TO RESTRICTIONS ON TRANSFERABILITY AND RESALE AND MAY NOT BE TRANSFERRED OR RESOLD EXCEPT AS PERMITTED UNDER THE SECURITIES ACT AND THE APPLICABLE SECURITIES LAWS OF ANY OTHER JURISDICTION. PROSPECTIVE PURCHASERS SHOULD BE AWARE THAT THEY MAY BE REQUIRED TO BEAR THE FINANCIAL RISKS OF THIS INVESTMENT FOR AN INDEFINITE PERIOD OF TIME.

EACH INVESTOR WILL BE DEEMED TO HAVE ACKNOWLEDGED, REPRESENTED AND WARRANTED THAT IT UNDERSTAND AND AGREES TO THE FOREGOING.

B. Notice to European Economic Area investors

In relation to each Member State of the European Economic Area (each, a “Relevant State”), no Shares have been offered or will be offered to the public in that Relevant State prior to the publication of a prospectus in relation to the Shares which has been approved by the competent authority in that Relevant State or, where appropriate, approved in another Member State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of Shares may be made to the public in that Relevant State under the following exemptions under Regulation EU 2017/1129 of the European Parliament and the Council (“EU Prospectus Regulation”):

(i) to any legal entity that is a qualified investor as defined in the EU Prospectus Regulation;

(ii) to fewer than 150 natural or legal persons (other than qualified investors as defined in the EU Prospectus Regulation), subject to obtaining the prior consent of the Company; or

(iii) in any other circumstances falling within article 1(4) of the EU Prospectus Regulation,

provided that no such offer of Shares shall require the Company to publish a prospectus pursuant to article 3 of the EU Prospectus Regulation or supplement a prospectus pursuant to article 23 of the EU Prospectus Regulation.

For the purposes of this provision, the expression an “offer to the public” in relation to any Shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and the Shares to be offered so as to enable an investor to decide to purchase or subscribe the Shares.

C. Notice to United Kingdom investors

No Shares have been offered or will be offered to the public in the United Kingdom prior to the publication of a prospectus in relation to the Shares which has been approved by the Financial Conduct Authority, except that the Shares may be offered to the public in the United Kingdom:

(i) to any legal entity that is a qualified investor as defined under article 2 of the EU Regulation 2017/1129 as it forms part of the United Kingdom domestic law by virtue of the European Union (Withdrawal) Act 2018 (the “UK Prospectus Regulation”);

(ii) to fewer than 150 natural or legal persons (other than qualified investors as defined in the UK Prospectus Regulation), subject to obtaining the prior consent of the Company; or

(iii) in any other circumstances falling within Section 86 of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005, as amended (“Order”),

provided that no such offer of Shares shall require the Company to publish a prospectus pursuant to section 86 of the Financial Services and Markets Act 2000 (“FSMA”) or a supplement prospectus pursuant to article 23 of the UK Prospectus Regulation. For the purposes of this provision, the expression an “offer to the public” in relation to any Shares in the United Kingdom means the communication in any form and by any means of sufficient information on the terms of the offer and the Shares to be offered so as to enable an investor to decide to purchase or subscribe the Shares.

In addition, this Prospectus is only directed at (a) persons who are outside the United Kingdom, or (b) persons within the United Kingdom to whom it would be lawful to direct this Prospectus (such as “investment professionals” as such term is defined in article 19(5) of the Order) (“Relevant Persons”). This Prospectus and any of its contents are directed solely at Relevant Persons and must not be acted or relied on by any person who is not a Relevant Person.
Any investment or investment activity to which this Prospectus relates is available only to Relevant Persons and dealings hereunder will be made only with Relevant Persons. Persons who are not investment professionals within the meaning of article 19 of the FPO should not rely on this Prospectus. As used herein, “United Kingdom” means the United Kingdom of Great Britain and Northern Ireland.

D. Notice to Prospective Investors in Other Jurisdictions

Applicable laws may restrict an offer of the Shares or distribution of this Prospectus in certain other jurisdictions. No action has been taken by the Company that would permit any of the Shares or possession or distribution of this Prospectus or any other publicity material or documentation recording an entitlement of the Shares in any jurisdiction where action for that purpose is required. Persons into whose possession this Prospectus comes must inform themselves about and observe any such restrictions. Any failure to comply with these restrictions may constitute a violation of the laws of such jurisdiction.

AVAILABILITY OF DOCUMENTS

Copies of this Prospectus and any supplement hereto are available free of charge at Spexis AG (formerly Polyphor), Hegenheimermattweg 125, CH-4123 Allschwil, Switzerland (telephone number: +41 (0)61 567 16 00, facsimile: +41 (0)61 567 16 01 or email: IR@polyphor.com), during regular business hours. Copies of the Company’s articles of association and financial statements can be downloaded from its website at http://www.polyphor.com as from the date of this Prospectus.

INDUSTRY AND MARKET DATA

Information contained in this Prospectus relating to markets, market sizes and growth potential prevalence of diseases, historical sales, third-party’s product candidates, anticipated sales of the Company or its subsidiaries or third-party’s product candidates and clinical development of competitors’ product candidates and other statistical information was derived either directly from the public domain, in particular academic journals and publications by industry research companies, or from estimates made by the Company based on publicly available data.

It should be noted that, in particular, information in this Prospectus concerning the market opportunities were obtained from third parties. The Company has accurately reproduced such information in the Prospectus and, as far as it is aware and able to ascertain from information set forth in the commissioned market study, no facts have been omitted that would render the reproduced information inaccurate or misleading. Nevertheless, prospective investors are advised to consider such data with caution. For example, market studies are often based on information or assumptions that may be inaccurate or inappropriate, and their methodology is inherently predictive and speculative.

The Company has not independently verified any third-party data and cannot assure prospective investors of the accuracy or completeness of, and takes no responsibility for, such data. While the Company believes the estimates of academic journals and publications by industry research companies from which such data was derived to be reasonable, it cannot assure prospective investors as to their accuracy or that another third-party using different methods to assemble, analyse or compute market sizes, growth potential, prevalence of diseases and historical and anticipated sales of third party’s product candidates would obtain the same result. The Company does not intend, and does not assume any obligation, to update industry or market data set forth in this Prospectus, except as required by law. Finally, behaviour, preferences and trends in the marketplace may change. As a result, prospective investors should be aware that data in this Prospectus and estimates based on that data may be unreliable indicators of future results.

FORWARD-LOOKING STATEMENTS

This Prospectus contains statements that are, or may be deemed to be, forward-looking statements. In some cases, these forward-looking statements can be identified by the use of forward-looking terminology or subjective assessments, including the words “aims”, “believes”, “estimates”, “anticipates”, “expects”, “targets”, “intends”, “may”, “will”, “plans”, “continue”, “projects”, “predicts”, “assumes”, “could” or “should” or, in each case, their negative or other variations or comparable terminology or by discussions of strategies, plans, objectives, targets, goals, future events or intentions. These forward-looking statements include matters that are not historical facts or that may not otherwise be provable by reference to past events, and are based on assumptions regarding the Company’s present and future business strategies and the environment in which it operates and will operate in the future. They include statements regarding the Company’s intentions, beliefs or current expectations. By their nature, forward-looking statements involve known and unknown risks and uncertainties because they relate to events and/or depend on circumstances that may or may not occur in the future.
Forward-looking statements are not guarantees of future performance and may prove to be erroneous or unfounded in the future. Prospective investors should not place undue reliance on these forward-looking statements. The risks and uncertainties facing the Company that could affect the future accuracy of these forward-looking statements include, but are not limited to, the factors discussed under “Risk Factors” beginning on page 12 and elsewhere.

The risks described under “Risk Factors” are not exhaustive. Other sections of this Prospectus describe additional factors that may adversely affect the Company’s results of operations, financial condition, liquidity, dividend policy and the development of the markets in which it operates. The Company urges prospective investors to read the sections of this Prospectus titled “Risk Factors”, “Business Activities and Prospects” and “Legal and Regulatory Environment” beginning on pages 12, 53, and 68 respectively, for a more complete discussion of the factors that could affect its future performance and the industry in which it operates.

Any forward-looking statements are only made as of the date of this Prospectus and the Company does not intend, and does not assume any obligation, to update any forward-looking statements contained in this Prospectus, except as required by Swiss law or applicable stock exchange regulations. New risks may emerge from time to time, and it is not possible for the Company to predict all such risks, nor can it assess the impact of all such risks on its business or the extent to which any risks, or combination of risks and other factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, prospective investors should not rely on forward-looking statements as a prediction of actual performance or results.

FINANCIAL AND OTHER INFORMATION INCORPORATED BY REFERENCE

The following documents, which have previously been published, are hereby incorporated into, and form a part of, this Prospectus:

- audited consolidated and statutory financial statements the Company as at and for the fiscal year ended December 31, 2018;
- audited consolidated and statutory financial statements the Company as at and for the fiscal year ended December 31, 2019;
- audited consolidated and statutory financial statements the Company as at and for the fiscal year ended December 31, 2020 (together with the audited consolidated financial statements of the Company for the fiscal years 2018 and 2019, the "Annual Consolidated Financial Statements");
- unaudited condensed consolidated financial statements of the Company as at and for the half-year ended June 30, 2020;
- unaudited condensed consolidated financial statements of the Company as at and for the half-year ended June 30, 2021.

Copies of documents incorporated by reference into this Prospectus can be obtained, free of charge, from the registered office of the Company and are also available on the Company's website at www.polyphor.com.

The Annual Consolidated Financial Statements are presented in Swiss Francs and have been prepared in accordance with International Financial Reporting Standards as issued by the International Accounting Standards Board ("IFRS"). For a further description of the Company’s accounting policies, see Note 2 to the Annual Consolidated Financial Statements.

The statutory annual financial statements are presented in Swiss Francs and have been prepared in accordance with the provisions governing the preparation of financial statements of Swiss law.

The Annual Consolidated Financial Statements have been audited by Ernst & Young AG, in Basel, ("EY"), in accordance with Swiss Auditing Standards and International Standards on Auditing, and the statutory financial statements have been audited by EY in accordance with Swiss law and Swiss Auditing Standards, as stated in their reports thereon.

The interim condensed consolidated financial statements (interim condensed consolidated statement of financial position, interim condensed consolidated income statement, interim condensed consolidated statement of comprehensive income, interim condensed consolidated statement of cash flows, interim condensed consolidated statements of changes in shareholders’ equity and notes to the interim condensed consolidated financial statements) have been prepared in in accordance with International Financial Reporting Standard IAS 34 “Interim Financial Reporting” and have been reviewed by our auditors EY in accordance with International Standard on Review Engagements 2410 “Review of Interim Financial Information Performed by the Independent Auditor of the Entity”. A review of interim financial information consists of
making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and consequently does not enable the auditor to obtain assurance that such auditor would become aware of all significant matters that might be identified in an audit.

Certain figures contained in this Prospectus, including financial information, have been subject to rounding adjustments. Accordingly, in certain instances, the amounts shown as totals in tables or elsewhere may not conform exactly to the arithmetic total figures that precede them. In addition, certain percentages in the Prospectus reflect calculations based upon the underlying information prior to rounding and, accordingly, may not conform exactly to the percentages that would be derived if the relevant calculations were based upon the rounded numbers.

Historical financial information relating to the Company’s results, financial position and cash flows presented in this Prospectus, unless stated otherwise, has been extracted or derived from the Annual Consolidated Financial Statements.

Investors should be aware that the accounting requirements of IFRS and the Swiss Code of Obligations (CO) differ in certain respects from each other and from generally accepted accounting principles in certain other countries. Therefore, the financial information contained herein that is prepared in accordance with either IFRS or the CO is not comparable with each other or such other generally accepted accounting principles. In addition, investors should be aware that the future financial performance of the Company may vary substantially from its historic financial performance.

AMENDMENTS

Any notices containing or announcing amendments or changes to this Prospectus will be announced through the electronic media. Notices required under the Listing Rules will be published in electronic form on the website of the SIX Swiss Exchange (currently: https://www.six-group.com/de/products-services/the-swiss-stock-exchange/market-data/news-tools/official-notices.html#/) in the form of an official notice. Changes so notified will be deemed to constitute an amendment or supplement of this Prospectus.

APPLICABLE LAW & JURISDICTION

This Prospectus is governed by Swiss law. Any disputes arising under or in connection with this Prospectus shall be settled by the competent courts at the domicile of the Company in Switzerland.
1. SUMMARY

The following summary is intended to be an introduction to the Prospectus. It is not complete and must be read together with the more detailed information set out elsewhere in this Prospectus, in particular the section “Business Activities and Prospects” beginning on page 53, and the section “Risk Factors” beginning on page 12. Any investment decision should be based on the Prospectus in its entirety and not only on this summary. A liability for statements made in this summary is limited to cases in which the information contained herein is misleading, inaccurate or inconsistent when read together with the other parts of the Prospectus.

A. Portfolio and Pipeline - Overview

Spexis is a research-driven clinical-stage biopharmaceutical company based in Allschwil, Switzerland with a strategic focus on rare diseases and oncology. As from completion of the Transaction, Polyphor and EnBiotix, a privately held late clinical-stage rare disease company currently focused on products for rare, chronic respiratory diseases, merged, whereby Polyphor acquired substantially all of the outstanding capital stock of EnBiotix in exchange for shares of Polyphor common stock. Therefore the portfolio and pipeline of the combined company going forward will be a combination of the two legacy companies, Polyphor and EnBiotix, and Polyphor has been renamed to Spexis AG and begins trading under the new ticker symbol "SPEX" on the SIX Swiss Exchange as from the date of this Prospectus.

The Company's pipeline includes:

- ColiFin® which EnBiotix has in-licensed from PARI Pharma GmbH, a global leader in nebulized therapies, for worldwide rights ex-Europe. Approved in Europe since 2010 as a front-line therapy for lung infections in cystic fibrosis ("CF"), ColiFin® has a proven safety, efficacy and commercial track record which the Company will leverage towards the U.S. and global markets - and both within and outside the field of CF.

- Inhaled murepavadin, a novel class inhaled antibiotic specifically targeting Pseudomonas aeruginosa ("PA"), is being developed for the treatment of PA infection in people with CF and is beginning Phase 1 development using eFlow® Technology nebulizer (PARI Pharma GmbH).

- EBX-002, a combination of amikacin (AMK) and a potentiator molecule for NTM infections which preclinical studies to date have shown potential for superior activity compared to ARYKACE®.

- Balixafortide, a potent and highly selective blocker of CXCR4. Following the closure of its Phase 3 program in advanced breast cancer, additional oncology and non-oncology indications for balixafortide will be evaluated in collaboration with Fosun Pharma who owns China rights.

- New CXCR4 inhibitor program focused on orphan, hematological malignancies.

- Preclinical OMPTA BamA and LptA programs funded by CARBX targeting WHO Priority 1 bacterial infections planned to be developed for hospital acquired bacterial infections.

- Company aims to in-license or acquire other rare disease and oncology assets that will consolidate its position in these therapeutic areas.

B. Timetable of principal events

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<td>Capital Increase Resolution</td>
<td>December 29, 2021</td>
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<tr>
<td>Registration of Capital Increase Shares in the commercial register</td>
<td>December 30, 2021</td>
</tr>
<tr>
<td>First Day of Trading of Capital Increase Shares</td>
<td>January 3, 2022</td>
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<tr>
<td>Change of SIX Ticker Symbol to &quot;SPEX&quot;</td>
<td>January 3, 2022</td>
</tr>
</tbody>
</table>

C. Summary of the Transaction

Issuer Name ......................... Spexis AG (formerly Polyphor Ltd)
Registered Office ..................... Hegenheimermattweg 125, CH-4123 Allschwil
Legal Form: Stock corporation

SIX Ticker Symbol: SPEX (formerly POLN)

Swiss Security Number (Valorennummer): 10.621.379

International Security Identification Number (ISIN): CH0106213793

Capital Increase Shares: Based on the resolution of the extraordinary general meeting of the shareholders dated October 28, 2021, up to 39'462'967 newly-issued registered shares of the Company with a nominal value of CHF 0.02 each have been issued to holders of EnBiotix capital stock under exclusion of the subscription rights of the existing shareholders. The Capital Increase Shares were issued out of an ordinary capital increase and rank pari passu in all respects with each other and with all other Shares. On December 29, 2021 the Board executed the capital increase, along with the relevant amendments to the Articles (Feststellungs- und Statutenänderungsbeschluss) (the "Capital Increase"). The Swiss federal issuance stamp duty (Emissionsabgabe) on the issuance of the Capital Increase Shares will be borne by the Company.

Number of Shares before the Transaction as per December 20, 2021: 12'367'491 Shares (of which 11'224'816 already recorded in the commercial register).

Number of Shares after completion of the Transaction: Upon completion of the Transaction, the share capital of the Company consists of 47'531'938 Shares (of which 46'375'777 have already been recorded in the commercial register).

Treasury Shares: As of the date of this Prospectus, the Company neither directly nor indirectly holds any treasury Shares.

Listing and Trading: An application has been made to, and approval has been given by, the SIX Swiss Exchange to list the Capital Increase Shares (and the Conditional Shares) under the International Reporting Standard of the SIX Swiss Exchange. The listing of the Capital Increase Shares (and the Conditional Shares) becomes effective, and trading in the Capital Increase Shares under the International Reporting Standard of the SIX Swiss Exchange commences, on January 3, 2022.

Dividends and Dividend Policy: All Capital Increase Shares are in principle entitled to dividends, if any, for the fiscal year 2021. The Capital Increase Shares carry the same entitlement to dividends and surplus arising from a liquidation, if any, as the existing Shares of the Company. For further details, see “Dividends and Other Distributions” beginning on page 147.

Voting Rights: Each Share carries one vote. See “Capital Structure and Shares” beginning on page 84.

Form of Capital Increase Shares: The Capital Increase Shares are issued as uncertificated securities (Wertrechte) within the meaning of article 973c of the CO and will be established as intermediated securities (Bucheffekten) within the meaning of the FISA. The Capital Increase Shares are registered in the main register (Hauptregister) maintained by SIS and will be credited to the securities account of each purchaser, and thus will become intermediated securities (Bucheffekten) within the meaning of the FISA.

Use of Proceeds: The Company received only shares of EnBiotix in the Transaction.
Transfer Restrictions

The Shares are subject to certain transfer restrictions as described in “Transfer of Shares and transfer restrictions” beginning on page 89.

Risk factors

Any investment in the Company are subject to a number of risks, which may adversely affect our business, operations, or financial position. These include but are not limited to the following:

- We have never been profitable and may never become so. We currently have no products approved for sale.
- We will require substantial additional financing for the further development of our product candidates, which may not be available on acceptable terms or at all.
- Preclinical and clinical drug development involves a lengthy and expensive process, with an uncertain outcome.
- Clinical trials may be subject to delays or disruptions and may not have the expected outcome.
- The required regulatory approval for the sale of our product candidates may not occur, or may be limited in a way that restricts the uptake of any approved products in the market.
- If our products are approved, the price we may be able to charge may be lower than we estimated.
- The market for our products may be smaller than anticipated.
- Cost-containment measures in pharmaceutical markets may impair our ability to operate profitably.
- Competitors may develop products superior to our own.
- Global economic conditions could adversely affect us or our suppliers.
- Legal proceedings could limit our ability to operate our business, harm our brands or reputation or lead to restrictions, fines and other damages.
- Manufacturing our product candidates is complex, time consuming and expensive.
- We are dependent on third party suppliers for the production of our product candidates and the conduct of preclinical studies and clinical trials, generally without backup being readily available. We may be adversely affected by their failure to deliver.
- We may face claims from third parties of intellectual property infringement or misappropriation which may prevent or delay the commercialization of our products and/or lead to significant costs and damages claims.
- We may not be able to enforce our intellectual property rights against third parties and our intellectual property rights may be attacked by third parties.
- We may be unable to attract and retain key personnel and skilled employees.
- The integration of EnBiotix may consume more resources than we had envisaged and may be subject to impediments or delays.
- A significant portion of our operations are currently conducted at a single location that may be at risk from fire, earthquakes or other natural disasters.
- A pandemic, epidemic, or outbreak of an infectious disease, such as COVID-19, may materially and adversely affect us and could cause a disruption to the development of our product candidates.
- Significant disruptions in our information technology systems could occur.

The Company urges prospective investors to read the sections of this Prospectus titled “Risk Factors”, “Business Activities and Prospects”, and “Legal and Regulatory Environment” beginning on pages 12, 53, and 68 respectively, for a more complete list and discussion of the factors that could affect its future performance and the industry in which it operates.
Tax

The acquisition, disposal, holding or ownership of Shares may lead to tax consequences, including but not limited to:

- Swiss federal, cantonal and communal individual income tax or corporate income tax;
- Swiss cantonal and communal private wealth tax and capital tax;
- Swiss federal withholding tax;
- Swiss federal stamp taxes;
- Other Swiss taxes on capital gains;
- Gift and inheritance taxes; and
- US tax consequences.

The Company urges prospective investors to read the sections of this Prospectus titled “Tax Considerations” beginning on page 152 and to consult their tax advisor with regard to the tax consequences of investing in Shares.

Listing Agent................................. VISCHER AG

Law/Jurisdiction.............................. Swiss law/Zurich, Switzerland

Notification/Amendments or Changes ..........................................

Any notices containing or announcing amendments or changes to this Prospectus will be announced through the electronic media. Notices required under the Listing Rules will be published in electronic form on the website of the SIX Swiss Exchange (currently: https://www.six-group.com/de/products-services/the-swiss-stock-exchange/market-data/news-tools/official-notices.html#/) in the form of an official notice. Changes so notified will be deemed to constitute an amendment or supplement of this Prospectus.

Prospectus Date & Authorization

Prospectus dated January 3, 2022, authorized by SIX Echange Regulation as review body pursuant to article 52 FinSA on January 3, 2022.
2. INFORMATION ON THE ISSUER

2.1 RISK FACTORS

Any investment in the Company are subject to a number of risks. Accordingly, prospective investors should carefully consider the risks and uncertainties described below, together with all other information contained in this Prospectus, prior to making an investment decision.

The risks and uncertainties described below represent those we consider to be material as of the date of this Prospectus. However, these risks and uncertainties are not the only ones we are facing. Additional risks and uncertainties not presently known to us, or that we currently consider not to be significant, could also materially and adversely affect our business, financial condition, results of operations and/or prospects. If any or a combination of these risks actually occurs, our business, financial condition, results of operations, and/or prospects could be materially and adversely affected. In such case or cases, the price of the Shares could decline and prospective investors may lose all or part of their investment. This Prospectus contains forward-looking statements that involve risks and uncertainties. The actual results could differ materially from those anticipated in such forward-looking statements as a result of certain factors, including the risks we face that are described below or elsewhere in this Prospectus. The selected sequence of the risk factors mentioned below represents neither a statement about the probability of the risks’ realisation nor an assessment of the extent of the economic effects or the importance of the risks.

Investment decisions should not be made solely on the basis of the risk warnings set out in the Prospectus since such information cannot serve as a substitute for individual advice and information that is tailored to the requirements, objectives, experience, knowledge and circumstances of each prospective investor individually. Therefore, before entering into any transaction, each prospective investor should consult with its own legal, regulatory, tax, financial and accounting advisors to the extent it considers necessary in order to determine whether an investment in the Shares is a fit, proper and suitable investment for it with a view to its financial situation, its constitutional documents, its internal policies and guidelines, the laws and regulations applicable to it and the impact an investment in the Shares will have on its overall investment portfolio.

Only prospective investors who are fully aware of the risks associated with an investment in the Shares and who are financially able to bear any losses that may arise should consider investing in the Shares.

Capitalised terms used but not defined herein have the meanings ascribed to them elsewhere in this Prospectus.

A. Risks relating to our business

We have incurred net operating losses during most fiscal periods since our inception and anticipate that we will continue to incur substantial operating losses for the foreseeable future. We may never become profitable.

We were founded in 1996. We have not yet begun to generate revenues from the commercialization of any of our product candidates. Accordingly, except for 2013, we have experienced operating losses in each of the financial years since our inception, resulting principally from costs incurred in research and development of our product candidates and general and administrative expenses. In the financial years ended December 31, 2018, 2019 and 2020 we had a net loss of CHF 50’920 thousand, CHF 64’671 thousand, and CHF 44’949 thousand respectively.

We expect to incur significant operating losses in the foreseeable future, primarily due to the costs of our research and development programs, including preclinical studies and clinical trials. The amount of future losses is uncertain as well as when, if ever, we will achieve profitability. Our expenses have increased substantially during the Phase 3 clinical development of balixafortide (POL6326). While this study is currently being closed, our expenses are expected to be substantial as we plan to initiate the Phase 3 clinical development of ColiFin® in 2022. Our ability to achieve profitability will depend on, among other things, successfully completing the development of our product candidates, obtaining regulatory approvals, establishing manufacturing, sales and marketing organizations and/or successful out-licensing of our products in part or in total, market acceptance of our products, arrangements with third parties and raising sufficient funds to finance our activities. No assurance can be given that our product development efforts will be successful, that required regulatory approvals will be obtained, that any of our product candidates will be manufactured at a competitive cost and will be of acceptable quality, that they will be reimbursed from third-party payers, or that we will be able to achieve profitability, or that profitability, if achieved, can be sustained. Our half-yearly and annual operating results may fluctuate significantly in the future due to a variety of factors, many of which are outside of our control and may be difficult to
predict, including the changing and volatile U.S. and global economic environments, including as a result of the COVID-19 pandemic.

**We do not have any products approved for sale. We have never generated any revenue from product sales, and our ability to generate revenue from product sales and become profitable will depend significantly on our success in achieving a number of goals and on other factors.**

We have no products approved for commercial sale, have not generated any revenue from product sales, and do not anticipate generating any revenue from product sales until after we have received marketing approval for the commercial sale of a product candidate, which we expect will not occur for at least the next several years, if ever. We are concentrating our research and development efforts on the successful development of ColiFin® for worldwide territories ex-Europe, which is our most advanced product candidate. Therefore, we depend heavily on the successful clinical development, obtaining regulatory approval, reimbursement and eventual commercialization of ColiFin®. There can be no assurance that we will not face unforeseen difficulties or delays in our efforts to directly or indirectly develop ColiFin® or that the respective development efforts will be successful, and that as a result our business, financial condition and results of operations will not be materially adversely affected.

Our ability to generate revenue and achieve profitability depends significantly on our success in achieving a number of goals, including:

- completing clinical studies that demonstrate the efficacy and safety of ColiFin® and future product candidates;
- receiving marketing authorizations from applicable regulatory authorities for ColiFin® worldwide in territories excluding Europe and future product candidates;
- achieving and maintaining compliance with all regulatory requirements applicable to ColiFin® or any future product candidates;
- establishing and maintaining commercially viable supply and manufacturing relationships with third parties for ColiFin® and future product candidates;
- if approved, launching and commercializing ColiFin® in worldwide territories outside Europe, and future product candidates for which we obtain marketing approvals, either directly or with a collaborator or distributor;
- if approved, obtaining market acceptance of ColiFin® in worldwide territories outside Europe, and for future product candidates as viable treatment options by patients, the medical community and third-party payors;
- achieving remunerative pricing and acceptance of reimbursement from third-party payors;
- addressing any competing technological and market developments and competing effectively with other therapies, whether with respect to ColiFin® or any of our other product candidates;
- identifying, assessing, acquiring and developing new product candidates;
- a continued acceptable safety profile(s) of ColiFin® and future product candidates following approval;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter;
- qualifying for, obtaining, maintaining, enforcing and defending our portfolio of intellectual property rights and claims, including patents, trade secrets and know-how, and not infringing on third parties’ intellectual property rights; and
- attracting, hiring, and retaining qualified personnel.

Even if ColiFin® or any future product candidates that we develop are approved for commercial sale, we anticipate incurring significant costs associated with commercializing any such product candidate. Our expenses could increase beyond expectations if we are required by the U.S. Food and Drug Administration (“FDA”) or comparable foreign
regulatory authorities to change our manufacturing processes or assays, or to perform clinical, nonclinical, or other types of studies in addition to those that we currently anticipate.

If we are successful in obtaining regulatory approvals to market ColiFin® in worldwide territories outside Europe or any future product candidates, our revenue will be dependent, in part, upon the size of the markets in the territories for which we gain marketing approval, the accepted price for the product, the ability to get reimbursement at any price, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, the labels for ColiFin® and future product candidates contain significant safety warnings, regulatory authorities impose burdensome or restrictive distribution requirements, or the reasonably accepted patient population for treatment is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such products, even if approved. If we are not able to generate revenue from the sale of any approved products, we could be prevented from or significantly delayed in achieving profitability.

We expect that we will require substantial additional financing and capital to fund our business and/or growth, which may not be available on acceptable terms or at all.

The process from the identification of preclinical drug candidates to the commercialization of pharmaceutical products is capital-intensive and requires significant financial resources. We expect our current funding to be sufficient to support the Company as a going concern to ensure the continuation of our operations into Q3 2022, but we depend on further financing to execute our strategy, to register our product candidates and to commercialize them. The availability to us of further funding is necessary for our ability to continue our operations as currently contemplated and the absence of such funding would make it impossible for us to continue all our projects and possibly to continue our business operation as a going concern. Under such circumstances, we would need to divest some of our products and possibly discontinue our business operation.

Our future capital requirements depend on many factors, including:

- the scope, progress, results and cost of researching and developing our product candidates;
- the timing of, and the costs involved in, obtaining regulatory approvals for our product candidates;
- the cost of commercialization activities for our candidates, including marketing, sales and distribution costs;
- our ability to establish and maintain strategic and other partnerships, licensing or other arrangements and the financial terms of such agreements;
- the timing, receipt, and amount of sales of, or royalties on, our future products, if any;
- the costs involved in improving and maintaining our technology;
- the effects of competing technological and market developments;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patent claims, including litigation costs and the outcome of such litigation;
- the potential additional expenses attributable to adjusting our development plans (including any supply related matters) to the COVID-19 pandemic; and
- the costs associated with being a public company.

Our ability to raise additional funds will depend on financial, economic and other factors, many of which are beyond management’s control. There can be no assurance that, when required, sufficient funds will be available to us on satisfactory terms, if at all. If necessary funds are not available, we may have to delay, limit, reduce or terminate our product development efforts or the establishment of late-stage development and commercialization capabilities, production or marketing, which could have a material adverse effect on our business, financial condition, results of operations and prospects.
Raising additional capital may restrict our operations or require us to relinquish rights to our technologies or products on terms unfavourable to us.

We may decide in the future to seek additional capital through a variety of means, including through partnership agreements, private and public equity offerings and debt financings. If we raise additional funds through strategic or other partnerships with third parties, we may have to relinquish valuable rights to our technologies or products, or grant licenses on terms that are not favourable to us. In addition, the terms of any financing may adversely affect the holdings or rights of the shareholders of the Company. The issuance of additional Shares by the Company, or the possibility of such issuance, may cause the market price of the Shares to decline. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take certain actions, such as incurring additional debt, making capital expenditures or declaring dividends. For example: In July 2020 the Company entered into an equity-linked financing arrangement with the French company IRIS to raise a gross amount of up to CHF 19.3 million over the period of two years. IRIS will receive shares to be created from the Company's conditional capital based on this interest-free mandatory convertible bonds program. During the term of the financing, IRIS will convert each month the mandatory convertible bonds into shares at a discount to the applicable volume weighted average price (VWAP). These shares are expected to be sold on the market or in block trades.

If we are unable to raise additional funds through equity or debt financing when needed, we may be required to delay, limit, reduce or terminate our product development or any commercialization efforts for our proprietary product candidates, or grant rights to develop and market products that we would otherwise prefer to develop and market ourselves.

Global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. For example, in 2008, the global financial crisis caused extreme volatility and disruptions in the capital and credit markets and the outbreak of the COVID-19 pandemic has caused significant volatility and uncertainty in U.S. and international markets. A severe or prolonged economic downturn could result in a variety of risks to our business, including, weakened demand for our product candidates and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy could also strain our suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our services. Similarly, a strong economy and limited capacity at suppliers and transport firms could lead to delays in product and equipment deliveries and cause other supply chain disruptions. Any of the foregoing could harm our business and we cannot anticipate all of the ways in which the current economic climate and financial market conditions could adversely impact our business.

Our limited resources require us to prioritize the development of certain product candidates and may require us to alter the development of others, potentially diverting resources away from better opportunities.

In line with our overall strategy to focus on rare diseases and oncology, we currently prioritize the development of our most advanced product candidates ColiFin® and inhaled murepavadin for the treatment of chronic lung infections in Cystic Fibrosis. Our decisions concerning the allocation of research, collaboration, management and financial resources toward particular compounds, product candidates or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from better opportunities and may require us to pursue strategies that do not allow us to realise the full commercial potential of our product candidates or even to alter their development (e.g. if we do not find partners for the co-development). Similarly, any potential decision to delay, terminate or collaborate with third parties in respect of certain product development programs may also prove not to be optimal and could cause us to not realise the full commercial potential of our product candidates. If we make incorrect determinations regarding the market potential of our product candidates or misread trends in the biopharmaceutical industry, our business, financial condition and results of operations could be materially adversely affected.

Preclinical and clinical drug development involves a lengthy and expensive process, with an uncertain outcome. Failure may occur at any stage of preclinical or clinical development and could have a material adverse effect on our prospects.

Before regulatory approval for any potential product can be obtained, we must undertake extensive clinical testing in humans to demonstrate the safety and efficacy of such product. While our lead product candidate, ColiFin®, has been approved in Europe since 2010 as a front-line therapy for lung infections in cystic fibrosis (CF), further clinicals trials are still required to receive other marketing authorizations, which may or may not be granted. Preclinical development and clinical trials are time-consuming, expensive, difficult to design and execute, unpredictable and can be subject to delays. It may take several years to complete the clinical development necessary to commercialize a product candidate, and delays or failure can occur at any stage. Interim results of preclinical studies do not necessarily predict final results and success in
preclinical testing and interim results of early clinical trials do not ensure that later clinical trials will be successful. In connection with preclinical development, we face risks that a product candidate may not prove to be effective or the results may not confirm the positive results of earlier studies.

For example, balixafortide was previously developed in advanced breast cancer in combination with eribulin. Following positive results of preclinical studies, a Phase 1b study was conducted and published in 2017 with around 54 patients suggested dose dependent potential for balixafortide to enhance the anti-tumor efficacy of chemotherapy. In the expanded cohort (n=24) the combination of Balixafortide and eribulin resulted in a response rate of 38%, comparing favorably with published data for eribulin alone in similar patient populations (response rate 12-14%). As a result the Company advanced balixafortide to Phase 3 development in advanced breast cancer in combination with eribulin. FORTRESS (POL6326-009) is an international, multicenter, randomized active-controlled, open-label Phase 3 trial which investigates the efficacy, safety and tolerability of intravenous balixafortide given with eribulin versus eribulin alone in the treatment of HER2 negative, locally recurrent or metastatic breast cancer (MBC) with a total of 432 patients. In June 2021 we announced that the combination of balixafortide (POL6326) and eribulin did not significantly improve objective response rate (ORR) over eribulin alone, missing the co-primary end point of the FORTRESS study. Subsequently in August 2021, the company announced that the primary endpoint of the study progression free survival (PFS) was also not met, with no overall survival (OS) benefit observed between study groups in interim OS analysis. Based on these results, the FORTRESS study is currently being closed. As this study missed its primary endpoint, additional oncology and non-oncology indications for balixafortide will be evaluated, both alone and in collaboration with Fosun Pharma who owns China rights. There can be no assurance that we will not face additional unforeseen difficulties or delays in our efforts to directly or indirectly develop balixafortide or that the respective development efforts will be successful, and that as a result our business, financial condition and results of operations will not be materially adversely affected.

We will invest significant efforts and financial resources in the development of ColiFin®, our most advanced product candidate. Our ability to generate product revenue from ColiFin® will depend heavily on the successful completion of development of, receipt of regulatory approval for, and commercialization of, ColiFin® in the U.S. ColiFin® has been approved in select countries in Europe starting in 2010 and marketed by PARI Pharma, from which EnBiotix has licensed its right for worldwide markets excluding Europe. While approximately 15K patients in the European Union have been dosed thus far with ColiFin®, a separate clinical development program is still necessary to obtain regulatory approval and commercialize ColiFin® in target territories outside of Europe. Clinical trials are time consuming, expensive, difficult to design and execute, unpredictable and can be subject to delays and failures. With the introduction of the CFTR modulators for the treatment of cystic fibrosis patients in recent years, design, execution and results of clinical studies necessary for approval in the U.S. might be different compared to the clinical environment which prevailed at the time of ColiFin® approval in Europe by PARI Pharma.

As is the case with many treatments for cancer and rare diseases, it is likely that there may be side effects associated with the use of our product candidates. If significant adverse events or other side effects are observed in any of our current or future clinical trials, we may have difficulty recruiting patients to our clinical trials, patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. Regulatory authorities may suspend or terminate clinical trials of a product candidate at any time for various reasons, including a belief that subjects in such trials are being exposed to unacceptable health risks or adverse side effects.

An unfavourable outcome in one or more of the trials in any one of our programs could be a major set-back for the program and could have a material adverse effect on our business, financial condition and results of operations. Even after regulatory approval a product may later be shown to be unsafe, cause side or reciprocal effects or not to have its purported effects, preventing its widespread use or requiring its withdrawal from the market.

**Delays in the commencement, enrolment or completion of clinical trials of our product candidates could result in increased costs to us as well as a delay or failure in obtaining marketing approval, or prevent us or our partners from commercializing our product candidates on a timely basis, or at all.**

We cannot guarantee that clinical trials will be conducted as planned or completed on schedule, if at all. A failure of one or more clinical trials can occur at any time during the clinical trial process. Events that may prevent successful or timely commencement, enrolment or completion of clinical trials include:

- delays by us or our partners in reaching a consensus with regulatory agencies on trial design;
• delays or failure to reach an agreement on acceptable terms with prospective clinical research organizations (“CROs”) and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and clinical trial sites;

• the delay or refusal of regulators, institutional review boards (“IRBs”) or ethics committees to authorize us or our partners to commence a clinical trial at a prospective clinical trial site;

• delays in recruiting suitable patients to participate in clinical trials and variability in the number and types of patients available for clinical trials;

• factors we may not be able to control, such as current or potential pandemics that may limit patients, principal investigators or staff or clinical site availability (e.g., outbreak of COVID-19);

• the inability to recruit a sufficient number of suitable patients;

• imposition of a clinical hold by regulatory agencies for any reason, including safety concerns or after an inspection of manufacturing facilities or clinical trial sites;

• negative or inconclusive results, which may require us or our partners to conduct additional preclinical or clinical trials or to abandon projects that we had expected to be promising;

• safety or tolerability concerns could cause us or our partners to suspend or terminate a clinical trial if we find that the participants are being exposed to unacceptable health risks;

• regulators or IRBs requiring that we, our partners or our or their investigators suspend or terminate clinical trials for various reasons, including, without limitation, noncompliance with regulatory requirements or safety concerns;

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

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

• delays in adding new clinical trial sites;

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

• delays in establishing 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 trials (in particular large-scale clinical trials could be delayed by the possible lack of availability of sufficient quantities of a given compound);

• exceeding budgeted costs due to difficulty in accurately predicting costs associated with clinical trials;

• obtaining, maintaining or enforcing our patents or other intellectual property rights; and

• our product candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs or ethics committees to suspend or terminate the trials, or reports may arise from preclinical or clinical testing of other cancer therapies that raise safety or efficacy concerns about our product candidates.

Moreover, we rely on third parties for assistance in overseeing and monitoring clinical trials, which may also result in delays or failure to complete trials if such third parties fail to perform their contractual obligations or to meet regulatory standards. In addition, data obtained from clinical trials and studies are susceptible to varying interpretations, and regulators may not interpret our data as favourably as we do, which may delay, limit or prevent regulatory approval.
There can be no assurance that any clinical testing will be completed successfully within any specified period or without significant additional expense, or at all. If we are not able to successfully complete clinical trials, we will not be able to obtain marketing approval and will not be able to commercialize our product candidates.

Further, as a result of the COVID-19 pandemic, the extent and length of which is uncertain, we may be required to develop and implement additional clinical trial policies and procedures designed to help protect subjects from the COVID-19 virus, which may include using telemedicine visits, remote monitoring of subjects and clinical sites and measures to ensure that data from clinical trials that may be disrupted as a result of the pandemic are collected. Subjects who may miss scheduled appointments, any interruption in study drug supply, or other consequences that may result in incomplete data being generated during a clinical trial as a result of the pandemic must be adequately documented and justified. For example, in March 2020 (updated in August 2021), the FDA issued guidance on conducting clinical trials during the pandemic, which describe a number of considerations for sponsors of clinical trials impacted by the pandemic, including the requirement to include in the clinical trial report contingency measures implemented to manage any disruption of the trial as a result of the COVID-19 pandemic, a list of all subjects affected by the COVID-19-pandemic related study disruption by unique subject identifier and by investigational site and a description of how the individual’s participation was altered, and analyses and corresponding discussions that address the impact of implemented contingency measures (e.g., participant discontinuation from investigational product and/or study, alternative procedures used to collect critical safety and/or efficacy data) on the safety and efficacy results reported for the trial.

If we experience delays or difficulties in the enrolment of patients in, or commencement of, clinical trials, our research and development efforts and receipt of necessary regulatory approvals could be significantly delayed or prevented.

Initiation and successful and timely completion of clinical trials will require us to enroll a sufficient number of eligible patients to participate in these trials as required by the FDA, EMA or comparable regulatory authorities in other relevant jurisdictions. Any delay or difficulty in enrolment of patients could significantly delay or otherwise hinder our research and development efforts and/or delay or prevent receipt of necessary regulatory approvals.

Patient enrolment may be affected by factors including:

- inability or delay in enrolment of patients due to a variety of reasons, including outbreaks and public health crises, such as the COVID-19 pandemic;
- the severity of the disease under investigation;
- the eligibility criteria for the study in question, including any misjudgement of, and resultant adjustment to, the appropriate ranges applicable to the exclusion and inclusion criteria;
- the perceived risks and benefits of the product candidate under study;
- the ongoing recruitment of other clinical trials sponsored by competitors that are seeking to enrol patients with similar eligibility criteria;
- the efforts to facilitate timely enrolment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

In addition to the competitive trial environment, the eligibility criteria of our planned clinical trials will further limit the pool of available study participants as we will require that patients have specific characteristics that we can measure. Additionally, the process of finding patients may prove costly. We also may not be able to identify, recruit and enroll a sufficient number of patients to complete our clinical studies because of the perceived risks and benefits of the product candidates under study, the availability and efficacy of competing therapies and clinical trials, the proximity and availability of clinical trial sites for prospective patients, and the patient referral practices of physicians. If patients are unwilling to participate in our studies for any reason, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed.
Our inability to enrol a sufficient number of patients for our clinical trials would result in significant delays or might require us to abandon one or more clinical trials altogether. Enrolment delays in our clinical trials may result in increased development costs for our product candidates, slow down or halt our product candidate development and approval process and jeopardize our ability to seek and obtain the marketing approval required to commence product sales and generate revenue, which would cause the value of the Company to decline and limit our ability to obtain additional financing if needed.

We may develop product candidates for use in combination with other therapies, which exposes us to additional risks.

We may develop product candidates for use in combination with one or more currently approved therapies. Even if a product candidate was to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to bear the risks that the regulatory authorities could revoke approval of the therapy used in combination with such product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially.

If regulatory authorities do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with a product candidate, we may be unable to obtain approval of or market such product candidate.

Interim, “top-line,” and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose preliminary or top-line data from our preclinical studies and clinical trials, based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, top-line data should be viewed with caution until the final data are available.

From time to time, we may also disclose interim data from our preclinical studies and clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our shares.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If we are not able to obtain, or if there are delays in obtaining, required marketing approvals, we will not be able to commercialize our product candidates, and our ability to generate revenue will be materially impaired.

Our research and development activities, preclinical studies, clinical trials, and the anticipated manufacturing and marketing of our product candidates are subject to extensive regulation by Swissmedic Schweizerisches Heilmittelinstitut, Swiss Agency for Therapeutic Products, United States Food and Drug Administration (“FDA”), the European Medicines Agency (“EMA”) and other government agencies in the jurisdictions in which we intend to test and market our product candidates. The approval of such government agencies will be required before any commercial sales of our product candidates may commence in the respective jurisdictions. Even if clinical trials have been completed there can be no assurance that we will receive marketing approval from such government agencies. Such marketing approval may be
delayed or may be obtained on restrictive terms, if the product candidate does not show acceptable safety and efficacy in preclinical studies and clinical trials or otherwise does not meet applicable regulatory standards for approval, or if the product candidate does not prove as effective as existing or future products used to treat the same or similar illness or conditions. A failure to obtain regulatory approval or a delay in obtaining these approvals would adversely affect the commercialisation of our product candidates and our ability to generate product revenue, which could have a material adverse effect on our business, financial condition, results of operations and prospects.

The ability of the regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, government shutdowns, including as a result of budget delays or other circumstances like the COVID-19 pandemic and statutory, regulatory and policy changes.

We must also obtain approval from the competent national authority before a clinical trial can begin. Additionally, the clinical trial application requires a favourable opinion from a competent ethics committee or an independent institutional review board. We cannot assure that we will obtain authorization for further testing of product candidates already in clinical trials or for human clinical trials of any or all of our other product candidates currently in research or preclinical development. We or regulatory authorities may suspend or terminate clinical trials at any time if it is thought that the participants are being exposed to unacceptable health risks. It may take us or our collaborators several years to complete this testing, and failure can occur at any stage of the process, resulting in our inability to successfully commercialize a product and therefore adversely affecting our business, financial condition, results of operations and prospects.

A fast track designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

We have obtained U.S. “Fast Track” designation for ColiFin®, and, as part of our business strategy and clinical development approach, we intend to seek such designation also for further current or future product candidates. If a product candidate is intended for the treatment of a serious or life-threatening condition and it demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for FDA “Fast Track” designation. The FDA has broad discretion whether or not to grant this designation. Even if we believe a particular product candidate is eligible for this designation, we cannot assure that the FDA would decide to grant it. Even if we do receive “Fast Track” designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw “Fast Track” designation if it believes that the designation is no longer supported by data from our clinical development program. Many drugs that have received “Fast Track” designation have failed to obtain regulatory approval.

An orphan drug designation and/or qualified infectious disease product (QIDP) designation by the FDA, even if granted for any of our product candidates, may not guarantee regulatory exclusivity and does not increase the likelihood that our product candidates will receive marketing approval.

The FDA has granted ColiFin® both Orphan Drug Designation for treatment of respiratory infections in patients with CF, and Qualified Infectious Disease Product (QIDP) Designation for the treatment of Pseudomonas aeruginosa lung infections in CF patients. As part of our business strategy and clinical development approach, we intend to also seek such designation for further current or future product candidates. The FDA has broad discretion whether or not to grant these designations, and the FDA may also withdraw them under certain circumstances, including if a competing product receives marketing approval. Such designations do not guarantee that ColiFin® will receive regulatory approval.

An orphan drug designation and/or qualified infectious disease product (QIDP) designation by the FDA, even if granted for any of our product candidates, may not guarantee regulatory exclusivity and does not increase the likelihood that our product candidates will receive marketing approval.

For a drug product to be designated as a QIDP, the sponsor is required to demonstrate that the drug is an "antibacterial or antifungal drug for human use intended to treat serious or life-threatening infections". QIDP designation applies to a specific drug product from a specific sponsor for a specific use for which it is being studied. The designation is granted only to the sponsor making the request, and it does not apply to a drug substance in general or beyond the specified indications. Subject to the specified statutory limitations, a drug that is designated as a QIDP and is approved for the use for which the QIDP designation was granted will receive a 5-year extension to any exclusivity for which the application qualifies upon approval. Many drugs that have QIDP designation have failed to obtain regulatory approval.
A breakthrough therapy designation by the FDA, even if granted for any of our product candidates, may not lead to a faster development or regulatory review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

We do not currently have breakthrough therapy designation for any of our product candidates, but as part of our business strategy and clinical development approach, we intend to seek such designation for one or more of our current or future product candidates.

A breakthrough therapy is defined as a product candidate that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor can help to identify the most efficient path for development.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe, after completing early clinical trials, that one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a breakthrough therapy designation for a product candidate may not result in a faster development process, review or approval compared to conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that such product candidates no longer meet the conditions for qualification and rescind such designations.

Obtaining and maintaining regulatory approval of ColiFin® or any future product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of ColiFin® or any future product candidates in other jurisdictions.

Obtaining and maintaining regulatory approval of ColiFin® or any future product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. ColiFin® has been approved in select markets in Europe beginning in 2010. It is currently marketed by PARI Pharma GmbH, which has licensed ColiFin® to EnBiotix for development and commercialization outside of Europe. A separate clinical development program is still necessary to obtain marketing authorization approval by regulatory authorities and commercialize ColiFin® in other territories. Clinical trials are time consuming, expensive, difficult to design and execute, unpredictable and can be subject to delays and failures. The designs, executions and results of the clinical studies might be different versus the ColiFin® clinical program which led to approval of ColiFin® in the EU by PARI Pharma. The approval of ColiFin® by EMA does not guarantee its approval by other regulatory authorities.

Approval procedures vary among jurisdictions and can involve requirements and administrative review periods. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures in other jurisdictions can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets or receive applicable marketing approvals, our target markets will be reduced and our ability to realize the full market potential of ColiFin® or any future product candidates will be harmed.
Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, or approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and other government agencies to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the ability to perform routine functions. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other government agencies may also slow the time necessary for new drugs, medical devices and biologics or modifications to cleared or approved drugs, medical devices and biologics to be reviewed and approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products, and subsequently, on March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities. In addition, on April 16, 2020, the FDA announced that although its New Drug Program was continuing to meet program user fee performance goals, due to many agency staff working on COVID-19 activities it was possible that the FDA would not be able to sustain its current level of performance. While some activities have been able to resume, the FDA acknowledged in its resiliency roadmap issued in May 2021 that even in a best case scenario the number of inspections in 2021 will be well below the usual rate, leading to a growing backlog. Regulatory authorities outside the United States have adopted similar restrictions or other policy measures in response to the COVID-19 pandemic and thus face similar difficulties. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Any product candidate for which we obtain marketing approval will be subject to extensive post-marketing regulatory requirements and could be subject to post-marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we or our partners experience unanticipated problems with our products, when and if any of them are approved.

Any products, for which we or our partners receive marketing approval in a particular jurisdiction and the activities associated with their commercialization, including their testing, manufacturing, recordkeeping, labelling, storage, approval, advertising, promotion, sale and distribution, will be subject to comprehensive regulation by the FDA, EMA or comparable regulatory authorities in other jurisdictions. These requirements include, without limitation, submissions of safety and other post-marketing information and reports, registration and listing requirements, as well as continued compliance with current Good Manufacturing Practices (“cGMP”), and with Good Clinical Practices (“GCP”) requirements relating to manufacturing, quality control, quality assurance and corresponding maintenance of records and documents.

In addition, marketing approvals, if granted, may not include all uses for which we may seek to market a product candidate, thereby limiting the potential market for the product candidate. In fact, regulatory agencies in certain key jurisdictions possess the authority to limit the scope of a drug to one particular indication if it is considered to be a last line therapy. Furthermore, the regulatory authorities actively enforce regulations prohibiting marketing of products for non-indicated uses. Failure to comply with applicable regulatory requirements may, among other things, result in fines, suspension of regulatory approvals, seizures or recalls of products, injunctions against a product’s manufacture, distribution, sales and marketing, operating restrictions and criminal prosecution. Regulatory approvals may also contain requirements for costly post-marketing studies or clinical trials and surveillance to monitor the safety or efficacy of the product.
We operate in a highly regulated business area and we are, and will continue to be, subject to healthcare fraud and abuse, false claims, marketing expenditure tracking and disclosure, government price reporting, and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face penalties exclusion from government-funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations.

Our business operations and activities may be directly or indirectly subject to various fraud and abuse laws, including, without limitation, the U.S. federal Anti-Kickback Statute and the U.S. federal False Claims Act. If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research subjects, as well as proposed and future sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by the federal government and state governments in which we conduct our business. The laws that may affect our ability to operate include, but are not limited to:

- the U.S. federal Anti-Kickback Statute, which 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, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;

- the federal false statements statute prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services;

- the U.S. federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which 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 of 2009 and the respective implementing regulations, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as the respective business associates that perform services for them involving the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization;

- the U.S. federal physician self-referral law, commonly known as the Stark Law, which prohibits a physician from making a referral to an entity for certain designated health services reimbursed by Medicare or Medicaid if the physician or a member of the physician’s family has a financial relationship with the entity, and which also prohibits the submission of any claims for reimbursement for designated health services furnished pursuant to a prohibited referral;

- the U.S. federal transparency requirements under the Health Care Reform Law will require manufacturers of products, devices, biologics and medical supplies to report to the Department of Health and Human Services information related to payments and other transfers of value to physicians and teaching hospitals and physician ownership and investment interests;

- the U.S. federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- the U.S. federal government price reporting laws, as changed by the Patient Protection and Affordable Care Act, and amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the “ACA”) that requires, among other things, increasing the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program and offering such rebates to additional populations, and that requires us to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on our marketed products (participation in these programs and compliance with the applicable requirements may subject us to potentially significant discounts on our products, increased infrastructure costs, and potentially limit our ability to offer certain marketplace discounts);
the U.S. Foreign Corrupt Practices Act, a U.S. law that regulates certain financial relationships with foreign government officials (which could include, for example, certain medical professionals); and

- analogous state laws and regulations.

In addition, the regulatory approval and commercialization of any of our product candidates outside the United States will also likely subject us to equivalents of the healthcare laws mentioned above, among other non-U.S. laws.

In the European Union, the Regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (the “General Data Protection Regulation”) imposes strict regulations and establishes a series of requirements regarding the storage of personally identifiable information on computers or recorded on other electronic media. This has been implemented by all European Union member states through national laws. The General Data Protection Regulation provide for specific regulations requiring all non-European Union countries doing business with European Union member states to provide adequate data privacy protection when receiving personal data from persons in any of the European Union member states. In addition, the use and disclosure of personal health and other private information is subject to regulation in other jurisdictions in which we do business or expect to do business in the future. Those jurisdictions may attempt to apply such laws extraterritorially or through treaties or other arrangements with European governmental entities. We cannot assure you that our privacy and security policies and practices will be found sufficient to protect us from liability or adverse publicity relating to the privacy and security of personal information.

Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If we are unable to comply, or have not fully complied, with such laws, we could face penalties, including, without limitation, civil, criminal, and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. We may become exposed to costly and damaging liability claims, either when testing our product candidates in the clinic or at the commercial stage, and our product liability insurance may not cover all damages from such claims.

Furthermore, regulatory requirements and healthcare (insurance) laws are evolving in an unpredictable manner. Current and future legislation may significantly change the regulatory approval requirements causing additional costs and delays in obtaining market authorization. Changes in existing regulations or the adoption of new regulations could prevent us from obtaining or maintaining regulatory approvals and could significantly increase our compliance burden and costs or otherwise impact the profitability of our products. In addition, as we expand into new regions, the overall complexity of our compliance obligations and resulting potential regulatory risk will increase.

All these factors have the potential to materially and adversely affect our business, financial condition, results of operations and prospects.

*Legal proceedings and adverse judgements or settlements resulting from legal proceedings could limit our ability to operate our business, harm our brands or reputation or lead to administrative orders, fines and other damages.*

We face the risk of litigation and other proceedings in relation to our business. Involvement in litigation may be costly and time-consuming and divert the attention of our management and resources from our business. Furthermore, we may be unsuccessful in defending ourselves against any such claims. Substantial legal liabilities arising out of any litigation or other proceedings may have a material adverse effect on our business, reputation, and results of operations and/or financial condition. Even if a claim against us is not successful, we may incur significant legal costs defending ourselves against the claim.

*Product liability lawsuits against us could divert our resources, cause us to incur substantial liabilities and limit commercialization of any products that we may develop.*

Researching, developing and commercializing pharmaceutical products entail significant product liability risks. Liability claims may arise from our use of products candidates in clinical trials or the commercial sale of those products. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities.
We currently have product liability insurance for products that are in clinical testing, however, our current product liability coverage may not be adequate in scope to protect us in the event of a successful product liability claim. Further, we may not be able to maintain our current insurance or obtain general product liability insurance on reasonable terms and at an acceptable cost if we or our collaborative partners begin commercial production of our product candidates. This insurance, even if we can obtain and maintain it, may not be sufficient to provide us with adequate coverage against potential liabilities.

In addition, and regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or products that we may develop;
- injury to our reputation and significant negative media attention;
- increased regulatory scrutiny;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- the inability to commercialize any products that we may develop.

Manufacturing our products is complex, time-consuming and expensive.

Manufacturing our products and product candidates necessitates authorization and compliance with regulatory requirements, such as cGMP, and is complex, time-consuming and expensive. There can be no assurance that products identified and developed by us and/or our licensees or contractual partners will be capable of being produced in the quality and quantities necessary for clinical development, launch and commercialization at an acceptable cost. An increase 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, it is not certain that supplies could be resumed (whether in part or in whole) within a reasonable timeframe and at an acceptable cost, if at all. Other events such as acts of God, strikes or other production disruptions or wilful misconduct during production, storage and shipment of products can result in the loss of batches and therefore lead to financial losses and substantial delays in development programs and launch of products.

We depend on third-party suppliers and other third parties for the production of our product candidates and our dependence on these third parties has the potential to adversely affect the clinical advancement of our product candidates, as well as any future commercialization efforts, should a contractor fail to deliver.

We currently rely, and expect to continue to rely, on third-party contract manufacturers ("CMs") for the manufacture and supply of our product candidates. As an example and without limitation, we currently rely upon one CM for each distinct step of the ColiFin® supply chain of all our clinical and projected commercial material: One CM for the manufacture of the active pharmaceutical ingredients (APIs, drug substances) and one different CM (fill finish provider) for the manufacture of the finished products (drug products). We currently do not have in-house facilities to manufacture products for clinical trials or in commercial quantities and have no experience in commercial-scale manufacturing and use certain third-parties for the manufacturing of our product candidates. Moreover, our finished product candidates for our clinical trials are provided by one single fill finish provider for each of our clinical studies. We expect to continue to rely on such third parties for the manufacture and supply of all of our product candidates for larger scale preclinical studies, clinical trials and any future commercialization.

Reliance on third-party providers may expose us to different risks than if we were to manufacture our products or product candidates ourselves. The facilities used by our CMs or other third-party manufacturers to manufacture our products or product candidates must be approved by the relevant regulatory authorities and we do not have control over a supplier’s or manufacturer’s compliance with the applicable regulations, cGMP standards and other laws and regulations.
If the FDA, the EMA or a comparable other regulatory authority does not approve these facilities for the manufacture of our products or product candidates or if it withdraws any such approval in the future, we or our partners may need to find alternative manufacturing facilities, which would significantly impact our or their ability to develop, obtain regulatory approval for or market our product candidates, if approved. Any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we or our partners 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. We are also unable to predict how changing global economic conditions or potential global health concerns such as the COVID-19 pandemic will affect our third-party suppliers and manufacturers. Such third-party manufacturers may also be subject to delays due to circumstances outside of their control for a variety of reasons, including outbreaks and public health crises, such as the COVID-19 pandemic, that could shut down or cause limited staffing of their facilities.

Furthermore, third-party providers may breach, terminate or refuse to renew their agreements with us, potentially at a time that is costly or otherwise inconvenient for us. In such cases, we would face the challenge of transferring complicated manufacturing techniques to other CMs, which may or may not be feasible. For example, as of the date of this Prospectus, there is currently only one manufacturer of colistimethate sodium (CMS), the active pharmaceutical ingredient in ColiFin®, which possesses an acceptable drug master file in the U.S. Even if a transfer to another CM is possible, we may incur significant costs and be required to devote significant time to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines. A transfer of the process for our product candidates would be time consuming and we may not be able to successfully achieve such a transfer. Moreover, we might be unable to source ingredients for our products or product candidates from other suppliers upon short notice and/or at all and, might be required to pay higher prices for these ingredients. If we were unable to find an adequate replacement or another acceptable solution in time, clinical trials for our product candidates could be delayed and our commercial activities could be harmed.

Our current and anticipated future dependence upon others for the manufacturing of our product candidates may adversely affect our future profit margins and our ability to commercialize any products that receive marketing approval on a timely and competitive basis.

**We rely or may in the future rely on third parties to conduct preclinical studies or clinical trials for our product candidates, and if they do not properly and successfully perform their obligations to us we may not be able to complete preclinical studies or clinical trials and to obtain regulatory approvals for our product candidates.**

We rely, and we expect that we will continue to rely, on CROs and other third parties to assist in managing, monitoring and otherwise carrying out preclinical studies and clinical trials for our product candidates. In particular with regard to our planned Phase 3 clinical trial for our lead product candidate ColiFin®, we expect to appoint at least two CROs to implement the required clinical trial(s). Therefore, we will depend heavily on the performance by these CROs of their services. We compete with many other companies for the resources of these third parties. If engagements with third parties on whom we rely are terminated, we would have to enter into alternative arrangements which would delay development and commercialization of our product candidates.

The FDA, the EMA and other comparable regulatory authorities require compliance with regulations and standards, including GCP, for designing, conducting, monitoring, recording, analysing, and reporting the results of preclinical studies and clinical trials to assure that the data and results are credible and accurate and that the rights, integrity and confidentiality of trial participants are protected. Although we rely on third parties to conduct many of our preclinical studies and clinical trials, we are responsible for ensuring that each of these preclinical studies and clinical trials is conducted in accordance with its general investigational plan, protocol and other requirements.

If these third parties do not successfully carry out their duties under their agreements, if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to preclinical studies and clinical trial protocols or to regulatory requirements, or if they otherwise fail to comply with preclinical studies and clinical trial protocols or meet expected deadlines, the clinical trials of our product candidates may not meet regulatory requirements. If preclinical studies and clinical trials do not meet regulatory requirements or if these third parties need to be replaced, preclinical development activities or clinical trials may be extended, delayed, suspended or terminated. If any of these events occur, we may not be able to obtain regulatory approval of our product candidates on a timely basis or at all.
We have entered into and may in the future seek to enter into collaboration and license agreements with third parties for the development and commercialization of our products. If such collaborations are not successful, we may not be successful in completing the development or commercialization of the product candidates.

Our business strategy for the commercialization of our product candidates includes entering into and maintaining various forms of collaboration arrangements and license agreements with other companies and other third parties to aid in research and development of product candidates, in undertaking preclinical and clinical studies, as well as in manufacturing, marketing and selling of our products. There can be no assurance that we will be able to maintain existing collaboration and license agreements, negotiate collaboration arrangements in the future on acceptable terms with suitable partners, if at all, or that any such collaboration arrangements will be successful. For example, we entered into a licensing agreement with Santhera Pharmaceuticals (Switzerland) Ltd. (“Santhera”) for the out-licensing of our product candidate POL6014 under which Santhera assumes full responsibility for its development. If Santhera is not successful in completing the development or commercialization of POL6014 we may not be able to draw further benefit from this partnership. To the extent that we are not able to maintain or establish such arrangements, we would be forced to seek alternatives, including undertaking product development and commercialization activities on our own, which would increase our capital requirements and could require us to limit the scope of our research and development activities in other fields.

We currently do not have a commercial infrastructure for the marketing, sale, and distribution of our product candidates. If ColiFin® or any future product candidates receive marketing approval, we intend to commercialize such product candidates with pharmaceutical or biotechnology partners or by our own sales force which we believe we can build, if we chose to do so. To the extent we rely on third parties to commercialize any products for which we obtain regulatory approval, we may receive less revenues than if we commercialized these products ourselves, which could materially harm our prospects. In addition, we would have less control over the sales efforts of any other third parties involved in our commercialization efforts, and could be held liable if they failed to comply with applicable legal or regulatory requirements.

We also depend in part on the continued availability of outside scientific collaborators (including researchers at clinical research organizations and universities) in certain areas relevant to our research and development. The competition for such relationships is intense, and there can be no assurance that we will be able to maintain such relationships on acceptable terms. In addition, these outside relationships generally may be terminated by the collaborator at any time, since the collaborators usually are not employed by us. As a result, we have limited control over their activities and can expect that only limited amounts of their time will be dedicated to us.

The size of the potential markets for ColiFin® in worldwide territories outside Europe or any future product candidates is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets may be smaller than our estimates.

The potential market opportunities for ColiFin® or any future product candidates are difficult to estimate and will depend in large part on the success of competing therapies and therapeutic approaches. Our estimates of the potential market opportunities in CF and other indications are predicated on many assumptions, which may include industry knowledge and publications, third-party research reports, and other surveys. Although we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain, and their reasonableness has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets and patient populations eligible for ColiFin® and future product candidates could be smaller than our estimates of the potential market opportunities.

Serious adverse events or other unexpected properties of any product candidate may be identified after approval that could cause the withdrawal of regulatory approval, limit the commercial potential, or result in significant negative consequences following marketing approval.

Serious adverse events or undesirable side effects caused by, or other unexpected properties of, our product candidates could result in a more restrictive label, the imposition of distribution or use restrictions by the FDA or the EMA or comparable regulatory authorities. If any of our product candidates are associated with serious adverse events or undesirable side effects or have properties that are unexpected, we may need to limit development to certain uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

A number of potentially significant negative consequences may result from undesirable side effects or other unexpected adverse events or properties of any of our product candidates, including:
• regulatory authorities may withdraw the approval of such product;
• regulatory authorities may require additional warnings on the label or impose marketing, distribution or use restrictions;
• regulatory authorities may require one or more post-market studies;
• regulatory authorities may require us to put clinical trials on hold;
• we may be required to create a medication guide outlining the risks of such side effects for distribution to patients;
• sales of the product may decrease significantly;
• in case of a partnered product, our partner may terminate the partnership;
• we could be sued and held liable for harm caused to patients; and
• our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidate or could substantially increase commercialization costs and expenses, which could delay or prevent us from generating revenue from the sale of our products and harm our business and results of operations.

Our future commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among patients and the medical community, and the market opportunity for the candidates may be smaller than we estimate.

Even if development of the product candidate is successful and all necessary regulatory approvals are obtained, there can be no assurance that our products will attain market acceptance. Even if the FDA, the EMA or 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 payers on the benefits of our product candidates may require significant resources and may not be successful. 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 patients perceive our novel products;
• the timing of regulatory approvals and market introduction, in particular compared to competing products;
• the number and clinical profile of competing products;
• the price of our products relative to competing products;
• availability of coverage, reimbursement and adequate payment from health maintenance organizations and other third-party payers, both public and private;
• 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;
• the continued projected growth of drug markets in our various indications;
marketing and distribution support, including marketing efforts by third-party distributors or agents that we retain; and/or

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, if any, return on our investments. Even if some products achieve market acceptance, the market may prove not to be large enough to allow generating significant revenues.

The potential market opportunities for our product candidates are difficult to estimate. Our estimates of the potential market opportunities are based, among other things, on industry knowledge and publications, third-party research reports and surveys. They are also predicated on assumptions that involve the exercise of significant judgment on the part of our management, are inherently uncertain and the reasonableness of these assumptions has not been assessed by an independent party. The aforementioned is in particular true for our assumptions with respect to patient population and price potential. If any of the assumptions prove to be inaccurate, the actual markets for our product candidates could be significantly smaller than estimated.

The markets in which we operate are highly competitive, and if we do not compete effectively our ability to successfully commercialize products may be adversely affected.

The development and commercialization of drugs is highly competitive. We compete with a variety of multinational pharmaceutical companies, specialized pharmaceutical companies, universities and other research institutions, some of which have significantly greater financial, technical, human, manufacturing, marketing, sales and drug resources or experience than we have. Our competitors have developed, are developing, or will develop, product candidates and processes that will compete with our product candidates. Competitors may enjoy a significant competitive advantage if they are able to achieve patent protection, obtain marketing approvals and commence commercial sales of their products before we do. Competing products could also present superior treatment alternatives, including those which are more effective, safer or more convenient, for our targeted indications and thus make our product candidate or know-how obsolete, even before it reaches the market. In addition, our commercial opportunity could be significantly reduced or even eliminated if our competitors develop and commercialize products that may have a better health-economic or risk/benefit profile. Our competitors also may obtain FDA, EMA or other regulatory approval for their products more rapidly than we do, which could result in our competitors establishing a strong market position (including, but not limited to, achieving approval under Orphan Drug or QIDP designations before we are able to do so) and/or which could prevent us from entering the market.

We face significant competition from other biopharmaceutical and biotechnology companies, academic institutions, government agencies, and other research organizations, which may result in others discovering, developing or commercializing products more quickly or marketing them more successfully than us. If their product candidates are shown to be safer or more effective than ours, our commercial opportunity may be reduced or eliminated.

Additionally, certain companies whom we view as our most direct potential competitors are currently developing therapies in CF that may have utility for similar indications that we are targeting. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization.

As for antibiotic product candidates targeting WHO Priority 1 pathogens, in July 2012, the U.S. Food and Drug Administration Safety and Innovation Act was passed, which included the U.S. Generating Antibiotics Incentives Now Act. In July 2020, several large drugmakers announced a creation of USD 1 billion fund, led by the International Federation of Pharmaceutical Manufacturers & Associations in order to bolster struggling antibiotic companies and sustain a pipeline for new treatments. Such initiatives are intended to provide incentives for the development of new, qualified infectious disease products and may result in more competition in the market for new antibiotics, and may cause pharmaceutical and biotechnology companies with more resources than we have to shift their efforts towards the development of product candidates that could be competitive with inhaled murepavadin and future antibiotics from our OMPTA class.

In addition, competitors may offer products below the price level at which appropriate return for the investment in product development is possible. As a result of these factors, we may be unable to successfully develop commercially feasible products and our commercial opportunity may be reduced or eliminated, and we may not be able to successfully compete. This would have a material adverse effect on our business, financial condition, results, operations and prospects.
Cost-containment measures in the pharmaceutical markets may impair our ability to operate profitably.

In addition to the successful development of product candidates, our ability to commercialize them will also, to varying degrees, depend on price levels and the extent to which reimbursement for the costs of these products will be available from third parties. These include from government health administration authorities, private health insurers and government healthcare programs.

In some countries, particularly member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. There can be considerable pressure by governments and other stakeholders on price levels, including as part of cost containment measures. In addition, even if an agreed price is negotiated, the reimbursement may be restricted only to specific patient subpopulations or to specific providers and institutions, and negotiated prices are subject, over time, to negotiation and/or to specific or general price cuts and/or reimbursement restrictions. The current context of healthcare cost control, coupled with the increase in healthcare budgets caused by the ongoing, long-term trend of aging populations, creates extra pressure on healthcare spending in most, if not all, countries, that is expected to continue for the foreseeable future. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement approval has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we or our partners may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain pricing approval. Publication of discounts by third-party payers or authorities may lead to further pressure on the prices within the country of publication and other countries. If pricing of our products is set at unsatisfactory levels, our business could be adversely affected.

Reimbursement by third-party payers depends on a number of factors, including the payer’s determination that use of the product is safe and effective, not experimental or investigational, medically necessary, appropriate for the specific patient and cost-effective. Seeking third-party reimbursement is a time-consuming and costly process which will require us to provide scientific and clinical support for the use of each of our products to each payer separately. Significant uncertainty exists as to the payment status of newly approved medical products, and there can be no assurance that adequate third-party reimbursement will be granted in a timely manner for patients eligible for treatment to enable us to establish or maintain price levels sufficient to realize an appropriate return on our investment in product development. If government and third-party payers do not provide adequate coverage and reimbursement levels for users of our prospective potential products, the market acceptance of these potential products could be materially adversely affected. In addition, we are unable to forecast 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.

If our marketing efforts are unsuccessful or if changes in rules and regulations regarding pharmaceutical advertising prevent us from pursuing our marketing efforts, we may be unable to attract new and retain existing customers.

We currently have no marketing and sales capability to market pharmaceutical products. In order to be in a position to commercialize our products we will need to rely on collaborations with third parties or to develop our own marketing and sales force with technical expertise and supporting distribution capability. To the extent that we enter into licensing or co-development arrangements, our revenues will depend in part upon established distribution systems and direct sales forces of third parties with respect to which we have little or no control. Developing marketing and sales forces will be expensive and time consuming and could delay any product launch. There can be no assurance that we will be in a position to build a satisfactory marketing and sales force.

We may face claims from third parties of intellectual property infringement or misappropriation which may prevent or delay the commercialization of our products and/or lead to significant costs and damages claims and adverse effects on our business.

Third parties may have intellectual property infringement or misappropriation claims that may lead them to sue us for damages or in order to prevent us from manufacturing, selling or developing our product candidates. Defending such claims would involve significant effort and expense and could divert management’s attention from our business. Furthermore, the outcomes of such proceedings may also be unfavourable to us. In the event that the manufacture, use or sale of any of our product candidates infringes the patents or violates other proprietary rights of third parties, we may be required to:
• pay actual damages or an account of profits, and if a court were to conclude that there was wilful infringement, increased damages up to triple the actual damages and the other party’s attorney’s fees, which may be substantial;

• cease the development, manufacture, use and sale of products that infringe the patent rights of others through an injunction;

• expend significant resources to redesign our technology so that it does not infringe others’ patent rights, or to develop or acquire non-infringing technology, which may not be possible; and/or

• obtain licenses to the infringed intellectual property, which may not be available to us on acceptable terms, or at all, and any licenses may require substantial royalties or other payments from us. Even if we were able to obtain rights to the third party’s intellectual property, these rights may be non-exclusive, thereby allowing our competitors access to the same intellectual property.

Many of our employees, consultants, and advisors are currently or were previously employed at universities or other pharmaceutical companies including our competitors and potential competitors. Although we try to ensure that our employees, consultants, and advisors 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 these individuals have used or disclosed intellectual property, trade secrets or other proprietary information, of any such individual’s current or former employer. Litigation may be necessary to defend 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 but even if we are successful, litigation could result in substantial costs and be a distraction for management.

An unfavourable outcome for us in patent or other intellectual property litigation could significantly harm our business if such outcome renders us unable to commercialize some or all of our current or future product candidates or if we have to cease some of our business operations. In addition, the defense costs and any damages resulting from litigation may materially and adversely affect our business and financial results. Litigation may also harm our relationships with existing customers and subject us to negative publicity, each of which could harm our business and financial results.

If we or our partners are unable to obtain or maintain intellectual property rights and trade secret protection relating to the proprietary technologies used in our business, we may not be able to continue our current business or to effectively pursue our growth strategy and may also be exposed to costs or liabilities.

Our success depends in part on our ability, and the ability of our licensors, to obtain patent protection for our products, product candidates and processes, preserve our trade secrets, defend and enforce our rights against infringement and operate without infringing the proprietary rights of third parties, both in Switzerland and in other countries. No assurance can be given that any patents based on pending patent applications or any of our future patent applications will be issued, that the scope of any patent protection will exclude competitors or provide us with competitive advantages, that any of the patents that have been or may be issued to us will be held valid if subsequently challenged or that others will not claim rights in the patents and other proprietary rights held or licensed by us. Furthermore, there can be no assurance that others have not developed or will not develop similar products, duplicate any of our products, or design around any patents that have been or may be issued to us or our licensors.

Since patent applications in many countries are maintained in secrecy until the issue of a patent, we also cannot be certain that others did not first file applications for inventions covered by our pending patent applications, nor can we be certain that we will not infringe any patents that may be issued to others on such applications. We also rely on trade secrets and non-patentable know-how which we seek to protect, in part, by confidentiality agreements with our employees, consultants, suppliers, licensees and other contractual partners. 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 will not otherwise become known or be independently developed by competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets would be expensive and time-consuming, and the outcomes are unpredictable. Misappropriation or unauthorized disclosure of our trade secrets could impair our competitive position and may have a material adverse effect on our business.

Any of our granted, valid and enforceable patents will provide protection only for a limited period of time. While it may be possible to obtain an extension of protection provided that certain clinical development extension application deadlines are met, we may not be able to obtain such extensions of protection. It may also be possible to seek method of use patents, which protect therapeutic indications of products. If a method of use patent is granted but no product patents
are granted or they have expired, third parties would be allowed to develop products for use in different indications if they were willing and able to conduct all development activities necessary to receive marketing approval.

If our technology components, devices, designs, products, processes or other subject matters are claimed under other existing patents or are otherwise protected by third party proprietary rights, we may be subject to infringement actions. If we are required to defend ourselves against charges of patent infringement or to protect our own proprietary rights against third parties, substantial costs could be incurred and significant management resources could be consumed regardless of whether we are successful. Such proceedings are typically protracted with no certainty of success. An adverse outcome could subject us to significant liabilities to third parties, and force us to curtail or cease the development and sale of our products and processes. We therefore cannot be certain that we will successfully achieve and enforce the desired protection of proprietary rights for our product candidates, technologies and know-how. Failure in this respect could have a material adverse effect on our business, financial condition, results of operations and prospects.

We enjoy only limited geographical protection with respect to certain patents and may face difficulties obtaining protection in certain jurisdictions, which may limit our ability to prevent competitors from using our products and proprietary technologies in such jurisdictions.

While, in general, we file patent applications for our key inventions in the most material jurisdictions, including, but not limited to, the United States, Europe, Canada and Japan, we have not filed for patent protection in all national and regional jurisdictions where such protection may be available. In addition, we may decide to abandon national and regional patent applications before they are granted. Further, the grant proceeding of each national/regional patent is an independent proceeding that may lead to situations in which applications might in some jurisdictions be refused by the relevant registration authorities, while granted by others. It is also common that depending on the country, the scope of patent protection may vary for the same product and/or technology.

The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the United States and Europe, and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. If we or our licensors encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished and we may face additional competition from others in those jurisdictions.

Some countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patents. If we or any of our licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired and our business and results of operations may be adversely affected.

We may not be able to enforce our intellectual property rights against third parties and our intellectual property rights may be attacked by third parties, each of which may limit our ability to prevent competitors from using our products, technologies and similar products and technologies.

In order to protect our own intellectual property rights, we may be required to initiate lawsuits against third parties, which could be costly and time-consuming, divert management and personnel from their business responsibilities or otherwise materially harm our business. Moreover, we cannot guarantee that we will have sufficient financial or other resources to conduct such actions, which typically continue for several years before a final legal judgment or settlement is obtained. Furthermore, the outcomes of such proceedings may also be unfavourable to us. If we are unsuccessful in any such action, third parties may be able to use our products and proprietary technologies, or similar products and technologies, in order to compete with us.

Furthermore, while we normally seek to obtain the right to control the prosecution, maintenance, enforcement and defence of intellectual property rights related to our products and product candidates, there may be times when our licensors or collaborators control, or have a first right to control, the filing, prosecution, enforcement and defence of such rights. We cannot be certain that our licensors or collaborators will prosecute, maintain, enforce and defend such intellectual property rights in a manner consistent with the best interests of our business, including by taking reasonable measures to protect the confidentiality of know-how and trade secrets, or the payment of all applicable prosecution and maintenance fees related to our technologies or any of our product candidates.
Any litigation or other proceedings to enforce our intellectual property rights could also put one or more of our patents or other intellectual property rights at risk of being invalidated or interpreted narrowly and could put any pending patent applications at risk of not being issued. A loss of intellectual property protection could have a material adverse impact on our business. We and our partners may be unable to prevent competitors from entering the market with a product that is similar to or the same as our product candidates.

In addition, there is a risk that some of our confidential information could be compromised by disclosure in judicial proceedings since they require a substantial amount of disclosure. Such disclosure could provide competitors with access to our proprietary information and may harm our competitive position.

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

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future arising from, for example, conflicting obligations of consultants or others who were involved in developing our products and product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. 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 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 employees.

We may encounter difficulties in managing our growth and expanding our operations successfully.

As we seek to advance our product candidates through clinical trials and commercialization, we will need to expand our late-stage clinical development and commercialization capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various partners, suppliers and other third parties. Future growth will impose significant added responsibilities on members of management. Our management may have to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to these growth activities. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative and, if necessary, sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing.

We may be unable to attract and retain key personnel and skilled employees.

Our success depends, to a significant extent, on the efforts and expertise of the top management and other key members of our management and scientific staff. We have endeavored to ensure that key personnel receive suitable incentives by establishing, among other things, an employee share option plan. However, there is intense competition for skilled personnel in the fields in which we operate and thus the retention of such personnel cannot be guaranteed. The loss of top management or any such other employees or the failure to attract new highly qualified employees could have a material adverse effect on our business, financial condition, results of operations and prospects. Our ability to recruit and retain skilled personnel, especially in the areas of management, research and development, as well as other relevant functions related to our projects will be critical to our success.

Our employees, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

Our employees, consultants, and commercial partners expose us to the risk of fraud or other misconduct. Misconduct by these parties could include intentional or unintentional failure to comply with regulations, provide accurate information to regulatory authorities, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Such misconduct also could involve the improper use of information obtained in the course of clinical trials or interactions with regulatory authorities, which could result in regulatory sanctions and cause serious harm to our reputation. Prior to the completion of the Transaction we have adopted a code of conduct applicable to all of our employees, but it is not always
possible to identify and deter employee misconduct, and the precautions we take may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. If any such actions are instigated against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, financial condition, results of operations, and prospects, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

_Disruptions in the credit and equity markets could increase the risk of default by counterparties to our financial instruments, undrawn credit facilities and cash investments and may impact our future financial position._

Although we seek to manage the credit risks associated with our financial instruments, cash and cash equivalents and undrawn debt facilities, disruptions in credit and equity markets could increase the risk that our counterparties could default on their obligations to us. Disruptions in the financial markets may make equity and debt financing more difficult to obtain. If one or more of our counterparties failed or was otherwise unable to meet its obligations to us, our cash flows, results of operations and financial condition could be adversely affected. We cannot predict how disruptions in the credit and equity markets and the associated difficult economic conditions could impact our future financial position. In this regard, the financial failure of any of our counterparties could reduce amounts available under committed credit facilities and adversely impact our ability to access cash deposited with any failed financial institution and future tightening of the credit markets could adversely impact our ability to access debt financing on favourable terms, or at all.

_The integration of EnBiotix may consume more resources than we had envisaged and may be subject to impediments or delays._

The integration of a business is a complex task which frequently takes longer and requires more resources than expected, both financial and in terms of management attention. While we aim for a smooth integration of EnBiotix and Polyphor following the Capital Increase, we cannot exclude that there may be disruptions or impediments which lead to delays and may require substantial resources to overcome, thus making such resources unavailable for day-to-day operations, which could adversely affect our ability to operate our business and our results of operations.

_The sole proceeds from the Capital Increase were shares of EnBiotix._

The sole proceeds to the Company from the Capital Increase were shares in EnBiotix, which became a subsidiary of the Company. However, EnBiotix closed a financing round in the amount of approximately USD 11m shortly prior to the closing of the Transaction, which will be used by the Company for the further development of its product pipeline and general corporate purposes. In addition to these funds, we will require additional funding over the next 12 months and beyond from other sources to support the development of our product candidates, including, but not limited to, ColiFin®.

_Currency fluctuations and exchange rate risks may adversely affect our results of operations._

Our business is affected by fluctuations in foreign exchange rates between the Swiss Franc and other currencies, in particular the U.S. Dollar, the Euro and the British Pound as well as the currencies of countries in which we conduct our clinical trials. Our reporting currency is the Swiss Franc, and as a result financial positions are converted into Swiss Francs at the applicable foreign exchange rates. We expect that a significant part of our revenues, including milestone payments and royalties, and a significant part of our costs, including costs for clinical trials, will be denominated in U.S. Dollar, in Euros or British Pounds. Therefore, unfavourable developments in the value of the Swiss Franc compared to the U.S. Dollar, the Euro, the British Pound or any other material currency could have a material adverse effect on our business, financial condition, results of operations and prospects in the future.

_A majority of our operations are currently conducted at a single location that may be at risk from fire, earthquakes or other natural disasters._

We currently conduct a significant portion of our research, development and management activities at a single location in Allschwil near Basel, Switzerland. The Basel area is exposed to a heightened risk of earthquakes. The most recent major earthquake to hit Switzerland was in Basel in 1356. Today, it is estimated that a similar event would cause about CHF/USD 80 billion in damages. We have taken precautions to safeguard our facilities, including insurance, health
and safety protocols, and off-site storage of computer data. However, any future natural disaster, such as a fire or an earthquake, could cause substantial delays in our operations, damage or destroy our equipment or inventory, and cause us to incur additional expenses. A disaster could seriously harm our business and results of operations. The insurance we maintain against fires, earthquakes and other natural disasters may not be adequate to cover our losses in any particular case. Any unplanned event, such as flood, fire, explosion, extreme weather condition, medical epidemics, including any potential effects from the current global spread of COVID-19, power shortage, telecommunication failure or other natural or man-made accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Natural disasters or pandemics such as the COVID-19 outbreak could further disrupt our operations, and have a material and adverse effect on our business, financial condition, results of operations and prospects. For example, due to the COVID-19 pandemic we instituted a temporary work from home policy for certain personnel and may do so again in the future. It is possible that this could have a negative impact on the execution of our business plans and operations.

A pandemic, epidemic, or outbreak of an infectious disease, such as COVID-19, may materially and adversely affect our business and our financial results and could cause a disruption to the development of our product candidates.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. Recently, a novel strain of a virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes COVID-19 has spread to most countries across the world, including Switzerland, including specifically the Canton of Basel-Landschaft, where our primary office and laboratory space is located. The coronavirus pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. The extent to which the coronavirus impacts our operations or those of our third party partners, including our preclinical studies or clinical trial operations, will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the outbreak, new information that will emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. The continued spread of COVID-19 globally could adversely impact our preclinical or clinical trial operations, including our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19 if an outbreak occurs in their geography. For example, similar to other biopharmaceutical companies, we may experience delays in initiating IND-enabling studies, protocol deviations, enrolling our clinical trials, or dosing of patients in our clinical trials as well as in activating new trial sites. COVID-19 may also affect employees of third-party CROs located in affected geographies that we rely upon to carry out our clinical trials. In addition, the patient populations that our product candidates target may be particularly susceptible to COVID-19, which may make it more difficult for us to identify patients able to enroll in our current and future clinical trials and may impact the ability of enrolled patients to complete any such trials. Any negative impact COVID-19 has to patient enrollment or treatment or the execution of our product candidates could cause costly delays to clinical trial activities, which could adversely affect our ability to obtain regulatory approval for and to commercialize our product candidates, increase our operating expenses, and have a material adverse effect on our financial results.

Additionally, timely enrolment in planned clinical trials is dependent upon clinical trial sites which could be adversely affected by global health matters, such as pandemics. We plan to conduct clinical trials for our product candidates in geographies which are currently being affected by the coronavirus. Some factors from the coronavirus outbreak that will delay or otherwise adversely affect enrollment in the clinical trials of our product candidates, as well as our business generally, include:

- the potential diversion of healthcare resources away from the conduct of clinical trials to focus on pandemic concerns, including the attention of physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our prospective clinical trials;
- limitations on travel that could interrupt key trial and business activities, such as clinical trial site initiations and monitoring, domestic and international travel by employees, contractors or patients to clinical trial sites, including any government-imposed travel restrictions or quarantines that will impact the ability or willingness of patients, employees or contractors to travel to our clinical trial sites or secure visas or entry permissions, a loss of face-to-face meetings and other interactions with potential partners, any of which could delay or adversely impact the conduct or progress of our prospective clinical trials;
- the potential negative affect on the operations of our third-party manufacturers;
• interruption in global shipping affecting the transport of clinical trial materials, such as patient samples, investigational drug product and conditioning drugs and other supplies used in our prospective clinical trials; and

• business disruptions caused by potential workplace, laboratory and office closures and an increased reliance on employees working from home, disruptions to or delays in ongoing laboratory experiments and operations, staffing shortages, travel limitations or mass transit disruptions, any of which could adversely impact our business operations or delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

We have in the past taken a number temporary precautionary measures intended to help minimize the risk of the virus to our employees, and may do so again depending on how the situation develops. Such measures could negatively affect our business. Measures taken include temporarily requiring all employees to work remotely, suspending all non-essential travel worldwide, participating in a mass testing campaign, ensuring social distancing at work, increasing cleaning volume and discouraging employee attendance at industry events and in-person work-related meetings, We cannot presently predict the scope and severity of potential shutdowns or disruptions of businesses and government agencies, such as the FDA.

These and other factors arising from the coronavirus (including novel strains thereof) could worsen in countries that are already afflicted with the coronavirus or could continue to spread to additional countries. Any of these factors, and other factors related to any such disruptions that are unforeseen, could have a material adverse effect on our business and our results of operation and financial condition. Further, uncertainty around these and related issues could lead to adverse effects on the economy, which could impact our ability to raise the necessary capital needed to develop and commercialize our product candidates.

The global outbreak of COVID-19 continues to rapidly evolve. While the extent of the impact of the COVID-19 pandemic on our business and financial results is uncertain, a continued and prolonged public health crisis such as the COVID-19 pandemic could have a material negative impact on our business, financial condition and operating results.

To the extent the COVID-19 pandemic adversely affects our business and financial results, it may also have the effect of heightening many of the other risks described in this section and in this “Risk Factors” section.

If we experience significant disruptions in our information technology systems, our business, results of operations and financial condition could be adversely affected.

The efficient operation of our business depends on our information technology systems. We rely on our information technology systems to effectively manage accounting and financial functions as well as our research and development data. Our information technology systems are vulnerable to damage or interruption from a number of factors including earthquakes, fires, floods and other natural disasters, terrorist attacks, attacks by computer viruses or hackers, power losses or computer systems, or internet, telecommunications or data network failures.

Should our information technology systems fail to perform as we anticipate or we fail to effectively implement new systems this could disrupt our entire operation and result in decreased sales, increased overhead costs, excess inventory and product shortages, all of which could have a material adverse effect on our reputation, business, results of operations and financial condition.

Our businesses may be exposed to risks associated with the implementation of the Swiss federal popular initiative against mass immigration.

On February 9, 2014, Swiss voters approved the federal popular initiative “Against Mass Immigration” (the “Immigration Initiative”). The Immigration Initiative sought to limit immigration into Switzerland by calling for annual quotas on residency permits and cross-border work permits. On December 16, 2016, the two chambers of the Swiss parliament passed the relevant legislation partially implementing the Immigration Initiative, which, to avoid violating bilateral agreements with the European Union, does not include quotas demanded by the Immigration Initiative. The legislation entered into force on July 1, 2018, along with revised ordinance provisions adopted by the federal government on December 8, 2017. Under the legislation, companies within industries in which the general unemployment rate in Switzerland is at or above a threshold of initially 5% are obligated to report new job opportunities first to job seekers registered with local employment agencies in Switzerland. The regulation resulting from the Immigration Initiative may make Switzerland a less desirable
location for non-Swiss residents, making it more difficult for us to attract and retain the personnel we need, which could have a material adverse effect on our business, financial condition and results of operations.

**If we fail to maintain proper and effective internal control over financial reporting, our operating results could be affected and our ability to operate our business could be impaired.**

Ensuring that we have adequate internal financial and accounting controls and procedures in place so that we can produce accurate financial statements on a timely basis is a costly and time-consuming effort that needs to be re-evaluated frequently. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements in accordance with IFRS.

The design of any internal control system is based in part upon certain assumptions relating to the likelihood of future events. Because of these and other inherent limitations of control systems, there can be no assurance that they will succeed in achieving their stated goals under all potential future conditions. If our controls cannot provide reliable financial reports or prevent fraud or other illegal acts, our financial results could be negatively affected.

In addition, as a result of our growth strategy and the continued operating complexity of our business, internal controls over financial reporting will need to be kept under regular review, which may place strain on our managerial and operational resources. Additionally, our systems may not be as advanced as other public companies. There is no guarantee that our internal controls over financial reporting will be capable of responding to these requirements as an exchange-listed Company difficulties or inefficiencies that cause us to incur significant additional costs or expose us to other fines or penalties, which could have a material adverse effect on our business, financial condition and results of operations.

In addition, other processes and procedures used throughout our business may not be as advanced as those of other public companies. If our processes and procedures were found not to be in compliance with certain relevant legal requirements, this could have a material adverse effect on our business, financial condition and results of operations.

**Our ability to use tax loss carryforwards in Switzerland may be limited**

As of December 31, 2020, we reported tax loss carryforwards in the aggregate amount of CHF 274'576 thousand. These tax losses 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. We may not be able to use all our tax losses carryforwards and changes in the tax legislation might occur, which would reduce the possibility to carry forward tax losses.

**B. Risks relating the Shares**

**We do not expect to pay dividends to the shareholders of the Company over the coming years.**

The Company has never paid dividends and it currently intends to retain all available funds and any future earnings to fund the development and growth of its business.

**The Company's shares may be subject to volume and price fluctuations.**

We expect the market price of the Shares to be highly volatile after completion of the Transaction. Such volatility may depend upon many factors within and beyond our control, including the risk factors listed in this Prospectus, in particular, the result of clinical trials of our product candidates, regulatory actions with respect to our product candidates, and the passage of legislation or other regulatory developments affecting us or our industry, our or our competitors’ financial and business performance, general market conditions and the volatility in financial and other markets (i.e., the degree to which prices fluctuate over a particular period in a particular market, regardless of market levels) in general. In some cases, the markets have produced downward pressure on stock prices for certain issuers seemingly without regard to those issuers’ underlying financial strength. Furthermore, pharmaceutical companies whose product candidates have not yet been commercialized have experienced significant price and volume fluctuations in recent years. Such fluctuations in the future could adversely affect the market price of the Shares without regard to our results of operations or financial condition.
Existing shareholders will incur immediate and substantial dilution as a result of issuances of equity or other securities convertible into equity.

The Company has issued and may in the future issue rights to acquire Shares at prices which may be below the assumed offer price (see “—Incentive and equity-based plans” beginning on page 49). As at the date of this Prospectus, such rights to acquire 519,508 Shares are outstanding. In addition, the Company entered into an equity-linked financing arrangement with the French company IRIS (see “—Material Agreements” beginning on page 63). To the extent that these rights will ultimately be exercised and settled in Shares, investors will incur further dilution.

To the extent that the Company issues shares or equity-linked instruments (e.g. for financing purposes or for employee participations), investors’ ownership interest will be diluted, and the terms of such issued shares may include liquidation or other preferences that adversely affect investors’ rights as a shareholder.

Shareholders outside Switzerland may not be able to exercise preemptive rights in future issuances of equity or other securities that are convertible into equity.

Under Swiss law, shareholders may receive certain preemptive rights to subscribe on a pro rata basis for issuances of newly issued equity or other securities that are convertible into equity. Due to laws and regulations in their respective jurisdictions, non-Swiss shareholders may not be able to exercise such rights unless we take action to register or otherwise qualify the rights offered under the laws of that jurisdiction. There can be no assurance that we would take any such action, and we will have the full discretion to decide not to take such action in one or more jurisdictions, including the European Union and the United States. If shareholders in such jurisdictions are unable to exercise their subscription rights, their ownership interest in the Company would be diluted.

Shareholders in countries other than Switzerland face additional investment risk from currency exchange rate fluctuations in connection with their holding of Shares.

The Shares will be quoted in Swiss Francs only and any future dividends, if any, will be denominated in Swiss Francs. If the Swiss Franc depreciates against a foreign currency that is the main currency of a shareholder, the value of the Shares, expressed in such foreign currency or the currency equivalent of any dividend paid on the Shares or received in connection with the sale of the Shares, will decrease accordingly. Prospective investors should be aware that exchange rates between currencies are highly volatile and are determined by various factors, including supply and demand for currencies in the international foreign exchange markets, economic factors including inflation rates in the countries concerned, interest rates differences between the respective countries, economic forecasts, international political factors, currency convertibility, safety of making investments in the currency concerned, speculation and measures taken by governments and central banks (including, without limitation, the imposition of currency controls and restrictions). Foreign exchange fluctuations between a shareholder’s home currency and the Swiss Franc may adversely affect shareholders who intend to convert the proceeds from the sale of the Shares into their home currency and may potentially cause a partial or total loss of the relevant shareholder’s initial investment.

If analysts do not publish research or publish inaccurate or unfavourable research about our business, the market price and/or trading volume of the Shares could decline.

The trading market for the Shares is likely to be influenced by the research and reports that securities or industry analysts publish about the Group or its industry. If no or few securities or industry analysts cover the Group, the market price for the Shares could be adversely affected. If one or more of the analysts who cover the Group downgrades a recommendation with regard to the Shares, publishes inaccurate or unfavourable research about the Group or its business, ceases to cover the Group or fails to publish reports on it regularly, the market price and/or trading volume of the Shares would likely decline.

An active trading market for the Shares may not be sustainable.

If a market for the Shares is not sustained, it may be difficult for investors to sell their Shares at an attractive price or at all. We cannot predict the prices at which the Shares will trade. It is possible that in one or more future periods our results of operations may be below the expectations of public market analysts and investors, and, as a result of these and other factors, the price of the Shares may fall.
U.S. shareholders may not be able to obtain judgments or enforce civil liabilities against the Company or its directors or executive officers.

The Company is organised under the laws of Switzerland and has its seat in the Canton of Basel-Landschaft, Switzerland. A significant portion of its assets are located outside of the United States. In addition, some directors and certain of its executive officers are not residents of the United States and all of or a substantial portion of their assets are located outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon the Company or such persons or to enforce against them judgments of U.S. courts, including judgments in actions predicated upon the civil liability provisions of the federal securities laws of the United States. We have been advised by our Swiss counsel that there is doubt as to the enforceability in Switzerland of original actions, or in actions for enforcement of judgments of U.S. courts, of civil liabilities to the extent predicated upon the federal and state securities laws of the United States. 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 International Private Law of December 18, 1987, as amended (“PILA”). 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. Also, mandatory provisions of Swiss law may be applicable regardless of any other law that would otherwise apply.

Switzerland and the United States 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 United States in Switzerland is governed by the principles set forth in the PILA. This statute provides in principle that a judgment rendered by a non-Swiss court may be enforced in Switzerland only if (i) the non-Swiss court had jurisdiction pursuant to the PILA; (ii) the judgment of such non-Swiss court has become final and non-appealable; (iii) the judgment does not contravene Swiss public policy; (iv) the court procedures and the service of documents leading to the judgment were in accordance with the due process of law; and (v) no proceeding involving the same position and the same subject matter was first brought in Switzerland, or adjudicated in Switzerland, or was earlier adjudicated in a third state and this decision is recognisable in Switzerland.

We may have to deduct Swiss federal withholding tax on dividends.

Generally, Swiss federal 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 par value or (ii) assuming certain conditions are met, qualifying capital contribution reserves accumulated on or after 1 January 1997, as further described under “—Swiss federal withholding tax” beginning on page 153. There can be no assurance that we will have sufficient qualifying capital contribution reserves to pay dividends free from Swiss federal withholding tax, or that Swiss withholding 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 qualifying capital contribution reserves 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 qualifying capital contribution reserves becoming subject to additional corporate law or other restrictions. In addition, in the long term, the amount of registered share capital available to us for registered share capital reductions or qualifying capital contribution reserves available to us to pay out as distributions is limited. If we are unable to make a distribution through a reduction in par value or out of qualifying capital contribution reserves, we may not be able to make distributions without subjecting our shareholders to Swiss federal withholding tax.

We may be classified as a passive foreign investment company, which could result in adverse U.S. tax consequences to U.S. shareholders.

A non-U.S. corporation, such as the Company, will be classified as a passive foreign investment company (a “PFIC”) for U.S. federal income tax purposes for any taxable year, if either (i) 75% or more of its gross income for such year consists of certain types of “passive” income or (ii) 50% or more of the value of its assets (determined on the basis of a quarterly average) during such year produce or are held for the production of passive income. For purposes of PFIC determination, passive income is foreign personal holding company income (“FPHCI”), and principal forms of FPHCI generally include dividends, interest, royalties, rents, annuities, net gains from the sale or exchange of property producing such income and net foreign currency gains. When using the asset test to determine PFIC status, assets that produce both nonpassive and passive income are classified based on the relative proportion of income produced in each category. For this purpose, cash and assets readily convertible into cash are categorized as passive assets and the company’s unbooked intangibles associated with active business activity are taken into account as non-passive assets. In addition, a non-U.S. corporation will be treated as owning its proportionate share of the assets and earning its proportionate share of the income of any other corporation in which it owns, directly or indirectly, 25% or more (by value) of the stock.
Based on our current income and assets and the expected value of the Shares, it is possible that we could be a PFIC for our current taxable year and/or in future taxable years; there can be no assurance that we will not be considered a PFIC for any taxable year. Even if we are not currently a PFIC, changes in the nature of our income or assets, or fluctuations in the market price of Shares, may cause us to become a PFIC for future taxable years. Our non-passive income consists primarily of milestone payments, which are tied to discontinuous events and therefore are non-recurring. Based on our past experience, we expect the discontinuous pattern in revenue generation to continue. Among other factors, if, in a given taxable year, we earn little milestone or other non-passive income, our passive investment income could cause us to be or become classified as a PFIC for the current or future taxable years. In addition, in estimating the value of our goodwill and other unbooked intangibles, we have taken into account our anticipated market capitalization, which may fluctuate over time. Under the market capitalization method, the total asset value of a company would be considered to equal the fair market value of its outstanding shares plus outstanding indebtedness on a relevant testing date. Because our market price has fluctuated substantially and is likely to fluctuate in the future, and the market price may affect the determination of whether we will be considered a PFIC, there can be no assurance that we will not be considered a PFIC for any taxable year. Among other factors, if our market capitalization is less than anticipated or subsequently declines or where we do not expend significant amounts of cash for working capital or other purposes, we may be or become classified as a PFIC for the current or future taxable years.

If we are classified as a PFIC for any taxable year during which a U.S. Holder (as defined below) holds Shares, such U.S. Holder may incur significantly increased U.S. federal income tax, including having gains realized on the sale or other disposition of Shares treated as ordinary income, rather than capital gain, the loss of the preferential rate applicable to dividends received on the Shares by individuals who are U.S. Holders, having interest charges apply to distributions by us and the proceeds of sales and additional reporting requirements. If we are so classified during a U.S. Holder’s holding period, Shares will generally continue to be treated as shares in a PFIC for all succeeding years during which such U.S. Holder holds Shares, even if we cease to be a PFIC, unless certain elections are made. We do not expect to provide to U.S. Holders the information needed to report income and gain pursuant to a “qualified electing fund” election, which election would alleviate some of the adverse tax consequences of PFIC status, and we make no undertaking to provide such information in the event that we are a PFIC.

The Transaction may have adverse U.S. tax consequences for certain U.S. shareholders.

We expect the completed exchange of EnBiotix stock for Capital Increase Shares to constitute a fully taxable transaction for U.S. federal income tax purposes. As a result, each former EnBiotix Stockholder will generally recognize gain or loss as a result of the exchange in an amount equal to the difference between the amount of the aggregate consideration received by such stockholder plus the stockholder’s adjusted tax basis in the EnBiotix capital stock surrendered by such stockholder in the Transaction. For further information, reference is made to the section entitled “Certain Material U.S. Federal Income Tax Consequences” beginning on page 155.
### 2.2 GENERAL INFORMATION ON THE ISSUER

<table>
<thead>
<tr>
<th><strong>Issuer Name</strong></th>
<th>Spexis AG (formerly Polyphor Ltd)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Registered Office</strong></td>
<td>Hegenheimermattweg 125, CH-4123 Allschwil (Head Office)</td>
</tr>
<tr>
<td><strong>Legal Form</strong></td>
<td>Stock corporation</td>
</tr>
<tr>
<td><strong>Legal System</strong></td>
<td>Laws of Switzerland</td>
</tr>
<tr>
<td><strong>Date of Establishment</strong></td>
<td>4 November 1996 (Date of registration: 6 November 1996)</td>
</tr>
<tr>
<td><strong>Purpose</strong></td>
<td>The purpose of the Company, as stated in article 2 of the Articles, is the research, development and production of drugs, their materials and commercialization as well as all related activities. The Company may acquire participations in other companies. The Company may engage in any commercial, contractual, financial and all other activities which are apt to favour the purpose of the Company directly or indirectly. The Company may open branch offices in Switzerland and abroad, acquire participations in other companies or merge with such companies. The Company may provide guarantees or other securities with regard to liabilities or its subsidiaries. The Company may also acquire and sell real estate.</td>
</tr>
<tr>
<td><strong>Date of the Articles of Association</strong></td>
<td>October 28, 2021 / December 29, 2021</td>
</tr>
<tr>
<td><strong>Registration Information</strong></td>
<td>The Company is registered with the commercial register of the canton of Basel-Landschaft under the registration number CHE-108.535.251.</td>
</tr>
<tr>
<td><strong>Group Structure</strong></td>
<td>The Company has three direct subsidiaries: (i) Polyphor UK Ltd. (&quot;Polyphor UK&quot;) was founded in 2012 as wholly owned subsidiary of the Company with a nominal share capital as of the date of this Prospectus of GBP 1’000. (ii) Polyphor Deutschland GmbH (&quot;Polyphor DE&quot;) was incorporated on February 7, 2019 as wholly owned subsidiary of the Company with a nominal share capital as of the date of this Prospectus of EUR 25’000, both for the purpose of acting as an agent for the registration of its clinical trials in the European Union, whereas both subsidiaries have no other purpose nor employees or operations. (iii) With completion of the Capital Increase, EnBiotix, Inc. has also become a subsidiary of the Company. EnBiotix, Inc. itself has two subsidiaries, EnBiotix GmbH (a German limited liability company founded in 2016 with a nominal share capital of EUR 25’000) and EnBiotix (Switzerland) GmbH (a Swiss limited liability company founded in 2021 with a nominal share capital of CHF 20’000).</td>
</tr>
<tr>
<td><strong>Financial Year</strong></td>
<td>Pursuant to the Articles, the Company’s financial year is determined by the Board. Currently, the Company’s financial year corresponds to the calendar year.</td>
</tr>
</tbody>
</table>
2.3 BOARD OF DIRECTORS, MANAGEMENT & AUDITORS

Unless otherwise noted, the summary below is based on the versions of those documents that are in effect as of the date of this Prospectus.

A. The Board of Directors

1. General information

The Company’s articles of association (Statuten) (the “Articles”) provide that the board of directors (Verwaltungsrat) of the Company (the “Board”) shall consist of a minimum of three and a maximum of seven members. As of the date of this Prospectus, the Board has six members (each, a “Director”).

Members of the Board, including the chairperson of the Board (the “Chairman”), are appointed to and removed from the Board exclusively by the general meeting of shareholders. The maximum term of office for a Director is the time period starting at his or her election and ending upon completion of the following annual general meeting of shareholders (ordentliche Generalversammlung, “AGM”). Re-election is permitted. Except for the election of the Chairman and the members of the Compensation and Nomination Committee (as defined below) by the AGM, the Board organizes itself. The secretary of the Board does not need to be a Board member. If the office of the Chairman is vacant or if the Compensation and Nomination Committee is not complete, then the Board shall appoint an acting Board member as substitute for the time period until the next AGM. If the Company does not have an independent proxy, the Board shall appoint a substitute for the AGM.

The Board elects from among its members a deputy chairperson (the “Vice-Chairman”). According to the Articles and the organisational regulations (Organisationsreglement) (the “Organisational Regulations”), the Board meets at the invitation of the Chairman or, if he is unable to do so, of the Vice-Chairman or of another Director, as often as required, or whenever a Director indicates the reasons so requests in writing. Board resolutions are passed by a majority of the votes cast. In the case of a tie, the Chairman (or if absent or not voting, the person chairing the meeting) has the deciding vote. Subject to certain exceptions, the Board is quorate when a majority of its members are present. Resolutions may be passed by way of circulation in writing, provided that no Director requests oral deliberations or a meeting, respectively.

2. Power and Duties

The Board is responsible for the ultimate direction of the Company’s business and the supervision of the persons entrusted with the Company’s management. The Board represents the Company vis-à-vis third parties and manages all matters that have not been delegated to another corporate body by law, the Articles, the Organisational Regulations or other regulations.

The Board’s non-transferable and inalienable duties include: (i) the ultimate management of the Company and the giving of the necessary directives in this regard; (ii) the determination of the organization of the Company; (iii) the structuring of the accounting system, financial controls and financial planning; (iv) the appointment and removal of the persons entrusted with the management and representation of the Company; (v) the ultimate supervision of the persons entrusted with the management of the Company, in particular with respect to their compliance with applicable law, the Articles, regulations and directives; (vi) the preparation of the annual report as well as the preparation of shareholders’ meetings and the implementation of their resolutions; (vii) notification of the judge in case of over-indebtedness; (viii) the adoption of resolutions concerning increases in share capital to the extent that such power is vested in the Board (Article 651 (4) CO), including resolutions concerning the confirmation of capital increases and respective amendments to the Articles, and (ix) the non-transferable and inalienable duties and powers of the Board pursuant to the Swiss Federal Merger Act (Fusionsgesetz) and any other applicable law.

In accordance with and subject to Swiss law, the Articles and the Organisational Regulations, the Board has delegated the Company’s management to the chief executive officer of the Company (the “CEO”), who leads the top tier of the Company’s executive management (the “Executive Management”). For further information on the Executive Management see “—Executive Management” beginning on page 46).
3. Board committees

The Board has established a compensation and nomination committee (the “Compensation and Nomination Committee”, or “CNC”) and an audit and finance committee (the “Audit and Finance Committee”, or “AFC”).

a. Compensation and Nomination Committee

According to the Articles, the Compensation and Nomination Committee shall comprise at least three members of the Board. As of the date of this Prospectus, the CNC consists of three members. The members of the CNC are appointed by the Company’s general meeting of shareholders for a term of office extending until completion of the following AGM. Re-election is possible. In case of vacancies on the CNC, the Board shall appoint from among its members substitutes for a term of office extending until completion of the following AGM.

The CNC has the following duties:

**Compensation:** (i) to draw up principles for compensation of members of the Board of Directors and the Executive Committee and to submit them to the Board of Directors for approval; (ii) to propose to the Board of Directors the resolution to be submitted to the AGM for the maximum total compensation of the Board of Directors and Executive Committee; (iii) subject to and within the bounds of the maximum compensation approved by the AGM, to request approval by the Board of Directors of the individual remuneration packages to be paid to members of the Board of Directors and members of the Executive Committee; (iv) to request approval by the Board of Directors regarding the determination of the compensation-related targets for the Executive Committee; (v) to request approval by the Board of Directors regarding the adjustments to the articles of association relating to remuneration; (vi) to prepare the Compensation Report and submit it to the Board of Directors; (vii) to propose to the Board the contractual terms (if any) and compensation of the members of the Board (incl. the Chairman of the Board) and the CEO; (viii) to determine, upon proposal by the CEO, the terms of employment, promotion or termination of the other members of the Executive Committee (except for the CEO); (ix) to determine, upon proposal by the CEO, the grants and awards under incentive-based compensation plans and equity-based plans, in each case consistent with the terms of such plans, provided that such grants and awards shall be within the bounds of the maximum compensation approved by the annual shareholders’ meeting; (x) to review and discuss with the Board corporate succession plans for the CEO and other members of the Executive Management of the Company.

**Nomination:** (i) to establish and periodically review the qualification criteria for Board candidates with the goal of achieving a composition of the Board that collectively has the skills and experience needed to determine the strategy of the Company and oversee the management in executing the Company's strategy and achieving its objectives; (ii) to conduct the search for Board candidates based on the qualification criteria established by the CNC and any other criteria that the CNC may consider appropriate, and recommend suitable candidates to the Board to be nominated for election by the shareholders; (iii) to conduct the search for candidates for the position of the CEO and for the Board committees and to recommend suitable candidates for evaluation and appointment by the Board; (iv) to review and discuss with the Board corporate succession plans for the CEO and other members of the Executive Management of the Company.

b. Audit and Finance Committee

The Audit and Finance Committee (“AFC”) currently comprises two members of the Board. The members and the chairman of the AFC are appointed by the Board. The term of office of the members of the AFC is until the next AGM. Re-election is possible. The Board of Directors appoints the chairperson.

The AFC assists the Board in fulfilling its duties to supervise management. In particular, the AFC has the following duties and responsibilities as set out in the AFC regulation: (i) assess the effectiveness and independence of the external auditors (the statutory auditors and group auditors) and the internal controls; (ii) make a quality assessment of the financial risk management framework and monitor its implementation within the Company; (iii) decide upon audit work outside the regular audit of the yearly accounts, including operational audits and system audits; (iv) review the statutory and consolidated financial statements and discuss these with the CFO and, separately with the responsible person(s) of the external auditors; (v) decide whether the statutory and consolidated financial statements are to be recommended to the Board for presentation to the AGM; (vi) assess the performance and the fees charged by the external auditors and ascertain their independence; (vii) review the scope of the prospective external audit and the estimated audit fees; (viii) take notice of all comments including on critical accounting policies and practices from the external auditors; (ix) support the Board of Directors in preparing the decision on appointment and/or removal of the external auditors; (x) discuss with the CFO any legal matters (including the status of purchase, financial and business development agreements) that may have a
material impact on the Company’s financial statements or which could materially impact the Company’s balance sheet; (xi) evaluate the CFO’s principles and proposals for, and formulate recommendations to the Board of Directors in regards to financial planning; and (xii) review finance policy and operations in treasury, controlling, insurance, taxes and investment and acquisitions.

4. Members of the Board

The following tables set forth the name, function and committee membership of each Director as at the date of this Prospectus. For each Director a short description of each Director’s business experience and education is included.

Other than disclosed below, none of the Directors has any significant business connections with the Company.

<table>
<thead>
<tr>
<th>Name</th>
<th>Function</th>
<th>Committee memberships</th>
<th>First elected to Board</th>
<th>End of current period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jeffrey D. Wager</td>
<td>Chairman</td>
<td></td>
<td>2021</td>
<td>2022</td>
</tr>
<tr>
<td>Dennis Ausiello</td>
<td>Vice-Chairman</td>
<td></td>
<td>2021</td>
<td>2022</td>
</tr>
<tr>
<td>Bernard Bollag</td>
<td>Member</td>
<td>AFC (Chair)</td>
<td>2013</td>
<td>2022</td>
</tr>
<tr>
<td>Kuno Sommer</td>
<td>Member</td>
<td>CNC</td>
<td>2017</td>
<td>2022</td>
</tr>
<tr>
<td>Dan Hartman</td>
<td>Member</td>
<td>CNC</td>
<td>2021</td>
<td>2022</td>
</tr>
<tr>
<td>Robert Clarke</td>
<td>Member</td>
<td>CNC</td>
<td>2021</td>
<td>2022</td>
</tr>
</tbody>
</table>

Composition of the AFC as well as chairmanship of the CNC will be discussed and decided by the Board in the near future.

A short description is set out below of each Director’s business experience, education and activities. The business address for each Director is Hegenheimermattweg 125, 4123 Allschwil, Switzerland.

a. Jeffrey D. Wager, M.D.

Between 2011-2017, Jeff Wager was co-creator and board observer to Grupo Biotoscana SL, a Latin American specialty pharma roll-up financed by Advent International and Essex Woodlands Healthcare Ventures, focused on cancer, infectious and rare diseases, leading to its USD 1 billion 2017 IPO on sales of ~$240M and 600 staff in 10 LatAm markets. From 2006 – 2010, he formed and led Artisan Pharma, Inc. as its founding CEO, raising $53M, building the entire team and implementing a 750 patient, 17 country Phase 2b/3 study ultimately leading to Artisan’s acquisition by Asahi Kasei Pharma Corporation (Japan) in 2011. In 2000, Jeff formed Apeiron Partners, a FINRA-registered (via its affiliate Commonwealth PharmaSecurities LLC) life sciences investment bank focused on corporate spin-outs, M&A, corporate venture capital and principal investments. In the process, successfully completed six spin-outs, including Targacept, Inc. (NASD: TRGT), Artisan Pharma (from Asahi Kasei), Biocritica ($120M annual revenue Xigris® franchise from Eli Lilly) and KBI BioPharma (acquired by JSR Corporation (Japan)). Between 2003 and 2006, advised on the establishment and investment of Z-Cubes r.s.l., the €60M corporate venture fund of the Zambon Group, a privately held Italian pharmaceutical company. Between 1995-2000, Jeff was with Medical Science Partners, a Harvard-founded VC fund focused on forming spin-outs from the Harvard medical system, including deCODE, ICAgen, Inspire, Oravax (subsequently Acambis), ZYCOS, Inc. and Diatide, amongst others.

Jeff Wager began his career with a life sciences unit of the Bank of Tokyo, where he led business development, responsible for helping Japanese pharmaceutical clients establish overseas affiliates, design, and conduct overseas clinical development and structure strategic alliances. Jeff is also a co-founder and Chairman of Proterris, Inc., a phase 2 clinical-stage firm focused on therapeutic uses of low-dose gaseous and small molecule carbon monoxide for transplant, fibrosis, and oncology indications. Jeff Wager earned his MD from Rush Medical College and his MBA from the University of Chicago.

b. Kuno Sommer, Ph.D.

Kuno Sommer, Ph.D., today focuses on active board memberships in the life sciences sector as non-executive member. He is Chairman of the Board of the Bachem Group; the Sunstar group; TaglImmune; PDS Pathology Data Systems AG and Kenta Biotech AG. In his last operational role he headed the contract research division of Harlan Laboratories Ltd. From 2000 until 2006 he was CEO of Berna Biotech Ltd, which was sold to Crucell N.V. in 2006 (today Johnson & Johnson). Starting in 1986 at F. Hoffmann-La Roche Ltd he worked in various functions until 1999 and spent 4 years in the US. In his last position at Roche he became a member of the Executive Committee, responsible for the
Flavours and Fragrances division (today Givaudan Ltd). Dr. Sommer holds a Ph.D. in Business Administration from the University of Basel as well as an MBA.

e. **Bernard Bollag, MBA**

Bernard Bollag, MBA, is a senior finance executive with broad experience in corporate finance and capital markets. Bernard was CFO in private equity, until 2012, with HomeSun in the UK Renewable Energy sector, as well as internationally, across a broad portfolio of sectors and investments. Prior to that, Bernard acted as Syngenta's Group Treasurer, leading the company’s banking and capital markets funding as it spun off from Novartis and Astra-Zeneca. He then established the company’s financial risk practice for the group and its international affiliates. Prior to that, he led an international finance career at Unisys, progressing through planning, operations, investments and funding. He is the founder and MD of Beaufort Capital, a boutique supporting High Net Worth individuals with their private equity and alternative investments. Bernard Bollag holds an MBA in Finance from the Columbia Business School in New York and a BA in Economics from the Bar-Ilan University of Tel-Aviv.

d. **Dennis Ausiello, M.D.**

Dennis A. Ausiello is the Jackson Distinguished Professor of Clinical Medicine at Harvard Medical School. He is concurrently the Director, Emeritus of the Harvard Medical School’s M.D./Ph.D. Program. He is also Chair of Medicine, Emeritus, and Director of the Center for Assessment Technology and Continuous Health (CATCH) at Massachusetts General Hospital and previously served as an editor of Cecil’s Textbook of Medicine. Dennis Ausiello serves on the board of directors of Alnylam Pharmaceuticals and Seres Therapeutics, Inc. and previously served on the board of directors of Pfizer as its Lead Director, where he currently serves on its advisory board. Dennis received his B.S. from Harvard College and his M.D. from the University of Pennsylvania School of Medicine. Throughout his career, Dennis Ausiello has made substantial contributions to the study of epithelial biology in the areas of membrane protein trafficking, ion channel regulation and signal transduction, and has published numerous articles, book chapters and textbooks.

e. **Dan Hartman, M.D.**

Dan Hartman is currently Director, Integrated Development for the Gates Foundation, leading a team that provides technical expertise in product development to other foundation teams and their partners. He joined the foundation in 2012 in his current role and served simultaneously as interim director of the Malaria team from 2016 to 2018. Dan has extensive management and pharmaceutical experience. Before joining the foundation, he served for four years as president and CEO of Great Lakes Drug Development, a consulting company providing strategic and operational support for early drug development projects. Previously, he served as senior vice president of product development at deCODE genetics, executive director of Pfizer Global Research and Development, and vice president of global clinical development at Esperion Therapeutics, and he held clinical research positions at Eli Lilly & Company. He has also provided consultation to the biopharmaceutical venture capital community and serves as a member/advisor on several nonprofit boards. Dan served as a member of the National Institutes of Health’s National Center for Advancing Translational Sciences and Cures Acceleration Network advisory board from 2016 to 2019 and was president of the American Society for Clinical Pharmacology & Therapeutics. Dan Hartman has received numerous awards, including Inventor of the Year from the Intellectual Property Owners Association. He received his bachelor’s degree from Calvin College and his medical degree from Wayne State University. Dan was trained in internal medicine and completed a fellowship in pulmonary medicine at Indiana University, where he also served as chief medical resident.

f. **Robert Clarke, Ph.D.**

Robert Clarke, has served as Chief Executive Officer / Board Member / Co-founder of Kinaset Therapeutics since 2020. He was previously Chief Executive Officer at Pulmatrix Inc. (NASDAQ: PULM), a clinical-stage respiratory drug delivery company, from 2012 to 2019 and successfully brought the company public in 2015. He joined Pulmatrix in 2004 as the first Ph.D.-level scientist and was appointed Chief Scientific Officer in 2010. In that role he was focused on developing the Pulmatrix technologies for the treatment of respiratory diseases. During his tenure as Chief Executive Officer, Pulmatrix raised more than $50 million in public equity, $80 million in venture capital funding and more than $10 million in non-dilutive funding to support the company’s development programs. Prior to his tenure at Pulmatrix, Robert was Associate Director, Life Sciences at Alkermes. He holds Board seats at several institutions including Johns Hopkins University and Boston University College of Engineering. Robert Clarke holds a Ph.D. in physiology from Johns Hopkins University and completed his post-doctoral training in respiratory biology at Brigham and Women’s Hospital and Harvard University.
5. Convictions/proceedings

There have been no convictions or sanctions against any of the Directors listed in “—Members of the Board” beginning on page 42 for finance or business-related crimes in the last five years, and no legal proceedings against any such Director by statutory or regulatory authorities (including designated professional associations) are ongoing.

B. Executive Management

1. General information

In accordance with Swiss law, the Articles and the Organisational Regulations and subject to those matters that lie within the responsibility of the Board by law, the Articles and the Organisational Regulations, the Board has delegated the executive management of the Company to the CEO. The CEO also chairs the Executive Management.

As per the Organisational Regulations, the Executive Management consists of the CEO, the Chief Financial Officer (the “CFO”), the Chief Scientific Officer (the “CSO”), the Chief Medical & Development Officer (the “CMO”) and the Chief Operating Officer (“COO”). The CEO is appointed by the Board upon proposal by the CNC. The other members of the Executive Management are appointed by the Board upon proposal by the CEO.

The CEO is responsible for, among other things, initiating and implementing the strategy of the Group, managing and monitoring his direct reports, including the other members of the Executive Management, preparing, convening and chairing meetings of the Executive Management, deciding in the case of overlapping interests of business or functional units, and updating the Chairman and the Board on the course of business of the Group.

The COO is responsible for, among other things, assisting the CEO and other members of Executive Management with formulating and implementing the strategy of the Group, coordinating implementation of the same with other members of the Executive Management, for management of the human resources and legal functions of the Company, and to support the CFO with the coordination, implementation and monitoring of the principles and directives regarding financing planning, accounting and financial control of the Group, facilities and PPE, and associated financial control mechanisms.

The CFO is responsible for, among other things, the Group’s finances and administration, in particular for the implementation and monitoring of the principles and directives regarding financial planning, accounting and financial control of the Group, appropriate financing of the Group and its units and subsidiaries and establishing the necessary control mechanisms, including risk management.

Under the supervision of the Board and under the leadership of the CEO, the Executive Management conducts the operational management of the Group in accordance with the Organisational Regulations and the function chart. The members of the Executive Management report to the CEO. The CFO may give directions to other members of the Executive Management, except the CEO, within his area of responsibility.

2. Members of the Executive Management

The following tables set forth the name and principal position of each member of the Executive Management the date of this Prospectus.

<table>
<thead>
<tr>
<th>Name</th>
<th>Appointed</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jeffrey D. Wager</td>
<td>2021</td>
<td>CEO</td>
</tr>
<tr>
<td>Hernan Levett</td>
<td>2019</td>
<td>CFO</td>
</tr>
<tr>
<td>Juergen Froehlich</td>
<td>2021</td>
<td>CMO</td>
</tr>
<tr>
<td>Stephan Wehselau</td>
<td>2021</td>
<td>COO</td>
</tr>
</tbody>
</table>

A short description is set out below of each Executive Management member’s business experience, education and activities. The business address for each member of the Executive Management is Hegenheimermattweg 125, 4123 Allschwil, Switzerland.
a. **Jeffrey D. Wager, M.D.**

Between 2011-2017, Jeff Wager was co-creator and board observer to Grupo Biotoscana SL, a Latin American specialty pharma roll-up financed by Advent International and Essex Woodlands Healthcare Ventures, focused on cancer, infectious, and rare diseases, leading to its USD 1 billion 2017 IPO on sales of ~$240M and 600 staff in 10 LatAm markets. From 2006 – 2010, he formed and led Artisan Pharma, Inc. as its founding CEO, raising $53M, building the entire team and implementing a 750 patient, 17 country Phase 2b/3 study ultimately leading to Artisan’s acquisition by Asahi Kasei Pharma Corporation (Japan) in 2011. In 2000, Jeff formed Apeiron Partners, a FINRA-registered (via its affiliate Commonwealth PharmaSecurities LLC) life sciences investment bank focused on corporate spin-outs, M&A, corporate venture capital and principal investments. In the process, successfully completed six spin-outs, including Targacept, Inc. (NASD: TRGT), Artisan Pharma (from Asahi Kasei), Biocritica ($120M annual revenue Xigris® franchise from Eli Lilly) and KBI BioPharma (acquired by JSR Corporation (Japan)). Between 2003 and 2006, advised on the establishment and investment of Z-Cube s.r.l., the €60M corporate venture fund of the Zambon Group, a privately held Italian pharmaceutical company. Between 1995-2000, Jeff was with Medical Science Partners, a Harvard-founded VC fund focused on forming spin-outs from the Harvard medical system, including deCODE, IC.Agen, Inspire, Oravax (subsequently Acambis), ZYCOS, Inc. and Diatide, amongst others.

Jeff Wager began his career with a life sciences unit of the Bank of Tokyo, where he led business development, responsible for helping Japanese pharmaceutical clients establish overseas affiliates, design, and conduct overseas clinical development and structure strategic alliances. Jeff is also a co-founder and Chairman of Proterris, Inc., a phase 2 clinical-stage firm focused on therapeutic uses of low-dose gaseous and small molecule carbon monoxide for transplant, fibrosis, and oncology indications. Jeff Wager earned his MD from Rush Medical College and his MBA from the University of Chicago.

b. **Hernan Levett**

Hernan Levett joined the Company from NASDAQ listed company Auris Medical where he served as CFO. He started his Pharma international career at Novartis where he held roles of increasing responsibility in various countries and regional functions and as CFO for one of its affiliates. Following a 10 year tenure at Novartis, Mr Levett continued to build his experience in biotech joining InterMune where he served as VP of Finance. Mr. Levett brings over 25 years of finance and pharma / biotech experience at leading companies and holds a CPA degree from the University of Buenos Aires, Faculty of Economics.

c. **Juergen Froehlich, M.D.**

Juergen Froehlich’s career in biotechnology spans three decades and covers a broad range of drug development projects and approvals across therapeutic areas such as cerebrovascular, cardiovascular, pulmonary, metabolic, oncologic, genetic and infectious disorders. He has worked with biologics, peptides, small molecules, and RNA therapeutics at companies including Boehringer Ingelheim, Genentech, Quintiles, Bristol-Myers-Squibb, Ipsen, Vertex, Aradigm and Genevant. Since 2005, he has mainly been involved with rare diseases including bronchiectasis, cystic fibrosis, non-tuberculous mycobacteria infection, acromegaly, neuroendocrine tumors, urea cycle disorders, cervical dystonia and hemophilia. Juergen was instrumental in obtaining successful marketing authorizations in the US, EMA and other countries for ODD designated products in cystic fibrosis, acromegaly and cervical dystonia. As Chief Medical Officer and Head of Regulatory Affairs of Aradigm Corporation, he implemented a Phase 3 trial program with inhaled liposomal ciprofloxacin in patients with bronchiectasis and chronic Pseudomonas aeruginosa lung infection and was an invited panel member at a U.S. Food and Drug Administration (FDA) workshop in 2018 for inhaled antibiotics in cystic fibrosis and bronchiectasis. Juergen Froehlich is also serving as a Board member of Appili Therapeutics, a publicly traded infectious disease company in Canada. He received his MD from the Medical School at Wuerzburg University, Germany, is a Diplomate of the American Board of Clinical Pharmacology and holds an executive MBA degree from the Graduate School of Business Administration in Zurich, Switzerland.

d. **Stephan Wehselau**

Stephan Wehselau is a serial entrepreneur with over 20 years' C-level experience as CFO, COO and CEO, having raised over $380 million in venture capital and private equity from high-profile international funds in the US, Europe and Asia in the life sciences & IT industries. Stephan is CFO and member of the Advisory Board of EnBiotix Inc. and Proterris Inc. During the last 22 years Stephan has been involved in the foundation of 5 Life Science companies (BioPharma, Medical Devices and Diagnostic) Xantos Biomedicine AG, JenaValve Technology Inc., Spherotec GmbH, Tube Pharmaceuticals GmbH and Granite Bio AG where he holds different executive and non-executive positions. He was a member of the Board
of Directors of Nasca Cell AG a public listed company in Germany for 4 years. Before Stephan entered into the Start-Up and VC / PE Industry he started his career in the pharma industry and worked first for Boehringer Mannheim and later on for Roche. Since 2015 he entered also into the ICT and Tech industry. Before he joined Advertima AG in 2020 he was from 2015 – 2018 CFO of censhare AG, an agile software company of the next generation marketing cloud, integrating different applications and functions. Stephan Wehselau studied economics and and holds a master’s degree from the University of Bremen, Germany.

3. Convictions/proceedings

There have been no convictions or sanctions against any of member of the Executive Management listed in “— Members of the Executive Management” beginning on page 46 for finance or business-related crimes in the last five years, and no legal proceedings against any such member by statutory or regulatory authorities (including designated professional associations) are ongoing.

C. Compensation

1. Overview

The Company is subject to the Ordinance against Excessive Compensation in Public corporations (Verordnung gegen übermässige Vergütungen bei börsenkotierten Aktiengesellschaften) of November 20, 2013 (the “Compensation Ordinance”), and the Directive on Information Relating to the Corporate Governance issued by the SIX Swiss Exchange (the “Corporate Governance Directive”).

The Compensation Ordinance requires a “say on pay” approval mechanism for the compensation of the Board and the Executive Management pursuant to which the shareholders must vote on the compensation of the Board and the Executive Management on an annual basis. In accordance therewith, the Articles provide that the general meeting of shareholders must, each year, vote separately on the proposals by the Board regarding the aggregate amounts of:

(a) the compensation of the Board of Directors for the next term of office, whereby the cash-based and the equity— based compensation may be voted in in two separate votes;

(b) a possible additional compensation of the Board of Directors for the preceding business year;

(c) the compensation of the Executive Committee for the next business year after the ordinary general meeting, whereby the cash-based and the equity-based compensation may be voted in in two separate votes.

If the AGM refuses to approve a respective motion by the Board, the Board may either submit a new motion at the same meeting or determine a maximum total remuneration or several maximum partial remunerations, subject to the relevant principles of the compensation, or submit a new motion to the next AGM for approval. The Company may pay remunerations within the framework of the maximum total or partial remuneration and subject to the approval by the AGM.

If new members of the Executive Management are appointed after the AGM has approved the maximum total compensation for members of the Executive Management for the year in question, the new members may be paid an additional amount for the period until the next AGM. The additional amount payable to all new members of the Executive Management may not exceed 50 percent of the respective total compensation already approved by the AGM. The additional compensation may only be paid if the total compensation amount that has been approved by the AGM for the compensation of the members of the Executive Management is insufficient to compensate the newly appointed members. The AGM is not required to vote on this additional amount.

The Compensation Ordinance further requires the Company to define in its Articles the principles for the determination of the compensation of the Board and the Executive Management. These principles have been included in the Articles as described further below.

The Compensation Ordinance also contains compensation disclosure rules. Pursuant to these rules, the Company is required to prepare an annual compensation report. The compensation report will, among other things, include (i) the compensation of the Directors on an aggregate and on an individual basis and (ii) the compensation of the members of the Executive Management on an aggregate basis as well as the amount for the highest paid member of the Executive Management. For further details see “—Compensation Ordinance” beginning on page 93. Pursuant to the Corporate Governance Directive, the Company is required to disclose basic principles and elements of compensation and shareholding
programs for both acting and former Directors and members of the Executive Management as well as the authority and procedures for determining such compensation.

In accordance with the Compensation Ordinance, the Articles provide that the members of the Board and the Executive Management may not be granted any loans, credits or securities. Excepted are advances in the maximum amount of CHF 200’000 per person for attorneys’ fees, court and other similar costs required for the defence of third-party liability claims.

The Compensation Ordinance finally prohibits certain types of compensation payments to Directors and members of the Executive Management, see “—Compensation Ordinance” beginning on page 93.

2. Compensation principles and elements

The Articles set out the principles for the elements of the compensation of the Directors and members of the Executive Management. The compensation of the Directors and members of the Executive Management consists of fixed and variable compensation elements as well as further compensation elements and benefits. The total compensation shall take into account the position and level of responsibility of the recipient.

The performance-related remuneration depends on the Company’s business success and the individual performance of the member of the Executive Management based on the achievement of pre-determined targets during a business year. The Board determines annually at the beginning of each relevant business year the decisive targets and their weighting upon proposal by the CNC. The amount of the performance-related remuneration for each member of the Executive Management is determined by the Board and may not exceed 100 percent of the respective individual fixed remuneration for the same year.

3. Incentive and equity-based plans

ESOP2013

In 2013, the Company established an Employee Stock Option Plan (“ESOP2013”) that entitles key management personnel and other employees to obtain rights to acquire options. Under this plan, holders of vested options are entitled to purchase shares at a price of CHF 5.00. The ESOP2013 was amended in 2017 and no new options are granted thereunder.

Based on this plan, the Company granted no stock options to employees in 2020, 65’850 stock options 2019 and 31’533 stock options in 2018. The fair value of the stock options has been determined at the grant date based on either the calculated share price of the Company’s last capital increase (prior to its listing) or the closing share price on SIX Swiss Exchange using the Black-Scholes model. The maximum term for exercising the options is 10 years.

ESOP2013 (Board)

During 2019 the Company established an additional share option program exclusively for Directors. This share option program is based on the terms of the ESOP2013 but with a vesting period until the annual general meeting 2020 for 100% of the granted options. Based on this plan the company granted no stock options to Directors in 2020, 7’750 stock options in 2019 and no stock options in 2018. Optionees are not entitled to sell any shares purchased under this specific share option plan within a period of three years after the vesting period has lapsed.

ESOP2019

During the third quarter 2019 the Company introduced a new Employee Stock Option Plan (“ESOP2019”, together with the ESOP2013 the “ESOP”) under which eligible persons like members of the Board, the Executive Management and employees of the Group obtain rights to acquire options. Under this new plan, holders of vested options are entitled to purchase shares at a price which is equal to the Company’s average share price of the last twenty trading days prior to grant. Based on this plan, the Company granted 575’989 options; thereof 35’500 to Directors in 2021, 26’500 to Directors in 2020, 27’500 stock options to Directors in 2019 and no stock options in 2018. The fair value of the stock options has been determined at the grant date based on the closing share price on SIX Swiss Exchange using the Black-Scholes model. The maximum term for exercising the options is 7 years.
Common Terms

Under both the ESOP2013 and ESOP2019, a quarter (25%) of the stock options vest after a period of one year from the grant date, thereafter, each calendar quarter 6.25% of the total stock options vest for twelve calendar quarters with an accelerated vesting in case of a change of control (including upon closing of the Transaction). When granting options, the Board may deviate from this vesting schedule in individual cases. In general for the Board, 25% of the stock options vest on the Grant Date, thereafter 25% vest on each of the three consecutive calendar quarters following the Grant Date. In addition, such options are subject to a three year lock up. During such vesting periods, employee stock options may lapse or become forfeited subject to certain conditions as defined by the ESOP2013 and the ESOP2019. Such conditions relate to death, retirement, disability, and termination of, or resignation from, employment. In such cases only the vested options, as well as options for certain pre-specified periods, may be exercised, while the remaining options lapse.

Outstanding Options

As of the date of this Prospectus, the number of outstanding options under the ESOP2013 and ESOP2019 are as follows:

<table>
<thead>
<tr>
<th>Plan</th>
<th># options outstanding</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESOP2013</td>
<td>116'734</td>
</tr>
<tr>
<td>ESOP2019</td>
<td>402'774</td>
</tr>
<tr>
<td>Total</td>
<td>519'508</td>
</tr>
</tbody>
</table>

D. Ownership of Shares and options

Shares held by Directors or members of the Executive Management are subject to the transfer restrictions as described in “Transfer of Shares and transfer restrictions” beginning on page 89. In addition, Swiss corporate law, stock exchange rules, insider regulations and other laws and regulations, as well as the articles of association or relevant internal guidelines of the Company may further restrict or prohibit the acquisition of Shares by Directors or members of the Executive Management or the transfer or other disposal of Shares. Such restrictions apply equally to any acquisition of Shares upon exercise of any Option. Except in the case of death, Options may not be sold, assigned, pledged, transferred or disposed of in any manner without prior written approval of the Company. If the Company agrees to a transfer of Options, the Company may impose additional conditions.

1. Directors

The table below shows the number of Shares and options that each Director owns at the date of this Prospectus.

<table>
<thead>
<tr>
<th>Name</th>
<th>Shares</th>
<th>Options</th>
<th>% of Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kuno Sommer(3)</td>
<td>5'000</td>
<td>19'000</td>
<td>0.05</td>
</tr>
<tr>
<td>Bernard Bollag(4)</td>
<td>5'240</td>
<td>14'250</td>
<td>0.04</td>
</tr>
<tr>
<td>Jeffrey D. Wager(5)</td>
<td>9'159'576</td>
<td>0</td>
<td>19.75</td>
</tr>
<tr>
<td>Dennis Ausiello</td>
<td>488'379</td>
<td>0</td>
<td>1.05</td>
</tr>
<tr>
<td>Robert Clarke</td>
<td>87'211</td>
<td>0</td>
<td>0.19</td>
</tr>
<tr>
<td>Dan Hartman</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

(1) The options are granted and are outstanding by the Company as per the ESOP (see “—Incentive and equity-based plans” beginning on page 49).

(2) Aggregate of shares and options, based on the 47'531'938 Shares outstanding at the date of this Prospectus (of which 46'375'777 have already been recorded in the commercial register).

(3) The terms of the options held by Kuno Sommer are as follows:

<table>
<thead>
<tr>
<th># of options</th>
<th>Vesting start date</th>
<th>Strike price per option</th>
<th>Exercise period</th>
</tr>
</thead>
<tbody>
<tr>
<td>1'250</td>
<td>April 6, 2018</td>
<td>CHF 5.00</td>
<td>10th anniversary from the vesting start date</td>
</tr>
<tr>
<td>1'250</td>
<td>May 1, 2019</td>
<td>CHF 5.00</td>
<td>10th anniversary from the vesting start date</td>
</tr>
<tr>
<td>3'000</td>
<td>March 31, 2020</td>
<td>CHF 5.69</td>
<td>7th anniversary from the vesting start date</td>
</tr>
<tr>
<td>4'500</td>
<td>June 30, 2020</td>
<td>CHF 7.22</td>
<td>7th anniversary from the vesting start date</td>
</tr>
</tbody>
</table>
The terms of the options held by Bernard Bollag are as follows:

<table>
<thead>
<tr>
<th># of options</th>
<th>Vesting start date</th>
<th>Strike price per option</th>
<th>Exercise period</th>
</tr>
</thead>
<tbody>
<tr>
<td>1'000</td>
<td>April 6, 2018</td>
<td>CHF 5.00</td>
<td>10th anniversary from the vesting start date</td>
</tr>
<tr>
<td>1'000</td>
<td>May 1, 2019</td>
<td>CHF 5.00</td>
<td>10th anniversary from the vesting start date</td>
</tr>
<tr>
<td>2'500</td>
<td>March 31, 2020</td>
<td>CHF 5.69</td>
<td>7th anniversary from the vesting start date</td>
</tr>
<tr>
<td>3'250</td>
<td>June 30, 2020</td>
<td>CHF 7.22</td>
<td>7th anniversary from the vesting start date</td>
</tr>
<tr>
<td>6'500</td>
<td>April 7, 2021</td>
<td>CHF 7.46</td>
<td>7th anniversary from the vesting start date</td>
</tr>
</tbody>
</table>

Jeffrey D. Wager holds 1'864'082 Shares directly and 7'295'494 Shares indirectly through Apeiron Holdings Limited.

2. Executive Management

The table below shows the number of Shares and options that each current member of the Executive Management owns at the date of this Prospectus.

<table>
<thead>
<tr>
<th>Name</th>
<th>Shares</th>
<th>Options(1)</th>
<th>% of Company(2)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hernan Levett(3)</td>
<td>0</td>
<td>42'938</td>
<td>0.09</td>
</tr>
<tr>
<td>Jeffrey D. Wager(4)</td>
<td>9'159'576</td>
<td>0</td>
<td>19.75</td>
</tr>
<tr>
<td>Juergen Froehlich</td>
<td>377'203</td>
<td>0</td>
<td>0.81</td>
</tr>
<tr>
<td>Stephan Wehselau(5)</td>
<td>357'563</td>
<td>0</td>
<td>0.77</td>
</tr>
</tbody>
</table>

(1) The options are granted and outstanding by the Company as per the ESOP (see “Incentive and equity-based plans” beginning on page 49).

(2) Aggregate of shares and options, based on the 47'531'938 Shares outstanding at the date of this Prospectus (of which 46'375'777 have already been recorded in the commercial register).

(3) The terms of the options held by Hernan Levett are as follows:

<table>
<thead>
<tr>
<th># of options</th>
<th>Vesting start date</th>
<th>Strike price per option</th>
<th>Exercise period</th>
</tr>
</thead>
<tbody>
<tr>
<td>18’338</td>
<td>March 31, 2020</td>
<td>CHF 5.69</td>
<td>7th anniversary from the vesting start date</td>
</tr>
<tr>
<td>24’600</td>
<td>March 31, 2021</td>
<td>CHF 7.46</td>
<td>7th anniversary from the vesting start date</td>
</tr>
</tbody>
</table>

(4) Jeffrey D. Wager holds 1'864'082 Shares directly and 7'295'494 Shares indirectly through Apeiron Holdings Limited.

(5) Stephan Wehselau holds his Shares indirectly through his wholly owned Company NIK Beteiligungsgesellschaft UG.

E. Loans, credits, post-retirement benefits

As of the date of this Prospectus, the Company has not granted any loans, credits or post-retirements benefits to Directors or members of the Executive Management or any closely related persons, except the following loans granted by EnBiotix in connection with the exercise of stock options prior to the Transaction:

<table>
<thead>
<tr>
<th>Name</th>
<th>Loan Amount (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jeffrey D. Wager</td>
<td>4'838.33</td>
</tr>
<tr>
<td>Ben Perrone</td>
<td>23'500.00</td>
</tr>
<tr>
<td>NIK Beteiligungsgesellschaft (Stephan Wehselau)</td>
<td>31'925.00</td>
</tr>
<tr>
<td>Juergen Froehlich</td>
<td>11'800.00</td>
</tr>
<tr>
<td>Robert Clarke</td>
<td>29'500.00</td>
</tr>
</tbody>
</table>
F. Transactions with Directors or members of the Executive Management

For information regarding transactions with Directors or members of the Executive Management, see “—Incentive and equity-based plans” beginning on page 49.

G. Agreements regarding compensation with Directors or members of the Executive Management

The CEO and the members of the Executive Management are employed under employment contracts of unlimited duration and are subject to a notice period of a maximum of twelve months. They are not entitled to any severance packages or termination payments.

Non-compete agreements for the time following termination of an employment contract and the associated compensation are permitted to the extent that this is justified from a business perspective. The compensation for such a non-compete obligation may not exceed in total the average of the (fixed) compensation paid to the respective member of the executing management during the last year.

H. Mandates outside the Company

As required by the Compensation Ordinance, the Articles limit the number of positions on the supreme governing body of companies other than the Company or its subsidiaries. According to article 34 of the Articles, the number of mandates held by a Board member in the top management and administrative bodies of a legal entity outside of the Group that is entered in the commercial register or a comparable foreign register is limited to 15 mandates in profit-making entities of which not more than seven can be in listed entities. Acceptance by a member of the Executive Management of a mandate in the management or administrative bodies of listed entities or profit-making, non-listed entities requires the prior approval of the Board. The maximum number of mandates per member of the Executive Management is limited to three mandates in profit-making entities of which not more than two can be in a listed entity. Mandates in companies controlled by the Company or performed by order of the Company as well as mandates in associations, organizations and legal entities with a public or charitable purpose, foundations, trusts and employee pension foundations are excluded from above restrictions. However, no Director or member of the Executive Management may hold more than five such mandates.

I. Conflicts of interest

Swiss law does not provide for a general provision regarding conflicts of interest. However, the CO contains a provision that requires directors and senior officers of a company to safeguard such company’s interests and imposes a duty of care and loyalty on the company’s directors and senior officers. This rule is generally understood as disqualifying members of the board of directors and senior officers from decisions that directly affect them. Members of the board of directors and senior officers are personally liable to the company, its shareholders and its creditors for damages caused by wilful or negligent violation of their duties. In addition, Swiss statutory law contains a provision under which payments made to a shareholder or a Board member or any person associated with such shareholder or Board member, other than at arm’s length, must be repaid to the company if the recipient of such payment was acting in bad faith (for further information, see “—Conflicts of interest, management transactions” beginning on page 90).

J. Auditors

Since 2005, the Company’s statutory auditors have been Ernst & Young AG, Aeschengraben 27, 4051, Basel (“EY’’). EY are subject to supervision of the Swiss Federal Audit Oversight Authority (Revisionsaufsichtsbehörde, RAB).

The Annual Consolidated Financial Statements and the statutory financial statements, which are incorporated by reference in this Prospectus, have been audited by EY, as stated in their respective reports thereon.

According to the Articles, the auditors are elected (or re-elected, as the case may be) at each annual general meeting of shareholders for a term of office until the completion of the following annual general meeting.
2.4a BUSINESS ACTIVITIES AND PROSPECTS

A. Portfolio and Pipeline - Overview

Spexis is a research-driven clinical-stage biopharmaceutical company based in Allschwil, Switzerland with a strategic focus on rare diseases and oncology. As from completion of the Capital Increase, Polyphor and EnBiotix, a privately held late clinical-stage rare disease company currently focused on products for rare, chronic respiratory diseases, merged, whereby Polyphor acquired substantially all of the outstanding capital stock of EnBiotix in exchange for shares of Polyphor common stock. Therefore the portfolio and pipeline of the combined company going forward will be a combination of the two legacy companies, Polyphor and EnBiotix, and Polyphor has been renamed to Spexis AG and begins trading under the new ticker symbol SPEX as from the date of this Prospectus.

a. Company's pipeline

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- ColiFin® which EnBiotix has in-licensed from PARI Pharma GmbH, a global leader in nebulized therapies, for worldwide rights ex-Europe. Approved in Europe since 2010 as a front-line therapy for lung infections in cystic fibrosis (CF), ColiFin® has a proven safety, efficacy and commercial track record which the Company will leverage towards the U.S. and global markets - and both within and outside the field of CF.

- Inhaled murepavadin, a novel class inhaled antibiotic specifically targeting Pseudomonas aeruginosa (PA), is being developed for the treatment of PA infection in people with CF and is beginning Phase 1 development using eFlow® Technology nebulizer (PARI Pharma GmbH).

- EBX-002, a combination of amikacin (AMK) and a potentiator molecule for nontuberculous mycobacterial (NTM) infections which preclinical studies to date have shown potential for superior activity compared to ARYKACE®.

- Balixafortide, a potent and highly selective blocker of CXCR4. Following the closure of its Phase 3 program in advanced breast cancer, additional oncology and non-oncology indications for balixafortide will be evaluated in collaboration with Fosun Pharma who owns China rights.

- New CXCR4 inhibitor program focused on orphan, hematological malignancies.

- Preclinical OMPTA BamA and LptA programs funded by CARBX targeting WHO Priority 1 bacterial infections planned to be developed for hospital acquired bacterial infections.
- Company aims to in-license or acquire other rare disease and oncology assets that will consolidate its position in these therapeutic areas.

b. Clinical trials planned in the near-term

The Company plans to advance its pipeline through multiple clinical trials and strategic transactions to build a rare disease and oncology company, as follows:

- Initiation of a single Phase 3 trial of ColiFin® for the treatment of CF patients in 2022, upon completion of which the Company plans to seek FDA approval in the US.
- Initiation of a Phase 1 trial of inhaled murepavadin in Q4 2021 to advance development for the treatment of people with CF.

c. Proprietary macrocycle-based discovery platform

We are committed to discover and develop best-in-class molecules, leveraging our leading macrocyclic peptide technology platform. Macrocycles are medium-sized cyclic molecules that complement the chemical space between small molecules and large biologics, and are designed to address complex and challenging extra- and intracellular biological targets, while retaining the advantages of small molecules. Compared to traditional peptides used in the pharmaceutical industry, macrocyclic engineered peptides have the advantage of being more stable towards degrading enzymes and more selective and potent towards protein targets with therapeutic value.

In collaboration with the University of Zurich, the Company has established a proprietary macrocycle-based discovery platform, based on two complementary technologies: PEMfinder® and MacroFinder®. Protein Epitope Mimetics (PEM) are conformationally constrained cyclopeptides mimicking the biologically most relevant protein surface epitopes such as the β-hairpin and α-helix motifs. PEMfinder® is a highly diverse library derived from sequences of many bioactive peptides including peptide hormones, ligands of G-protein coupled receptors and ion channels, and host defense peptides. The MacroFinder® concept is based on non-peptidic, cell-permeable and orally bioavailable macrocycles which can address complex and challenging intracellular targets.

We are developing a new class of antibiotics, the Outer Membrane Protein Targeting Antibiotics (OMPTA), which we discovered using our PEM platform and which constitutes a novel class of antibiotics. OMPTAs are characterized by a low rate of resistance development and offer new treatment options for patients with difficult-to-treat infections caused by Gram-negative pathogens, including multidrug-resistant (MDR) and extensively drug-resistant (XDR) strains. The lead product candidate of the OMPTA class is the inhaled formulation of murepavadin, a pathogen specific antibiotic in Phase 1 to treat chronic Pseudomonas aeruginosa infections in people with cystic fibrosis (CF). The Clinical Trial Authorization (CTA) was granted in December 2020 and the patient enrollment in the Phase 1 study is expected to start in Q4 2021. In addition we are developing BamA antibiotics within the OMPTA class, a medium spectrum antibiotic targeting the most resistant MDR strains of all Gram-negative ESKAPE pathogens, and LptA antibiotics, a narrow spectrum Gram-negative antibiotic program within the OMPTA class targeting specifically Enterobacteriaceae, one of the most common and resistant pathogens.
Balixafortide (POL6326), is a potent and highly selective blocker of CXCR4 which was investigated in a Phase 3 clinical program in combination with eribulin in patients with advanced breast cancer. The study is currently being closed due to not meeting the co-primary and the primary endpoint of the study progression respectively, objective response rate (ORR) and free survival (PFS). We plan to explore other oncology and non-oncology indications with orphan disease designation potential for balixafortide in collaboration with Fosun Pharma who owns China rights.

d. AMPT discovery platform

On November 03, 2016, EnBiotix Inc. completed the asset acquisition of AMP Therapeutics GmbH (“AMPT”), an anti-microbial peptide portfolio company of Boehringer Ingelheim Venture Fund and Novartis Venture Fund. Antimicrobial peptides (AMPs) are found in virtually every species, from microbes to humans. They comprise the first line of defense against infection through the innate immune system. The AMPT portfolio of unique antimicrobial peptides overcomes many of the issues associated with AMPs as anti-bacterial therapeutics, most notably potency, spectrum, stability and toxicity. The unique mechanism of action of these compounds positions these molecules as a promising new class of anti-bacterials.

e. Anti-Persisters platform:

EnBiotix’s anti-persisters platform aims to develop potentiators that sensitize “transiently resistant” or persistent bacteria to antibiotics, enabling the effective treatment of debilitating chronic infections. Bacteria can, in response to antibiotic treatment, enter into a metabolically dormant persister state. This sub-population of non-growing bacteria are genetically identical to the population from which they emerge, and serve as the nidus for future re-infections. Recurrent infections that are attributable to bacterial persisters occur in a wide variety of indications (e.g., biofilm-related lung, urinary tract, device-associated, and wound infections) and are caused by an array of bacterial pathogens.

EBX-001 is a combination of the aminoglycoside tobramycin (TOB) with fumarate as a potentiator that is anticipated to be a clinically-viable treatment for eradicating persisters. EBX-001 significantly enhances the killing of Pseudomonas aeruginosa (PA) persisters through a novel proton-motive-force (PMF) enhancing mechanism. EBX-001 is initially being developed for the treatment of chronic, recurrent PA infections in cystic fibrosis (CF) patients, although market expansion to non-CF bronchiectasis (nCFBE) and chronic obstructive pulmonary disease (COPD) is possible. CF patients are typically treated with 28-day on/off cycles of inhaled TOB administration as front-line therapy. It has long been known that TOB modulates but does not eradicate PA infections, and that the clinical impact of TOB diminishes over time. Genetic resistance to TOB does not account for the lessening reduction in sputum bacterial density observed with subsequent on-off cycles. The decreasing efficacy of TOB over time is consistent with an increase in the presence of persisters.

EnBiotix co-founder, Prof. James J. Collins (MIT), discovered that metabolite stimulation of PMF allows for the uptake of aminoglycosides and subsequent killing of persistent bacteria in E. coli and S. aureus (http://dx.doi.org/10.1038/nature10069). In PA, Collins and co-workers subsequently showed that TCA cycle and respiratory activity is required for both the uptake and downstream lethality of aminoglycosides (http://dx.doi.org/10.1016/j.chembiol.2016.12.015). Our data show enhanced killing of up to 6 orders of magnitude of PA persisters over a range of CF isolates including mucoid and non-mucoid strains for the TOB-fumarate combination compared to TOB alone, as well as complete eradication of PA biofilm due to fumarate potentiation (http://dx.doi.org/10.1128/AAC.00987-17) as described in more detail below. Data suggest that persisters may also be sensitized to quinolones and beta-lactams by similar mechanisms.

Overall, our anti-persisters approach has the potential to revitalize the aminoglycoside and possibly other classes of antibiotics. EBX-001 is also expected to support antibiotic stewardship by potentially reducing time on antibiotics. For example, by targeting persisters, it may be possible to treat for 14-days on and 42-days off, for example, instead of 28-days on/off. In addition, it may be possible to reduce the dose of TOB, since we suspect that if persisters are eliminated as they form, and before they can reawaken as part of an acute infection, EBX-001 may show an effect on the acute infection. Furthermore, the rate of resistance development to TOB is low, and our metabolite enhancement, due to its mechanism, is not expected to exacerbate and may indeed slow this trend. In fact, EBX-001, by rapidly eliminating bacterial persisters, may limit the development of resistance to TOB thereby extending the therapeutic lifetime of this very beneficial agent.

EnBiotix has additionally filed a joint PCT with Oregon State University regarding potentiation of existing front-line antibiotics in non-tuberculosis mycobacterial infections. We intend to develop this as a second anti-persisters product (EBX-002).
B. ColiFin® (inhaled colistimethate sodium)

a. Disease Overview and Current Treatment Options

Cystic fibrosis (CF) is a genetic disease affecting multiple organ systems. The respiratory system is affected by complications resulting from impaired mucociliary clearance in the airways and is the primary cause of disease manifestation. Impaired host defense against inhaled debris and microbes results in persistent lower airway bacterial infection, most commonly caused by PA and Staphylococcus aureus. PA is linked to greater airway inflammation and is a major etiologic factor in disease progression and overall decline in health. Chronic PA infection results in a vicious cycle of infection and inflammation, which causes airway surface damage, airway plugging, which progressively leads to lung function decline and reduced survival. Strategies to administer anti-pseudomonal antibiotics to the airways have been a cornerstone of CF clinical care for many years. Although the overall prevalence of PA has gradually decreased in the last 25 years, it remains one of the most prevalent bacterial pathogens in CF, especially in adults > 25 years.

Infections will remain a major problem in CF post CFTR modulator era as patients live longer. PA infection is estimated to account for more than half of the chronic infections in Cystic Fibrosis. Data from the 2016 Cystic Fibrosis Foundation (CFF) Patient Registry indicate that 46.9% of CF patients in the US had at least one positive culture for PA, of which 29.1% were classified by as having chronic infection, and 17.8% as having intermittent infection. In approximately 18% of US patients with positive PA culture, the isolated strains were multi-drug resistant. Chronic PA infection is the leading cause of exacerbations, lung function decline and mortality in Cystic Fibrosis. Given infections remain to be a major problem in cystic fibrosis, the CFF has committed at least USD 100 million to the Infection Research Initiative in 2019.

The introduction of anti-pseudomonal antibiotics for the management of people with CF patients has played a major role in increasing their median survival. Inhaled antibiotics, which have been used in Europe since the 1980s and in the US since the late 1990s, are a key element of these antibiotic regimens. Despite the approval of cystic fibrosis transmembrane conductance regulator (CFTR) modulator therapies that substantially improve the genetic malfunction of the CFTR protein, there is an increasing need for the use of inhaled antibiotics. Currently, the only commercially available formulations of inhaled broad spectrum antibiotics include tobramycin, aztreonam, colistimethate sodium, and levofloxacins, depending on the geographic location of the patient. Tobramycin and aztreonam are the most commonly used inhaled antibiotics for CF and were developed nearly 10-20 years ago for 2-3 times daily dosing and were initially typically administered every other month in cycles to reduce antibiotics resistance. In the US, only tobramycin and aztreonam are authorized for marketing and are now commonly used for through “continuous alternating therapy” to avoid off-months without inhaled antibiotic therapy. Still, large numbers of CF patients continue to experience acute pulmonary exacerbations and declining lung function. Treatment for acute exacerbation events in patients with PA infection often requires intravenous drug administration of antibiotics with associated health risks, such as hearing loss, renal impairment, and socioeconomic costs. The clinical decline that many patients continue to experience highlights a need to develop new therapies, which includes additional effective and safe inhaled antibiotics.

b. ColiFin® Overview

EnBiotix has in-licensed ColiFin® from PARI Pharma GmbH, a global leader in nebulized therapies, for worldwide rights ex-Europe. ColiFin® represents a class of cyclic polypeptide antibiotics (polymyxins), with activity against gram-negative pathogens which acts via a different mechanism of action, compared to the other approved inhaled antibiotics and does not exhibit cross-resistance with these other classes. Chronic PA infection in people with CF requires lifelong antibiotic therapy; thus, the risk of developing resistance and the emergence of multi-drug resistant PA strains are a significant health concern. The significantly lower rate of resistance to colistimethate sodium (CMS) compared to other antipseudomonal antibiotics therefore renders CMS an invaluable treatment option.

CMS, the active substance in ColiFin®, has been developed as a nonactive prodrug of colistin to reduce the toxic side effects of active colistin. CMS undergoes hydrolysis to generate colistin, has shown not be less toxic following parenteral administration and is well tolerated after inhalation. ColiFin has been approved in Europe since 2010 at doses of 1 MIU (~80 mg CMS) and 2MIU (~160 mg CMS) administered two or three times daily with the PARI eRapid nebulizer system. ColiFin® has become a front-line therapy for chronic lung infections in CF with a proven safety and efficacy track record. EnBiotix has received from the FDA a “Study may Proceed” letter to initiate a single Phase 3 trial (COPA) of inhaled ColiFin® in adult and adolescent subjects with cystic fibrosis and chronic PA lung infection to support a future US marketing authorization.
The clinical development of ColiFin® is supported by the FDA granting of Orphan Drug Designation for treatment of respiratory infection in patients with cystic fibrosis, Qualified Infectious Disease Product (QIDP) Designation for ColiFin® for the treatment of PA lung infections in CF patients, and Fast Track Designation.

c. ColiFin® Phase 3 Program Plan

The Company is currently finalizing details of the COPA protocol (“Study May Proceed” letter received in May 2020) in collaboration with the FDA. The Phase 3 trial is expected to start in mid 2022 and will be conducted in two parts: a 28-day randomized, ColiFin® vs placebo double-blind period (Part A) for efficacy assessment, after which study subjects will be switched to a 20-week open label period (Part B) for safety assessment of ColiFin® vs. usual care therapy with inhaled antibacterials. All subjects randomized to ColiFin® will receive a total of 24 weeks of continuous ColiFin® in Part A and Part B. Subjects randomized to placebo in Part A, will receive usual care therapy with inhaled antibiotics during in Part B.

ColiFin® will be administered with an investigational PARI eFlow nebulizer system that is a modified, more efficient version of the eRapid system. The investigational eFlow nebulizer handset has a modified version of the medication reservoir and a larger nebulization chamber but is otherwise technically identical to the eRapid nebulizer. Laboratory studies have shown that the modified device has a higher dose delivery and reduces the treatment time of ColiFin® per inhalation session while maintaining similar aerosolization characteristics. This allows us to reach the same dose delivered to the lung at a reduced Phase 3 dose of ColiFin® 1.25 MIU with the modified eFlow device.

Enrollment of the first COPA subject is expected in the third quarter of 2022 with trial completion projected for the second quarter 2024 and data read out 6-8 weeks thereafter.

C. Inhaled Murepavadin

Inhaled murepavadin is our most advanced product candidate of the OMPTA class, a novel class of antibiotics coming from our macrocyclic peptide technology platform. In contrast to commonly used broad-spectrum antibiotics, murepavadin is pathogen specific. This makes it a precision medicine, highly potent against Pseudomonas aeruginosa (PA), including most resistant strains, with a reduced risk of increasing resistance in other pathogens. Despite the use of inhaled broad spectrum antibiotics, persistent lung infection with PA still leads to pulmonary exacerbations, lung function decline and increased mortality in people with CF. Whether in severe CF lung disease, there is an association between decreased microbial diversity with disease severity or the use of broad spectrum antibiotics is not well established. Hence, an inhaled antibiotic targeting PA is urgently needed to reduce morbidity and mortality in people with CF.

We are developing an inhaled formulation of murepavadin for the treatment of chronic PA infections in patients with cystic fibrosis and potentially also for other indications such as chronic obstructive pulmonary disease (COPD) and non-cystic fibrosis bronchiectasis.

The development of an inhaled formulation of murepavadin for the treatment of chronic PA infections in patients with cystic fibrosis and potentially also for non-cystic fibrosis bronchiectasis leverages the iABC (inhaled Antibiotics in Bronchiectasis and Cystic Fibrosis) project dedicated to the development of inhaled antibiotics – a consortium including leading lung specialists in 18 hospitals and research institutions in eight European countries. These institutions will receive up to EUR 5 million from the Innovative Medicines Initiative (IMI) for their support of the development of the inhaled formulation of murepavadin up to proof of concept in man, representing up to 50% of the anticipated costs to this stage.

Inhaled murepavadin is a novel class selective inhaled antibiotic for Cystic Fibrosis. It is (i) potentially first new class (OMPTA) and Pseudomonas aeruginosa specific inhaled antibiotic for Cystic Fibrosis, (ii) has best in vitro activity against Pseudomonas aeruginosa including multidrug resistant and extreme drug resistant strains, (iii) biofilm activity (in vitro) and low resistance potential; (iv) high safety margin (least 5-10 fold above IV application; safety margins are based on available preclinical GLP Tox data) in preclinical GLP, (v) no cross-resistance with other antibiotics, (vi) potent activity in lung infection models.

The following attributes measured in clinical trials could potentially make inhaled murepavadin change the treatment paradigm: (i) efficacy including refractory patients to standard of care (SoC), (ii) reduction in pulmonary exacerbations, and (iii) dosing vs. SoC.
Following the successful completion of the preclinical program suggesting efficacy and a broader safety margin compared to the I.V. formulation, a Clinical Trial Authorization (CTA) for inhaled murepavadin was granted in December 2020 by the MHRA leading to the initiation of the Phase 1 program. The start of subject enrollment in the the Phase 1 study, evaluating safety and tolerability of single and multiple ascending doses of the novel antibiotic in healthy volunteers, is expected in Q4 2021. The Company expects results of the Phase 1 study in 2022.

Assuming sufficient funding, the Company could start a Phase 1b/2 trial in 2023. In November 2020, we concluded a funding agreement with the Cystic Fibrosis Foundation to advance clinical development up to 3.3M $ to fund a Phase 1b/2a clinical trial of inhaled murepavadin further extending the potential funding for this program. Comparators’ peak sales for this orphan market opportunity are in the USD 200–400 million range. It may be possible to expand from Cystic Fibrosis to COPD, Non Cystic Fibrosis Bronchiectasis and beyond.

D. Balixafortide (POL6326)

a. Overview

Balixafortide (POL6326) is a potent, specific and highly selective antagonist of the chemokine receptor CXCR4, a G-protein coupled receptor (GPCR) that regulates the trafficking and homing of both cancer cells and cells of the patient’s immune system. Signaling through chemokine receptor, C-X-C chemokine receptor type 4 (CXCR4) regulates essential processes in normal physiology, including embryogenesis, tissue repair, angiogenesis, and trafficking of immune cells. CXCR4 is a promising target for therapy of both hematologic and solid tumor as well as other non-oncology indications.

The chemokine receptor CXCR4 plays a critical role in tumour growth and survival, angiogenesis and metastasis. It allows tumour cells to proliferate and migrate to sites where its natural ligand, the chemokine CXCL12, (also known as SDF-1, stromal-derived factor 1) is expressed and acts as a chemoattractant, for example in the bone marrow of breast cancer patients (Source: Mukherjee and Zhao, 2013). CXCR4 overexpression has been detected in more than 23 different human cancer types and correlates with a poor prognosis (Source: Chatterjee et al., 2014). In particular, primary breast cancer cells as well as breast cancer cells in metastatic sites frequently express high levels of the functional CXCR4 receptor (Source: Muller et al., 2001). Studies have provided increasing evidence that activation of the chemokine CXCL12 pathway by binding to CXCR4 is a potential mechanism of tumour resistance to both conventional therapies and biological agents via multiple complementary actions. Balixafortide is a macrocyclic peptide of the PEM class consisting of 16 amino acids and is a potent, reversible CXCR4 antagonist. Reversible CXCR4 blockade by balixafortide blocks the CXCL12 induced signaling pathway, is believed to play a key role in the interplay between cancer cells and their tumour microenvironment and may render tumour cells more susceptible to chemotherapeutic agents and cancer immunotherapy.

Additional publications also point towards a potential role of CXCR4 in the field of immuno-oncology. CXCR4 antagonism decreases infiltration of immunosuppressive regulatory T-cells (Treg) and myeloid-derived suppressor (MDSC) cells into the tumor. In contrast, CXCR4 antagonism increases the number of tumour-eliminating CD8+ and CD4+ T-cells in the tumour microenvironment which can be further activated in combination with checkpoint inhibitors (Abraham et al., 2017).
Balixafortide’s key attributes are:

- Potent and highly selective CXCR4 inhibitor with anti-cancer response on multiple levels.
- Not cytotoxic at clinically relevant doses, ideal for drug combinations.
- Resulted from a stringent selection process to obtain favorable physicochemical properties without any CYP or HERG inhibition up to maximum tested concentrations.
- Potentially best-in-class relative drug exposure, compared to other CXCR4 antagonists in development.

b. **Preclinical studies**

In vitro, receptor binding studies have been performed which demonstrated a high affinity of balixafortide for the human CXCR4 receptor, as well as a general lack of significant binding to other potential target receptors. Preclinical studies demonstrate the efficacy of balixafortide or close analogues in combination with chemotherapy in a variety of hematological and solid malignancies.

POL5551, a close analogue to balixafortide with similar CXCR4 antagonistic potency, selectivity and in vivo properties, was studied in a comprehensive animal study in combination with low-dose eribulin chemotherapy. When administered as a “framing dosing” shortly before and after eribulin, the combination with POL5551 showed an enhanced cytotoxic effect, as well as inhibition of metastasis and prolonged survival, in Triple Negative Breast Cancer models [ncbi.nlm.nih.gov/pmc/articles/PMC4784694/]. These findings provided the scientific basis to initiate the clinical trial of balixafortide in combination with eribulin in metastatic breast cancer.

In 2020, Balixafortide was studied in a comprehensive breast cancer PDX (patient-derived xenograft model in humanized mice) animal study in combination with paclitaxel chemotherapy. The combination of balixafortide and paclitaxel showed a clear synergistic and statistically significant effect in tumor volume versus paclitaxel alone. We have also conducted preclinical work to establish the potential additional oncology applications for balixafortide.

In a research collaboration with the University of Basel, Department of Biomedicine, balixafortide has demonstrated a strong and robust activity against SARS-CoV-2 (COVID-19) infection in a CPE (cytopathic effect) assay at clinically relevant concentrations. Based on positive in vitro findings, the Company has entered into academic collaborations with leading scientific institutions in the field of COVID-19 conducting non-clinical experiments to confirm in vivo efficacy, confirm projected dosing and understand mechanism of action.

c. **Clinical studies (Advanced Breast Cancer)**

Balixafortide has been investigated in eight clinical trials with a total of 462 subjects either as a single agent or in combination with other drugs. Six clinical studies have been completed.

Most recently, Balixafortide has been investigated for advanced breast cancers in combination with eribulin. Clinical proof of concept was achieved in a Phase 1b study in combination with eribulin in patients with advanced metastatic breast cancer [https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(18)30147-5/fulltext], and the FDA granted Fast Track designation. The pivotal FORTRESS Phase 3 study was started in mid-2019 and the first patient was dosed in June 2019.

FORTRESS (POL6326-009) is an international, multicenter, randomized active-controlled, open-label Phase 3 trial which investigated the efficacy, safety and tolerability of intravenous balixafortide given with eribulin versus eribulin alone in the treatment of HER2 negative, locally recurrent or metastatic breast cancer (MBC). The study was designed for a total of 432 patients with HER2 negative MBC, with 348 patients receiving third or subsequent line and 84 patients receiving second line chemotherapy. On June 28, 2021 we announced that the combination of balixafortide (POL6326) and eribulin did not significantly improve objective response rate (ORR) over eribulin alone in the treatment of patients with HER2-negative, locally recurrent or metastatic breast cancer, missing the co-primary end point of the FORTRESS study. Based on the analysis we have announced on August 3, 2021, the primary endpoint of the study progression free survival (PFS) was also not met. Pre-specified interim analysis of overall survival (OS) showed no statistically significant differences between study groups. Based on these results, the FORTRESS study is currently being closed and the pre-specified secondary efficacy analysis of OS after reaching 284 events in the overall population will not be performed. The analysis of the safety and tolerance of Balixafortide in combination with Eribulin in the FORTRESS study was consistent with the previously reported safety profile with a numerically higher number of patients having had serious adverse events in the balixafortide arm.
The Company also conducted preclinical studies to establish the potential for balixafortide in combination with other drugs (e.g. chemotherapy and immunotherapies) in MBC and in other oncology indications. Most notably, an investigator initiated Phase 1b/2a study was planned in first-line metastatic breast cancer in combination with nab-paclitaxel after positive preclinical findings regarding this combination. Based on the outcomes of the FORTRESS trial in combination with eribulin in advanced breast cancer, company will evaluate this study in the future.

d. Other Clinical studies

Balixafortide has been investigated in five completed studies exploring the safety, tolerability, pharmacokinetics and pharmacodynamics and evaluating its efficacy in the following indications: multiple myeloma, stem cell mobilisation and tissue repair. We conducted (i) a single intravenous dose study assessing safety, tolerability, pharmacokinetics and pharmacodynamics in healthy subjects, (ii) a Phase 2/proof of concept study to determine the mobilisation of haemopoetic stem cells (HSC) with balixafortide in multiple myeloma patients for autologous transplantation, (iii) a Phase 1 pharmacokinetics and pharmacodynamics study in healthy volunteers as potential HSC donors, (iv) a Phase 1/2 study evaluating the safety and efficacy of balixafortide for the mobilisation of HSCs in HLA-matched sibling donors and transplantation in patients with advanced hematological malignancies, which was stopped early for administrative reasons after an analysis of other studies concluded that higher doses for this product should be investigated, and (v) a Phase 2 study for tissue repair in patients with acute myocardial infarction which was also stopped early as an analysis lead to the conclusion that the criterion for futility were fulfilled. In these studies we established the median half-life for balixafortide of 8.6 hours and demonstrated proof of mechanism as HSC were mobilised. Benefits in patients with myocardial infarction were not demonstrated.

e. Clinical safety

The safety of balixafortide was investigated in all eight clinical studies. 462 subjects received at least one dose of balixafortide. Overall data generated to date support an acceptable safety and tolerability profile of balixafortide. In upcoming clinical trials, the potential risks related to localized histamine related events/infusion related reactions will continue to be monitored and mitigated. Data shows that these reactions are mainly mild, transient, related to first dose and manageable with anti-histamines and slower infusion rates.

The analysis of the safety and tolerability of Balixafortide (B) in combination with Eribulin (E) in the FORTRESS study was consistent with the previously reported safety profile with a numerically higher number of patients having had serious adverse events (SAEs) or treatment emergent adverse events (TEAEs) of a grade 3 or higher severity. In the B+E combination therapy arm neutropenia and febrile neutropenia were lower, however any grade TEAEs contributing to a decrease in patients therapy compliance were higher, such as infusion related reactions, nausea, pruritus, headache, dyspnea, rash and vomiting. Of importance, TEAEs that lead to death (6.9% (B+E) vs 6.4% (E)) or were of particular concern for overall patient survival, such as pneumonia, hypotension, pulmonary embolism, of which SAEs and Neutropenic Infections were as well higher in the B+E combination therapy arm vs the E monotherapy arm.

f. Further development strategy

Following the negative outcomes of the FOTRESS Phase 3 study in advanced breast cancer, additional oncology and non-oncology indications for balixafortide will be evaluated, both alone and in collaboration with Fosun Pharma, who owns China rights.

E. Novel CXCR4 antagonist program for haematological malignancies

CXCR4 is a validated target in several haematological malignancies and expression level correlates strongly with worse prognosis. The Company has identified a novel potent and selective CXCR4 antagonist to start non-clinical research and preclinical development for the treatment of haematological malignancies. Pharmacological in vitro and in-vivo data generated in collaboration with leading academic centre in Switzerland (IOR Bellinzona). In vitro studies demonstrate good potential of compound on top of standard of care in several liquid cancers. Experiments in several hematologic cancer types and combinations are planned. The compound remains undisclosed until relevant patent application is filed.
F. OMPTA Preclinical Programs

a. OMPTA BamA Program

We have discovered a novel class of antibiotics, the Outer Membrane Protein Targeting Antibiotics (OMPTA). This new class has the potential to provide breakthrough treatment options for difficult to treat infections caused by Gram-negative bacteria (including MDR and XDR strains). The current lead compounds demonstrate potent antibacterial activity against a broad range of pathogens, such as Escherichia coli, Klebsiella pneumoniae, Enterobacter spp, Acinetobacter baumannii, Stenotrophomonas maltophilia and Pseudomonas aeruginosa – including the pandrug-resistant isolates where there are currently no treatment options available. The potent in vitro activity has also been demonstrated in vivo. Significantly, the compounds have shown both potent in vitro and in vivo activity towards colistin-resistant isolates (colistin is considered as the treatment of last resort against Gram-negative ESKAPE pathogens). The OMPTA class is the result of the Company's innovative chemistry ("macrocycle") platform. An important part of this platform and source of the novel antibiotics are macrocyclic “Protein Epitope Mimetics” (PEM), medium-sized (0.7-2 kDa), fully synthetic, cyclic peptide-like molecules that mimic secondary structures of proteins. This new class is characterized by a low rate of resistance development and offers new treatment options for patients with difficult-to-treat infections caused by Gram-negative bacteria (including MDR strains).

Growing antibiotic resistance is a global health hazard, partly because no new classes of antibiotics have been developed for several decades. Moreover, it is a global rather than a local issue, as antimicrobial resistance can now rapidly spread between countries or continents more than ever before. Consequently, the development and commercialization of efficacious new antibiotics are strongly supported by the regulatory authorities and health institutions around the globe.

Antibiotics candidates of the OMPTA class combine high-affinity binding to both Lipopolysaccharide (LPS) and outer membrane proteins, resulting in high specificity towards Gram-negative bacteria and effective bactericidal activity. The LPS export mechanism by LptD-LptE is inhibited by murepavadin.

Bacteria species grouped under the term “Gram-negative” (as they do not retain a stain developed by the Danish researcher Hans-Christian Gram) are of particular concern as they are especially well protected by an inner and outer membrane from the action of antibiotics. Gram-negative bacteria are a common cause of serious and often life-threatening infections including intra-abdominal infections, urinary tract infections, pneumonia and bacteremia (blood stream infections).

Pre-clinical studies have shown the following key properties of the Company's broad-spectrum OMPTA

- favorable safety profile in animals
- favorable resistance profile compared to known antibiotics
- excellent activity in animal systemic infection models

Overall, these studies indicate that OMPTA display a promising broad and potent coverage against Gram-negative bacteria species belonging to the difficult-to-treat ESKAPE pathogens. So far, there has been very low cross-resistance observed with comparator antibiotics. OMPTA seem to overcome colistin resistance in all of the tested ESKAPE pathogens, including K. pneumoniae, well known to overproduce capsule polysaccharides (CPS) which serve as a protective shield and limit the killing effect of current antibiotics. No activity has been observed against Gram-positive bacteria.

The Company continues to invest in research on broad-spectrum Gram-negative PEM antibiotics of the OMPTA class. Currently, the Company is concentrating its efforts on further optimizing the potency and properties of the PEM molecules required for a development candidate. The project has been supported by the Wellcome Trust foundation and Novo Holdings A/S and is now being supported by CARB-X (Combating Antibiotic-Resistant Bacteria Biopharmaceutical Accelerator), a global partnership led by Boston University dedicated to supporting the development of antibacterial products. In December 2020, the existing grant agreement with CARB-X for this program was extended.

b. OMPTA LptA Program (Thanatin Derivatives)

In May 2019 the Company and the University of Zurich received an award from Innosuisse to accelerate the development of a new class of antibiotics, derived from the antimicrobial natural peptide thanatin. The new antibiotic,
which is being developed in collaboration with the University of Zurich, is used for the treatment of serious infections caused by carbapenem-resistant Enterobacteriaceae by inhibiting the lipopolysaccharide (LPS) transport pathway. Thanatin derivatives may lead to another family of compounds inhibiting the outer membrane assembly of Gram-negative pathogens through a different mechanism than other OMPTAs developed so far. We initiated a program targeting specifically Enterobacteriaceae including MDR strains, one of the most common and resistant strains. It has the potential to be gold standard in treating suspected and/or confirmed XDR Enterobacteriaceae in patients with limited treatment options. The commercial potential is estimated to USD 350 million. Thanatin project is currently in the hit-to-lead stage.

In October 2020, the Company received a new and second non-dilutive funding award from CARB-X to support the development of this program. CARB-X will provide the Company with initial funding of up to USD 2.62 million to complete the hit-to-lead stage and up to USD 15.82 million if certain project milestones are met.

We believe that new financial incentives (e.g. US DISARM, UK AMR plan) are a matter of time, given the increased global awareness of infectious diseases, not least because of COVID-19 (50% of non-survivors with COVID had secondary infections vs. 1% in survivors according to a recent Lancet publication). Our science aligns well with proposed incentives and AB pipeline is a long term value generation opportunity. The programs are in early preclinical phase and will be continued, provided they are largely funded through non-dilutive and/or external financing.

G. Our Strategy and Business Prospects

The following business prospects are uncertain and represent the Company's current assessment at the date of this Prospectus.

Our main objective is to build a sustainable biopharmaceutical company focused on innovative compounds and programs focusing on rare disease and oncology. Our strategy to achieve this goal is:

a. **Near-term Pipeline Goals in Rare Disease (Cystic Fibrosis):**

   - Initiation of a single Phase 3 trial of ColiFin® for the treatment of CF patients, upon completion of which the Company plans to seek FDA approval in the US.
   - Initiation of a Phase 1 trial of inhaled murepavadin for the treatment of CF patients.

b. **Mid to Long Term Pipeline Goals in Rare Disease and Oncology:**

   - EBX-002, a combination of amikacin (AMK) and a potentiator molecule for NTM infections which preclinical studies to date have shown potential for superior activity compared to ARYKACE®.
   - Additional oncology and non-oncology indications for balixafortide will be evaluated, both alone and in collaboration with Fosun Pharma, who owns China rights.
   - The Company’s new CXCR4 inhibitors focused on orphan, hematological malignancies.
   - Preclinical OMPTA BamA and LptA programs funded by CARBX targeting WHO Priority 1 bacterial infections planned to be developed for hospital acquired bacterial infections.
   - Company aims to in-license or acquire other rare disease and oncology assets post-closing that will consolidate its position in these therapeutic areas.

c. **Business Prospects**

ColiFin® will be the main value driver for the Company in the near-term. Through the potential launch of ColiFin® in the U.S., currently expected to occur at the end of 2024 or in early 2025, we expect to achieve cash flow breakeven in 2028.
H. History and development of the company

The Company was founded in 1996 by Dr. Daniel Obrecht and Dr. Jean-Pierre Obrecht for the purpose of the research and development of an innovative chemistry (“macrocycle”) platform. We pioneered the research of macrocycles, thereby establishing our unique proprietary macrocycle-based discovery platform consisting of PEMfinder® and MacroFinder®. Our existing clinical development pipeline and product candidates originate from this macrocycle platform. Until 2018, the Company assisted science-based pharmaceutical companies such as large pharmaceutical companies and biotech companies in identifying novel compounds against drug targets of their interest. Following the strategic review of our business operations this business was discontinued. On September 1st 2021, Polyphor and EnBiotix Inc., a privately held late clinical-stage rare disease company currently focused on products for rare, chronic respiratory diseases, announced a merger agreement pursuant to which Polyphor acquired substantially all of the outstanding capital stock of EnBiotix in exchange for shares of Polyphor common stock. The combination closed upon completion of the Capital Increase on December 29, 2021 and Polyphor has been renamed as Spexis AG and begins trading under the new ticker symbol SPEX on the SIX Swiss Exchange as from the date of this Prospectus.

EnBiotix Inc. was co-founded in 2012 by Apeiron Partners, LLC, Boston University, James J Collins, MIT, and Omega Fund, among others, for the purpose of commercializing the human applications of James J Collins’s systems and synthetic biology platforms. The primary platform applications in anti-infectives were the Reactive Oxygen Species (ROS) platform, the Anti-Persisters platform, and the Engineered Bacteriophage platform. These platforms led to a Series-A financing in 2014, various strategic partnerships and grants in 2015-2018, and Series B & C financings in 2019. In 2016, EnBiotix purchased significant IP (three patent families in the field of “Linear Peptide Antimicrobials”) of Germany-based AMP Therapeutics GmbH, to continue preclinical development of their anti-microbial peptides portfolio. Shortly thereafter, EnBiotix licensed worldwide ex-EU rights for ColiFin® from PARI Pharma GmbH, a worldwide leader in inhalational drug development. EnBiotix has since achieved Orphan Drug designation, QIDP designation and Fast Track designation status, and a “Study May Proceed” letter from the FDA regarding a single Phase 3 trial of ColiFin® was granted with said trial expected to begin in mid 2022.

I. Material agreements

On October 30, 2019, EnBiotix finalized a License and Clinical Supply agreement with PARI Pharma GmbH, a privately-held inhalation device and therapy company based in Starnberg, Germany. Under the agreement, EnBiotix is granted an exclusive transferable license to exploit the device/drug product for all human pharmaceutical uses worldwide, excluding the European Union, UK, Norway, and Switzerland. Under the terms of the agreement, EnBiotix will pay PARI clinical milestone payments and a royalty on net non-device sales. The agreement also specifies transfer pricing for clinical device supply for the upcoming Phase 3 trial, and for commercial device supply.

On February 14, 2018, we entered into a global license agreement with Santhera to further develop and commercialise POL6014 (Lonodelestat). Santhera is a publicly listed specialty pharmaceutical company focused on the development of drugs for rare diseases with experience in late stage respiratory trials. Under the terms of the agreement, we have received an upfront payment of CHF 6.5 million paid in the form of Santhera shares and could receive up to an additional CHF 121 million in potential development. regulatory and sales milestones for the initial indication, as well as tiered royalties up to 10% on sales. Santhera will have the exclusive worldwide rights to develop and commercialise POL6014, and will assume full responsibility for its development within the agreed upon timelines. If other indications are successfully developed, we would then be entitled to additional milestone payments and royalties.

In July 2020 the Company entered into an equity-linked financing arrangement with the French company IRIS to raise a gross amount of up to CHF 19.3 million over the period of two years. IRIS will receive shares to be created from the Company's conditional capital based on this interest-free mandatory convertible bonds program. It remains at the sole discretion of the Company to suspend or terminate the staggered financing. IRIS is committed to buy on a monthly basis over a period of two years twenty-four tranches of CHF 800'000 of unsecured zero-coupon mandatory convertible bonds. The program can be tailor-made in terms of period and tranche size, according to the Company's financing needs. During the term of the financing, IRIS will convert each month the mandatory convertible bonds into shares at a discount to the applicable volume weighted average price (VWAP). These shares are expected to be sold on the market or in block trades.

In August 2020 the Company entered into an exclusive licensing agreement for balixafortide in China with Fosun Pharma, one of the leading Chinese healthcare companies, which has a global footprint. This agreement represents an important next milestone for the development and commercialization of balixafortide in one of the largest markets in oncology, and is a strong validation from a leading innovative Chinese healthcare company. The Company received a USD 15 million upfront payment, is eligible for additional development and sales milestone payments depending on the progress
of the program and royalties on net sales in the territory, which start in the low double digits and increase to the mid-teens based on net sales achieved. The Company announced the finalization of this agreement on 29 September 2020.

In October 2014, EnBiotix entered into an exclusive licensing agreement with Boston University (and through them Massachusetts Institute of Technology and Howard Hughes Medical Institute) for all human, animal and agricultural diagnostic, prophylactic and therapeutic uses of a portfolio of patents emerging from James J Collins’ laboratory (then at Boston University). These patents enabled early research and development work on the Anti-Persisters, Engineered Bacteriophage, Tunable Target Degradation, and MINE platforms. In addition to patent costs, EnBiotix agreed to pay clinical milestone payments totaling USD $2M, 2% royalties on commercial sales, and annual minimum royalties. In connection with this agreement, Boston University was issued Series A Preferred shares in consideration of accrued patent costs to date.

In May 2016, EnBiotix entered into a know-how license agreement with the Mayo Foundation for Medical Education and Research, in which Mayo Clinic investigators committed to assist in development of engineered bacteriophage products using proprietary Mayo Clinic techniques. EnBiotix was further granted a non-exclusive, royalty-bearing, worldwide license, with the right to grant sublicenses, to use the Know-How to develop licensed Engineered Phage products. In consideration of the license grant, Mayo Clinic was granted $100,000 worth of EnBiotix common stock at a price of $1.32 per share. Mayo Clinic further committed in-kind project funding in return for a $78,930 promissory note.

J. Intellectual property

Our success depends significantly on our ability to obtain and maintain proprietary protection for our product candidates, technology and know-how, to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary 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.

We typically file provisional patent applications in Europe and/or US to establish a priority date for the subject matter of an invention and subsequently file corresponding international applications under the Patent Cooperation Treaty (“PCT”). Following the international phase we enter the national or regional phases in selected countries or regions which we believe are of general importance to our technology or represent potential markets for our product candidates. Depending on the importance of an invention we seek patent protection in approximate five to 50 countries or legal territories for a patent family, including Europe, United States, Canada, Japan, China, Brazil, South Africa, Australia, Hong Kong and Singapore.

We have exclusively licensed two patent families from Boston University (exclusively licensed to Enbiotix) that relate to our aminoglycoside potentiation platform. These patent families currently include three granted United States patents, and one granted European patent, as well as Applications pending in the United States, Europe, and Canada. These patents and applications have 20-year terms expiring in the range of 2032 to 2034. Our license with Boston University includes exclusive rights to other patents based on technologies invented in the laboratory of James Collins. In addition, we are the owner of a patent family that is pending in the U.S., Europe, China, and Canada, and co-owner of a pending PCT Application with Oregon State University, which also relate to our aminoglycoside potentiation platform. These owned and jointly-owned application families have 20-year terms expiring in 2037 and 2040, respectively.

Our license with PARI Pharma GmbH includes a license to ten patent families relating to a nebulizer system for delivering ColiFin®. These patent families include patents issued in Europe, United States, Japan, Canada, and Australia. Including Patent Term Adjustments in the U.S., these licensed patents expire in the range of January 2022 to December 2036.

We have additional patent assets relating to antimicrobial peptides, which include three patent families having expiration dates in the range of 2028 to 2031. These include issued patents in the United States, Canada, Europe, China, Japan, Russia, Australia, and Brazil.

By now the development and exploitation of our macrocycle platforms PEMfinder® and MacroFinder® resulted in 60 patent families comprising over 550 patents and patent applications across more than 50 countries. Our patent families are directed to compounds, formulations, processes and uses. Based on our first patent directed to the process of manufacture of PEMfinder® compounds several peptidic candidate drug molecules have been identified and patent protected, among them our most advanced product candidates balixafortide and inhaled murepavadin. Balixafortide is the
centrepiece of 16 patent families related to CXCR4 inhibitors, whereas murepavadin is embedded in 14 antibiotics-related patent families. In addition to the granted patents, additional patent protection has been sought for balixafortide in combination with different approved drugs for treating cancer.

Relevant dates for the most important compound patents (composition of matter) for balixafortide and murepavadin can be found in the table below.

<table>
<thead>
<tr>
<th>Product candidate</th>
<th>Title of Patent (International publication number)</th>
<th>Granted</th>
<th>Expiry Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Murepavadin (POL7080)</td>
<td>Template-Fixed Peptidomimetics (WO2007/079605)</td>
<td>USA</td>
<td>2031 (PTA)</td>
</tr>
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<tr>
<td>Balixafortide (POL6326)</td>
<td>Template-Fixed Peptidomimetics (WO2008/104090)</td>
<td>USA</td>
<td>2028 (PTA)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Europe</td>
<td>2027</td>
</tr>
</tbody>
</table>

We own 10 patent families jointly with the University of Zürich and 50 patent families are solely owned by us. We have exclusive, worldwide, perpetual, royalty-bearing licenses to the jointly owned patents and patent applications covering balixafortide and murepavadin for the duration of the licensed intellectual property rights with the right to sublicense. The royalties due to the University of Zurich are fixed as a low single digit percentage of net sales.

The term of an individual patent depends upon the legal term for patents in the countries in which they are granted. In most jurisdictions, including the United States and countries being member of the European Patent Convention, the patent term is generally 20 years from the earliest claimed filing date of a non-provisional patent application in the applicable country. Patent term provisions are available in the United States, the member states of the European Union and certain other jurisdictions to extend the term of a patent that covers an approved drug. In the future, if and when our product candidates, including balixafortide and murepavadin, receive approval by the FDA, EMA or any other relevant jurisdiction’s regulatory authorities, we expect, where possible, to apply for patent term extensions on issued patents covering those products, depending upon the length of the clinical trials for each product candidate and other factors. The expiry dates referred to in the table above are without regard to potential patent term extensions that may be available for us. We also rely on trade secret protection for some of our confidential and proprietary information directed to our technology, processes and candidate drug molecules. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, scientific advisors, collaborating partners and contractors. In addition, we use license agreements to access external products and technologies as well as we convey to others rights to our own intellectual property.

We own registrations for the trademarks “Polyphor”, “Polyphor Innovation in Drug Discovery”, and “Macrofinder” in Switzerland, the European Union, the United States and Japan, for “Pemfinder” and “Pemitopes” in Switzerland, the European Union and the United States and for “Polyphoresin” in Switzerland. Further, we intend to build up a trademark portfolio for the names of our product candidates as potential commercialization approaches.

K. Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third-party contract manufacturers (“CMs”) for the manufacture of our product candidates for larger scale preclinical and clinical testing, as well as for commercial quantities of any product candidates, if they are approved. We currently rely on one CM for each distinct step of the supply chain of all our clinical material: One CM for the manufacture of the active pharmaceutical ingredients (APIs, drug substances) and one different CM (fill finish provider) for the manufacture of the finished products (drug products).

To date we do not have long-term supply commitments or other arrangements in place with our existing CMs. We also do not currently have arrangements in place for redundant supply of bulk drug substance or drug product although for commercialization this is envisaged to be implemented in time. We do not have any current contractual relationships for the manufacture of commercial supplies of any of our product candidates, if they are approved. Such agreements will need to be implemented as our product candidates near potential approval.
Any product candidates to be used in clinical trials and any approved product candidate that we may commercialize will need to be manufactured in facilities, and by processes, that comply with regulatory requirements such as cGMP and comparable requirements of the regulatory agencies in the jurisdictions in which we are seeking approval. We currently employ internal resources to manage our CMs.

For our Phase 3 product ColiFin®, we are currently finalizing a supply agreement for clinical trial material and commercial product with the same CM that is providing drug product to PARI for commercialized ColiFin® in Europe. We are also working on an agreement with another experienced CM to provide both placebo drug product and saline solution for dissolution of lyophilized trial drug product (ColiFin® and placebo).

We believe that our clinical-stage product candidate inhaled murepavadin, as well as balixafortide and any future preclinical OMPTA product candidates can be manufactured in reliable and reproducible fully synthetic or semi-synthetic processes from readily available starting materials. The two clinical-stage product candidates are fully synthetic and rely on industry standard Solid Phase Peptide Synthesis. Purification is achieved by preparative High Performance Liquid Chromatography for balixafortide and murepavadin. This manufacturing technology is used for a large variety of peptides and related molecules worldwide and at least three major companies offer commercial manufacturing thereof. We believe that our manufacturing processes are amenable to scale-up and will not require unusual or expensive dedicated equipment. For the OMPTA preclinical candidate a semi-synthetic manufacturing route is being evaluated.

L. Sales and marketing

Our goal is to become a sustainable biopharmaceutical company that will be able to retain marketing rights, in whole or in part, to our product candidates and allow us to commercialize such products where attractive. Our commercial strategy will be influenced by the addressable patient population, the degree of unmet medical need and pricing and reimbursement practices in different jurisdictions and we expect to develop our strategy as we advance product candidates in our pipeline. While we do not have an established commercial, sales or distribution structure, we believe we can build it, if we chose to do so.

M. Employees

As of November 1, 2021 we had 32 employees, of which 21 were involved in research and development activities and 11 were involved in general administration. As of December 31, 2020 we had 56 employees, of which 42 were involved in research and development activities and 14 were involved in general administration. As of December 31, 2019, we had 67 employees, of which 48 were involved in research and development activities and 19 were involved in general administration. As of December 31, 2018, we had 64 employees, of which 49 were involved in research and development activities and 15 were involved in general administration.

In July 2021, the Company announced a restructuring of up to 29 positions to create operational efficiencies and reduce costs following the negative results of the FORTRESS study for balixafortide.

As per the date of this Prospectus, the Company has 37 employees, of which 23 are involved in research and development activities and 14 will be involved in general administration.

Historically we had a very strong scientific focus with many long term committed employees. With the exception of 5 former EnBiotix employees, who became employees of the Group as per the completion of the Capital Increase, all of our employees are located in our office in Allschwil, Switzerland. We have no collective bargaining agreements with our employees and we have not experienced any work stoppages. We consider our relations with our employees to be good.

N. Property

The Company does not own any real property. We rent facilities at Hegenheimermattweg 125, Allschwil, Switzerland where we occupy offices of approx. 800 sqm and use laboratories of approx. 1’055 sqm and storage space of approx. 275 sqm. The rent agreement is fixed until September 30, 2027.

The Company subleases lab area of 150sqm to a third party.

EnBiotix and its subsidiary EnBiotix GmbH respectively rent facilities at 197 West Springfield Street, Boston, Massachusetts 02118, USA and at Zschortauer Straße 18, 04129 Leipzig, Germany.
O. Legal and regulatory proceedings

As of the date of this Prospectus, there are no pending or threatened court, arbitral or administrative proceedings that are of material importance to the Company’s assets and liabilities or profits and losses.

P. Pension plans

In accordance with the Swiss Federal Occupational Retirement, Survivors’ and Disability Pension Plans Act ("OPA"), the Company is affiliated with a collective independent pension fund. The fund provides for retirement benefits, as well as risk benefits (death and disability). The Company entered into an agreement with Vita Sammelstiftungen for occupational benefits. Vita Sammelstiftungen is responsible for the governance of the plans; its board is composed of an equal number of representatives from the employers and employees chosen from all affiliated companies. Vita Sammelstiftungen has set up investment guidelines, defining in particular the strategic allocation with margins. Vita Sammelstiftungen has reinsured its risks (investment, mortality and disability risks) with Zurich Life Insurance Company Ltd. Zurich Investment Foundation manages the savings capital/investments on behalf of Vita Sammelstiftungen. The accumulated saving capital is allocated to each insured individual and consists of annual contributions, saving credits and interest credits. In certain situations, additional payments or increased periodic contributions by the employer may become due based on the pension plans’ funded status as measured under the OPA. The assets cannot revert to the employer. Contributions to the plans are shared 40% by the employees and 60% by the employer. Contributions are computed as a percentage of the salary, depending on age. There is two separate plans for Employees and the Executive Management.

EnBiotix does not offer a pension plan, but does offer participation in a 401(k) plan to all W-2 employees, currently administered by Sure401K. EnBiotix does not presently offer an employer match for employee contributions.
2.4b LEGAL AND REGULATORY ENVIRONMENT

The following summary is based on the laws, regulations and regulatory practices of the United States and the European Union as in effect on the date hereof, which are subject to change (or subject to changes in interpretation), possibly with retroactive effect.

A. Regulation in the United States

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (the “FDCA”) and related regulations and guidance documents. Drugs are also subject to other federal, state and local statutes and regulations. The FDA and comparable regulatory agencies in state and local jurisdictions impose substantial requirements upon, among other things, the testing, development, manufacture, quality control, safety, purity, potency, labelling, storage, distribution, record keeping and reporting, approval, import and export, advertising and promotion, and post-market surveillance of products.

The FDA’s policies may change and additional government regulations may be enacted that could prevent or delay marketing approval of any product candidates, product or manufacturing changes, additional disease indications, or label changes. We cannot predict the likelihood, nature or extent of government regulation that might arise from future legislative or administrative action.

Failure to comply with the applicable United States regulatory requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial enforcement actions. These actions could include the suspension or termination of clinical trials by the FDA, the FDA’s refusal to approve pending applications or supplemental applications, withdrawal of an approval, warnings or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, import detention, injunctions, fines, civil penalties or criminal prosecution. Any such administrative or judicial action could have a material adverse effect on us.

1. Product development process

The process required by the FDA before a drug may be marketed in the United States generally involves the following:

• the completion of preclinical laboratory tests and animal studies conducted in accordance with applicable regulations, including the FDA’s Good Laboratory Practice (“GLP”) regulations;

• the submission to the FDA of an Investigational New Drug (“IND”) application for human clinical testing, which must become effective before human clinical trials commence;

• the performance of adequate and well-controlled human clinical trials in accordance with applicable regulations, including the FDA’s GCP regulations, to establish the safety and efficacy of the proposed product for its intended use or uses;

• the submission to the FDA of a New Drug Application (“NDA”);

• a determination by the FDA to accept the NDA;

• satisfactory completion of an FDA inspection of the manufacturing facilities at which the product is made to assess compliance with the FDA’s cGMP regulations to ensure that the facilities, methods and controls are adequate to preserve the product’s identity, strength, quality and purity;

• a potential FDA audit of the preclinical and/or clinical trial sites that generated the data in support of the NDA; and

• the FDA’s review and approval of an NDA prior to any commercial marketing or sale of the product in the United States.

The testing and approval process requires substantial time, effort and financial resources, and the receipt and timing of any approval is uncertain.
2. Preclinical testing

Before testing any compounds with potential therapeutic value in humans, the product candidate enters the preclinical testing stage. Preclinical tests include laboratory evaluations of product chemistry and formulation, as well as animal studies to assess the potential safety, toxicity profile and efficacy of the product candidate. The conduct of the preclinical tests must comply with federal regulations and requirements, including GLP regulations.

3. IND application

Prior to commencing the first clinical trial in humans, an IND application must be submitted to the FDA, and the IND application must become effective. A sponsor must submit preclinical testing results to the FDA as part of the IND application and the FDA must evaluate whether there is an adequate basis for testing the product in humans. The IND application will automatically become effective 30 days after receipt by the FDA, unless the FDA within the 30-day time period raises concerns or questions about the submitted data or the conduct of the proposed clinical trial and places the IND application on clinical hold. In this case, the IND application sponsor must resolve any outstanding concerns with the FDA before a clinical trial may begin. A separate submission to the existing IND application must be made for each successive clinical trial to be conducted during product development.

4. Clinical trials

Clinical trials involve the administration of the product candidates to healthy volunteers or patients with the disease to be treated under the supervision of a qualified principal investigator. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in monitoring safety, and the efficacy criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND application. Further, each clinical trial must be reviewed and approved by an independent IRB and/or by ethics committees, either centrally or individually at each institution at which the clinical trial will be conducted. The IRB will consider, among other things, ethical factors, the safety of human subjects and the possible liability of the institution. Additionally, some clinical trials (typically Phase 3 clinical trials) are overseen by an independent group of qualified experts organized by the clinical trial sponsor, known as a data safety monitoring board or committee. This group provides confirmation as to whether or not a trial may move forward at designated check points based on access to certain data from the study.

Progress reports detailing the results of the clinical trials must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators for any serious and unexpected adverse event or finding from tests in laboratory animals that suggest a significant risk for human subjects. There are also requirements governing the reporting of ongoing clinical trials and clinical trial results to public registries.

The FDA, the IRB or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate its prior approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB’s requirements or if the product has been associated with unexpected serious harm to patients. A sponsor may also suspend or terminate a clinical trial based on evolving business objectives and/or competitive climate.

Clinical trials are typically conducted in three sequential phases prior to approval, but the phases may overlap. These phases generally include the following:

Phase 1: Phase 1 clinical trials represent the initial introduction of a product candidate into human subjects, frequently healthy volunteers. In Phase 1, the product candidate is usually tested for safety, including adverse effects, dosage tolerance, absorption, distribution, metabolism, excretion and pharmacodynamics. Phase 1 studies are sometimes separated into Phase 1a and Phase 1b. Although there is no specific regulatory definition, Phase 1b is often used to denote studies in patients rather than healthy volunteers (in which clinical responses as well as safety are evaluated), studies conducted with combinations of investigational agents, multiple dose studies or expanded cohort studies (as opposed to single ascending dose studies) or clinical pharmacology/pharmacokinetic studies. In the case of product candidates for severe or life-threatening diseases, such as cancer, especially when the product candidate may be inherently too toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
Phase 2: Phase 2 clinical trials usually involve studies in a limited patient population to (1) preliminarily evaluate the efficacy of the product candidate for specific indications, (2) determine dosage tolerance, optimal dosage and dosing schedule and (3) continue to identify possible adverse effects and safety risks.

Phase 3: If a product candidate is found to be potentially effective and to have an acceptable safety profile in Phase 2 studies, the clinical trial program will be expanded to Phase 3 clinical studies to further demonstrate clinical efficacy, optimal dosage and safety within an expanded patient population at geographically dispersed clinical study sites. These clinical trials are intended to establish the overall benefit-risk ratio of the product and to provide an adequate basis for product approval by the FDA.

A pivotal study is a clinical study that adequately meets FDA requirements for the evaluation of a product candidate’s efficacy and safety such that it can be used to justify the approval of the product. Generally, pivotal studies are also Phase 3 studies, but may be Phase 2 studies if the trial design provides a reliable assessment of clinical benefit. See also “—Expedited review programs” below beginning on page 71.

Post-approval studies, or Phase 4 clinical trials, may be conducted after receiving initial marketing approval. These studies may be required by the FDA as a condition of approval and are used to gain additional experience from the treatment of patients in the intended therapeutic indication. The FDA also has express statutory authority to require post-market clinical studies to address safety issues.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product as well as finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and include, among other things, developed methods for testing the identity, strength, quality and purity of the finished product. Additionally, appropriate packaging must be selected and tested and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life.

5. Disclosure of clinical trial information

Sponsors of clinical trials (other than Phase 1 trials) of FDA-regulated products, including drugs, are required to register and disclose certain clinical trial information. Information related to the product, comparator, patient population, phase of investigation, trial sites and investigators and other aspects of the clinical trial is made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of certain trials may be delayed until the new product or new indication being studied has been approved. However, there are evolving rules and increasing requirements for publication of trial-related information, and it is possible that data and other information from trials involving products that never garner approval could in the future be required to be disclosed. In addition, publication policies of major medical journals mandate certain registration and disclosures as a pre-condition for potential publication, even when this is not presently mandated as a matter of law. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

6. FDA NDA review and approval processes

The results of preclinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information on the manufacture, composition and quality of the product as well as the behaviour of the drug in the body, are submitted to the FDA in the form of an NDA for a new drug requesting approval to market the product. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators. The FDA has substantial discretion in the approval process and may refuse to accept any application or decide that the data is insufficient for approval and require additional preclinical, clinical or other studies. The NDA must be accompanied by a significant user fee payment.

In addition, under the U.S. Pediatric Research Equity Act (the “PREA”), an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may grant deferrals for submission of data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug for an indication for which orphan designation has been granted. However, if only one indication for a product has orphan designation, a pediatric assessment may still be required for any applications to market that same product for the non-orphan indication(s).
Once the NDA submission has been submitted, the FDA has 60 days after submission of the NDA to conduct an initial review to determine whether it is sufficient to accept for filing. Once the submission is accepted for filing, the FDA begins an in-depth review. Under the U.S. Prescription Drug User Fee Act (the “PDUFA”), the FDA sets a goal date by which it plans to complete its review. This is typically 12 months from the date of submission of the NDA application. The review process is often extended by FDA requests for additional information or clarification. The FDA reviews an NDA to determine, among other things, whether a product candidate is safe and effective for its intended use and indication for use, including use of a product as a combination therapy. Before approving an NDA, the FDA will inspect the facilities at which the product candidate is manufactured and will not approve the product candidate unless the manufacturing facility complies with CGMPs and may also inspect clinical trial sites for integrity of data supporting safety and efficacy. The FDA may also convene an advisory committee of external experts to provide input on certain review issues relating to risk, benefit and interpretation of clinical trial data. The FDA is not bound by the recommendations of an advisory committee, but generally follows such recommendations in making its decisions. The FDA may delay approval of an NDA if applicable regulatory criteria are not satisfied and/or the FDA requires additional testing or information. The FDA may require post-marketing testing and surveillance to monitor safety or efficacy of a product.

After the FDA evaluates the NDA, reviews the information on the product’s proposed labelling, and conducts inspections of manufacturing facilities where the product candidate and/or its API will be manufactured, it may issue an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A complete response letter indicates that the review cycle of the application is complete and the application is not ready for approval. A complete response letter may require additional clinical data and/or an additional pivotal Phase 3 clinical trial(s), and/or other significant, expensive and time-consuming requirements related to clinical trials, preclinical studies or manufacturing. Even if such additional information is submitted, the FDA may ultimately decide that the NDA does not satisfy the criteria for approval. The FDA could also require the submission of an NDA with a Risk Evaluation and Mitigation Strategy (“REMS”) plan to mitigate risks, which could include medication guides, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labelling, development of adequate controls and specifications, or a commitment to conduct one or more post-market studies or clinical trials. Such post-market testing may include Phase 4 clinical trials and surveillance to further assess and monitor the product’s safety and effectiveness after commercialization.

7. Certain U.S. regulatory incentives and other programs

a. Expedited review programs

The FDA has established four programs that are intended to facilitate and expedite development and review of new drugs to address unmet medical need in the treatment of a serious or life-threatening condition: fast track designation, breakthrough therapy designation, priority review designation and accelerated approval. Fast track designation, breakthrough therapy designation, priority review designation and accelerated approval do not change the standards for approval, but may expedite the development or review process.

Fast track designation. The FDA has a fast track program that is intended to facilitate development and expedite review of the process for reviewing new product candidates that meet certain criteria. Specifically, new products are eligible for fast track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product and the specific indication for which it is being studied. There are opportunities for frequent interactions with the review team for a fast track product candidate. These include meetings with the FDA, including pre-IND meetings, end-of-Phase 1 meetings, and end-of-Phase 2 meetings to discuss study design, extent of safety data required to support approval, dose-response concerns, and the use of biomarkers. Other meetings may be scheduled as appropriate (e.g., to discuss accelerated approval, the structure and content of an NDA and other critical issues). For a fast track product candidate, the FDA may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. The FDA may rescind a fast track designation in the event that qualifying criteria for designation are no longer met. In addition, a product candidate with a fast track designation may also be eligible for a priority review designation if supported by clinical data at the time of the NDA submission.

Breakthrough therapy designation. The FDA may also expedite the review of a drug designated as a breakthrough therapy, which is a product that is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the product may demonstrate...
substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A sponsor may request the FDA to designate a product as a breakthrough therapy at the time of, or any time after, the submission of an IND application for the drug. The designation of a product as a breakthrough therapy provides the same benefits as are available under the fast track program, as well as intensive FDA guidance on the product candidate’s development program. If the FDA designates a product as a breakthrough therapy, it must take actions appropriate to expedite the development and review of the NDA, which may include holding meetings with the sponsor and the review team throughout the development of the product, providing timely advice to, and interactive communication with, the sponsor regarding the development of the product to ensure that the development program to gather the nonclinical and clinical data necessary for approval is as efficient as practicable, involving senior managers and experienced review staff, as appropriate, in a collaborative, cross-disciplinary review, assigning a cross-disciplinary project lead for the FDA review team to facilitate an efficient review of the development program and to serve as a scientific liaison between the review team and the sponsor, and taking steps to ensure that the design of the clinical trials is as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment. In addition, the FDA may consider for review particular sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA. The FDA may rescind a breakthrough therapy designation in the future if further clinical development later shows that the criteria for designation are no longer met. In addition, a product candidate with a breakthrough therapy designation may also be eligible for a priority review designation if supported by clinical data at the time of the NDA submission.

Accelerated approval. The FDA may grant accelerated approval to a product candidate for a serious or life-threatening disease or condition upon a determination that the product candidate has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA may require that a sponsor of a product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies, with failure to complete such studies or failure to demonstrate the relevant clinical benefit potentially leading to withdrawal of the approval. In addition, the FDA requires as a condition for accelerated approval the pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Priority review designation. An NDA will receive priority review designation if it is for a product that treats a serious condition and, if approved, would provide a significant improvement in safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications and means that the FDA’s goal is to take action on an application within six months (compared to ten months under standard review).

b. Special protocol assessment

The FDA and an IND sponsor may agree in writing on the design and size of clinical studies intended to form the primary basis of a claim of effectiveness in an NDA. This process is known as a special protocol assessment (“SPA”). Upon a specific request for a SPA by an IND sponsor, the FDA will evaluate the protocol. If a SPA agreement is reached, however, it is not a guarantee of product approval by the FDA or approval of any permissible claims about the product. The FDA retains significant latitude and discretion in interpreting the terms of the SPA agreement and the data and results from any study that is the subject of the SPA agreement. In particular, the SPA agreement is not binding on the FDA if previously unrecognized public health concerns later come to light, other new scientific concerns regarding product safety or efficacy arise, the IND sponsor fails to comply with the protocol agreed upon, or the relevant data, assumptions, or information provided by the IND sponsor when requesting a SPA agreement change, are found to be false statements or misstatements, or are found to omit relevant facts. A SPA agreement may not be changed by the sponsor or the FDA after the trial begins except with the written agreement of the sponsor and the FDA, or if the FDA determines that a substantial scientific issue essential to determining the safety or effectiveness of the product was identified after the testing began.

c. Qualified Infectious Disease Product Exclusivity

In July 2012, the Food and Drug Administration Safety and Innovation Act was passed, which included the Generating Antibiotics Incentives Now Act (“GAIN Act”) under which the FDA may designate a product as a qualified infectious disease product (“QIDP”). In order to receive this designation, a drug must qualify as an antibiotic or antifungal drug for human use intended to treat serious or life-threatening infections, including those caused by either (i) an antibiotic
or antifungal resistant pathogen, including novel or emerging infectious pathogens, or (ii) a so-called “qualifying pathogen” found on a list of potentially dangerous, drug-resistant organisms to be established and maintained by the FDA under the new law. A sponsor must request such designation before submitting a marketing application.

Upon approving an application for a qualified infectious disease product, the FDA will extend by an additional five years any non-patent marketing exclusivity period awarded, such as a five-year exclusivity period awarded for a new molecular entity. This extension is in addition to any pediatric exclusivity extension awarded, and the extension will be awarded only to a drug first approved on or after the date of enactment.

The GAIN Act provisions prohibit the grant of an exclusivity extension where the application is a supplement to an application for which an extension is in effect or has expired, is a subsequent application for a specified change to an approved product, or is an application for a product that does not meet the definition of QIDP based on the uses for which it is ultimately approved.

d. **Orphan Drug Designation**

Orphan drug designation in the United States is designed to encourage sponsors to develop products intended for rare diseases or conditions. In the United States, a rare disease or condition is statutorily defined as a condition that affects fewer than 200'000 individuals in the United States or that affects more than 200'000 individuals in the United States and for which there is no reasonable expectation that the cost of developing and making available the product for the disease or condition will be recovered from sales of the product in the United States.

The FDA cannot, however, approve the same product made by another manufacturer for the same indication during the market exclusivity period unless it has the consent of the sponsor or the sponsor is unable to provide sufficient quantities.

8. **Post-approval requirements**

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product distribution, advertising and promotion and reporting of adverse experiences with the product. After approval, most changes to the approved product, such as adding new indications or other labelling claims are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

9. **Good Manufacturing Practices**

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements, which impose certain quality processes, manufacturing controls and documentation requirements upon manufacturers in order to ensure that the product is safe, has the identity and strength, and meets the quality and purity characteristics that it purports to have. The FDA and certain states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain.
of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. Noncompliance with cGMP or other requirements can result in issuance of warning letters, civil and criminal penalties, seizures and injunctive action.

10. Advertising and promotion

The FDA strictly regulates marketing, labelling, advertising and promotion of an approved product. While doctors are free to prescribe any product approved by the FDA for any use, a company can only make claims relating to safety and efficacy of a drug that is consistent with the FDA approval, and the company is allowed to actively market a product only for the particular use and treatment approved by the FDA. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of “off-label” uses (i.e., outside the FDA-approved indication, dosing and/or population), and a company that is found to have improperly promoted off-label uses may be subject to significant liability, such as heavy fines, obligation to submit all future promotional material to the FDA’s review before distribution, and other reporting obligations. In addition, any claims a company makes for its products in advertising or promotion must be appropriately balanced with important safety information and otherwise adequately substantiated. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising, injunctions and potential civil and criminal penalties. Government regulators recently have increased their scrutiny of the promotion and marketing of approved products.

In addition, certain products (or classes of products, such as immunosuppressants) that have special problems (particularly ones that may lead to death or serious injury) are required to include warning information displayed within a box in the prescribing information (a so-called “boxed” or “black box warning”). Products with boxed warnings are subject to certain promotion and advertising restrictions (e.g., they may be the subject of so-called “reminder advertisements”, which are ads that call attention to the name of the product but do not the product’s ‘use’).

11. Withdrawal of approval

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labelling to add new safety information, imposition of post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and/or
- injunctions or the imposition of civil or criminal penalties.

12. U.S. Federal and State fraud and abuse and data privacy and security laws and regulations

Healthcare providers and third-party payer’s play a primary role in the recommendation and prescription of pharmaceutical products that are granted marketing approval. Our current and future arrangements with providers, researchers, consultants, third-party payer’s and customers are subject to broadly applicable federal and state fraud and abuse, anti-kickback, false claims, transparency and patient privacy laws and regulations and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Restrictions under applicable federal and state healthcare laws and regulations include, without limitation, the following:
• the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, receiving, offering, or paying 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, in whole or in part, under a federal healthcare program such as Medicare and Medicaid;

• the U.S. federal civil and criminal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false, fictitious, or fraudulent or knowingly making, using, or causing to made or used a false record or statement to avoid, decrease, or conceal an obligation to pay money to the federal government;

• HIPAA, which created additional federal criminal laws that prohibit, among other things, knowingly and willfully executing, or attempting to execute, 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 of 2009, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information without the appropriate authorization by entities subject to the law, such as healthcare providers, health plans and healthcare clearinghouses and their respective business associates;

• the U.S. federal transparency requirements known as the federal Physician Payments Sunshine Act, under the ACA, which requires certain manufacturers of drugs, devices, biologics and medical supplies to report annually to the Centers for Medicare & Medicaid Services (“CMS”) within the U.S. Department of Health and Human Services, information related to payments and other transfers of value made by that entity to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

• analogous state and non-U.S. laws and regulations, such as state anti-kickback and false claims laws, which may apply to healthcare items or services that are reimbursed by non-governmental third-party payers, including private insurers.

Some state laws require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring pharmaceutical manufacturers to report information related to payments to physicians and other health care providers or marketing expenditures. State and non-U.S. laws also govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

We will be required to spend substantial time and money to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations. Recent healthcare reform legislation has strengthened these federal and state healthcare laws. For example, the ACA amends the intent requirement of the federal Anti-Kickback Statute and criminal healthcare fraud statutes to clarify that liability under these statutes does not require a person or entity to have actual knowledge of the statutes or a specific intent to violate them. Moreover, the ACA provides that the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Violations of these laws can subject us to criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight, if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, and we may be required to curtail or restructure our operations. Moreover, we expect that there will continue to be federal and state laws and regulations, proposed and implemented, that could impact our future operations and business.
Because of the breadth of these laws and the narrowness of available statutory and regulatory exemptions, it is possible that some of our business activities could be subject to challenge, investigation or legal action under one or more of such laws. If our operations are found to be in violation of any of the federal and state laws described above or any other governmental regulations that apply to us, we may be subject to significant civil, criminal, and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. To the extent that any of our product candidates receive approval and are sold in a country outside the United States, we may be subject to similar laws and regulations in that country, which may include, for instance, applicable post-marketing requirements, including safety surveillance, anti-fraud and abuse laws, international data protection laws, and implementation of corporate compliance programs and reporting of payments or transfers of value to healthcare professionals.

**Healthcare reform in the United States**

A primary trend in the U.S. healthcare industry and elsewhere is cost containment. There have been a number of federal and state proposals during the last few years to reduce the cost of care through changes in the healthcare system, including limits on the pricing, coverage and reimbursement of pharmaceutical and biopharmaceutical products, especially under government-funded health care programs, and increased governmental control of drug pricing.

By way of example, in March 2010, the U.S. Congress enacted the ACA, which, among other things, includes changes to the coverage and payment for products under governmental and private insurance plans. Among the provisions of the ACA of importance to our potential product candidates are:

- an annual, non-deductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications;

- expansion of eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer’s Medicaid rebate liability;

- expansion of manufacturers’ rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of “average manufacturer price”, or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices and extending rebate liability to prescriptions for individuals enrolled in Medicare Advantage plans;

- a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for products that are inhaled, infused, instilled, implanted or injected;

- expanding the types of entities eligible for the 340B drug discount program;

- establishing the Medicare Part D coverage gap discount program, which requires manufacturers to provide a 50% point-of-sale-discount off the negotiated price of applicable products to eligible beneficiaries during their coverage gap period as a condition for the manufacturers’ outpatient products to be covered under Medicare Part D;

- a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research;

- creation of the Independent Payment Advisory Board, or IPAB, which, if impaneled, would have authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription products; and

- establishment of the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription product spending (funding has been allocated to support the mission of the Center for Medicare and Medicaid Innovation through 2019).
Since its enactment, there have been judicial and Congressional challenges to numerous aspects of the ACA. For example, with enactment of the Tax Cuts and Jobs Act, Congress repealed the “individual mandate.” The repeal of this provision, which requires most Americans to carry a minimal level of health insurance, became effective in 2019. Litigation and legislation over the ACA are likely to continue, with unpredictable and uncertain results. We cannot predict how the ACA, its possible repeal, or any legislation that may be proposed to replace the ACA will impact our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least USD 1.2 trillion for the years 2012 through 2021, was unable to reach required goals, thereby triggering the legislation’s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers of up to 2% per fiscal year, which went into effect in April 2013 and will remain in effect through 2024 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centres and cancer treatment centres, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

There have been, and likely will continue to be, legislative and regulatory proposals directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. Such reforms could have an adverse effect on anticipated revenues from product candidates that we may successfully develop and for which we may obtain marketing approval and may affect our overall financial condition and ability to develop product candidates.

Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs.

In addition to FDA restrictions on marketing of pharmaceutical products, federal and state healthcare laws restrict certain business practices in the biopharmaceutical industry. These laws include, but are not limited to, anti-kickback, false claims, data privacy and security, and transparency statutes and regulations.

B. Regulation in the European Union

The process governing approval of medicinal products in the European Union generally follows the same lines as in the United States. It entails satisfactory completion of pharmaceutical development, nonclinical studies and adequate and well-controlled clinical trials to establish the safety and efficacy of the medicinal product for each proposed indication. It also requires the submission to relevant competent authorities for clinical trials authorization and to EMA for a marketing authorization application (“MAA”), and granting of a marketing authorization by these authorities before the product can be marketed and sold in the European Union.

1. Clinical trial approval

Pursuant to the currently applicable Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (the “Clinical Trials Directive”) and the Commission Directive 2005/28/EC of 8 April 2005 laying down principles and detailed guidelines for good clinical practice (“GCP”) as regards investigational medicinal products for human use, as well as the requirements for authorization of the manufacturing or importation of such products (the “GCP Directive”), a system for the approval of clinical trials in the European Union has been implemented through national legislation of the Member States. Under this system, an applicant must obtain approval from the competent national authority of a European Union Member State in which the clinical trial is to be conducted or in multiple Member States if the clinical trial is to be conducted in a number of Member States. Furthermore, the applicant may only start a clinical trial at a specific study site after the independent ethics committee has issued a favourable opinion. The clinical trial application (“CTA”), must be accompanied by an investigational medicinal product dossier with supporting information prescribed by the Clinical Trials Directive and the GCP Directive and corresponding national laws of the Member States and further detailed in applicable guidance documents.
A new regulation of the European Union, Regulation EU No. 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC has been adopted, which is set to replace the current Clinical Trials Directive. It is expected that the new regulation will apply from late 2021. It will overhaul the current system of approvals for clinical trials in the European Union. Specifically, the new regulation, which will be directly applicable in all Member States, aims at simplifying and streamlining the approval of clinical trials in the European Union. For instance, the new regulation provides for a streamlined application procedure using a single entry point and strictly defined deadlines for the assessment of clinical trial applications.

2. Marketing authorization

To obtain a marketing authorization for a product under the European Union regulatory system, an applicant must submit an MAA, either under a centralized procedure administered by the EMA or one of the procedures administered by competent authorities in European Union Member States (decentralized procedure, national procedure, or mutual recognition procedure). A marketing authorization may be granted only to an applicant established in the European Union. Regulation (EC) No. 1901/2006 of the European Union and of the Council of 12 December 2006 on medicinal products for pediatrics use provides that prior to obtaining a marketing authorization in the European Union, an applicant must demonstrate compliance with all measures included in an EMA-approved Pediatric Investigation Plan ("PIP"), covering all subsets of the pediatric population, unless the EMA has granted a product-specific waiver, class waiver, or a deferral for one or more of the measures included in the PIP.

The centralized procedure provides for the grant of a single marketing authorization by the European Commission that is valid for all European Union Member States. Pursuant to Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, the centralized procedure is compulsory for specific products, including for medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure may be optional.

3. Accelerated Assessment and PRIME initiative

Under the centralized procedure, the Committee for Medicinal Products for Human Use ("CHMP"), established at the EMA is responsible for conducting the assessment of a product to define its risk/benefit profile. Under the centralized procedure, the maximum timeframe for the evaluation of an MAA is 210 days, excluding clock stops when additional information or written or oral explanation is to be provided by the applicant in response to questions of the CHMP. However, the applicant may request an accelerated assessment procedure in order to meet, in particular the legitimate expectations of patients and to take account of the increasingly rapid progress of science and therapies, for medicinal products of major interest from the point of view of public health and in particular from the viewpoint of therapeutic innovation. Applicants requesting an accelerated assessment procedure must justify that the medicinal product is expected to be of major public health interest. If the CHMP accepts the request, the maximum timeframe for the evaluation of the marketing authorization application is reduced to 150 days, excluding clock stops.

The EMA launched the Priority Medicines ("PRIME") initiative in March 2016 to foster research and development of medicines that may offer a major therapeutic advantage over existing treatments, or benefit patients without or with limited treatment options. PRIME aims to strengthen clinical trial designs to facilitate the generation of high-quality data for the evaluation of an application for marketing authorization. To be accepted for PRIME, a medicine has to show its potential to benefit patients with unmet medical needs based on preclinical and/or early clinical data. These medicines are considered priority medicines within the European Union. After an investigational candidate has been selected for PRIME, developers are assigned a rapporteur from the CHMP to provide continuous support and help to build knowledge ahead of a MAA. A multidisciplinary group of experts will provide broader guidance on the overall development plan and regulatory strategy of the product. Companies are also eligible for accelerated assessment at the time of their regulatory application.

4. EMA Orphan Designation and Exclusivity

In the European Union, Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products, complemented by various other regulations, lay down the rules of orphan drug designation. The EMA’s Committee for Orphan Medicinal Products ("COMP") grants orphan drug designation to
promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions that affect not more than five in 10,000 persons in the European Union, or when, without incentives, it is unlikely that sales of such products in the European Union may be sufficient to justify the necessary investment in developing the products. Orphan drug designation is only available where no satisfactory method of diagnosis, prevention or treatment of the condition has been authorized (or the product would be a significant benefit to those affected).

In the European Union, orphan drug designation, if maintained by the time of the European Commission’s decision on the marketing authorization, entitles a company to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity following grant of the medicinal product approval. This period may be reduced to six years if the orphan drug designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity. Two years’ additional orphan exclusivity protection can be applied for when an applicant has complied with all requirements as set forth in an approved PIP. Market exclusivity would not prevent the approval of a similar drug that is shown to be safer, more effective or otherwise clinically superior.

Companies that classify as small or medium-sized enterprises ("SME") benefit from further incentives, including administrative and procedural assistance from the EMA’s SME office and fee reductions.

Orphan drug designation must be requested before submitting an application for marketing approval. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. Sponsors must submit orphan drug applications to the EMA. The evaluation process by the COMP takes a maximum of 90 days from successful completion of the validation process. The European Commission will issue a decision on a COMP opinion within 30 days of receipt of such opinion.

A sponsor may file a common application for orphan drug designation in the European Union and in the United States if it wishes to receive orphan drug designation in both territories. In that case, a common application must be filed with both the EMA and the OOPD.

5. Exceptional Circumstances/Conditional Approval

Orphan drugs or drugs with unmet medical needs may be eligible for approval in the European Union under exceptional circumstances or with conditional approval. Approval under exceptional circumstances is used when an applicant is unable to provide comprehensive data on the efficacy and safety under normal conditions of use because the indication for which the product is intended is encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence, when the present state of scientific knowledge does not allow comprehensive information to be provided, or when it is medically unethical to collect such information. An approval under exceptional circumstances must be subject to post-authorization controls or conditions, such as an obligation to conduct further studies, restrictions on supply, use or prescription or special labelling. An approval under exceptional circumstances is based on the assumption that the company will never be able to generate a complete data package. The authorization is valid for the standard five-year period (during which it is reviewed annually), after which it must usually be renewed only once.

A conditional marketing authorization may be applicable to orphan medicinal products, medicinal products for seriously debilitating or life-threatening diseases or medicinal products to be used in emergency situations in response to recognized public threats. Conditional marketing authorization can be granted on the basis of less complete data than is normally required in order to meet unmet medical needs and in the interest of public health, provided the risk-benefit balance is positive, it is likely that the applicant will be able to provide the comprehensive clinical data, and unmet medical needs will be fulfilled. Conditional marketing authorization is subject to specific obligations, usually including the obligation to generate and submit additional clinical data, and must be renewed annually until the obligations have been completed and the authorities have reviewed the new data and confirmed the approvability of the product.

6. Periods of Authorization and Renewals

A marketing authorization is valid for five years, in principle, and it may be renewed after five years on the basis of a reevaluation of the risk benefit balance by the EMA or by the competent authority of the authorizing Member State. To that end, the marketing authorization holder must provide the EMA or the competent authority with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission or the competent authority decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal period. Any
authorization that is not followed by the placement of the product on the European Union market (in the case of the centralized procedure) or on the market of the authorizing Member State within three years after authorization ceases to be valid.

7. Post-approval requirements

Following approval, the holder of the marketing authorization is required to comply with a range of requirements applicable to the manufacturing, marketing, promotion and sale of the medicinal product. These include compliance with the European Union’s stringent pharmacovigilance or safety reporting rules, pursuant to which post-authorization studies and additional monitoring obligations can be imposed. In addition, the manufacturing of authorized products, for which a separate manufacturer’s license is mandatory, must also be conducted in strict compliance with the EMA’s cGMP requirements and comparable requirements of other regulatory bodies in the European Union, which mandate the methods, facilities and controls used in manufacturing, processing and packing of products to assure their safety and identity. Finally, the marketing and promotion of authorized products, including industry-sponsored continuing medical education and advertising directed toward, among others, persons qualified to prescribe the products and general public are strictly regulated in the European Union under Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the community code relating to medicinal products for human use, as amended.

C. Regulation in Switzerland

In Switzerland, we are subject to various regulations concerning the development of pharmaceutical products, such as, but not limited to, the approval of clinical studies in the laboratory by the Ethical Commission for Clinical Tests (Ethikkommission für klinische Versuche) as well as the authorization for animal studies by the cantonal veterinary office (kantonales Veterinäramt), and the marketing of pharmaceutical products, such as the approval by the Swiss Agency for therapeutic products Swissmedic (Schweizerisches Heilmittelinstitut Swissmedic).

D. Other regulations

1. Clinical trials and marketing authorization of medicinal products in other countries

Although the above discussion focuses on regulation in the United States and the European Union, we anticipate seeking approval for and marketing of our product candidates also in other countries. In order to market any product outside of the United States and the European Union, we would need to comply with numerous and varying regulatory requirements of other countries and jurisdictions regarding quality, safety and efficacy and governing, among other things, clinical trials, marketing authorization, commercial sales and distribution of our products. Whether or not we obtain FDA or EMA approval for a product, we would need to obtain the necessary approvals by the comparable regulatory authority before we can commence clinical trials or marketing of the product in such other country or jurisdiction outside of the United States and the European Union. Marketing approval in one country or jurisdiction does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country or jurisdiction may negatively impact the regulatory process in others. Generally, our product candidates will be subject to regulation in other countries that is similar in nature and scope as those imposed in the United States and the European Union, although there can be important differences.

2. Pharmaceutical coverage, pricing and reimbursement

In the United States, the European Union and other countries and jurisdictions, sales of any products for which we may receive marketing approval will depend in part on the availability of coverage and adequate reimbursement to healthcare providers and patients from third-party payers. Third-party payers include government authorities (including government health programs, such as Medicare and Medicaid in the United States), 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 payers 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 those products. Sales of any products for which we may receive marketing approval will therefore depend substantially on the extent to which the costs of those products will be paid by third-party payers. These third-party payers 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 any products for which we may receive marketing approval will depend significantly on the degree to which these products are listed on third-party payers’ drug formularies, or lists of medications
for which third-party payers provide coverage and reimbursement to the extent products for which we may receive marketing approval are covered under a pharmacy benefit or are otherwise subject to a formulary. The industry competition to be included on such formularies often leads to downward pricing pressures on pharmaceutical companies. Also, third-party payers may refuse to include a particular branded drug on their formularies or otherwise restrict patient access to a branded drug when a less costly equivalent or other alternative is available. Furthermore, third-party payer reimbursement to providers for any product candidates for which we may receive marketing approval may be subject to a bundled payment that also includes the procedure administering such products. To the extent there is no separate payment for any such products, there may be further uncertainty as to the adequacy of reimbursement amounts. In addition, because each third-party payer 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 payer separately with no assurance that coverage and reimbursement approval would be obtained, and we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the cost-effectiveness of our products. We cannot be certain that any product candidates for which we may receive marketing approval will be considered cost-effective. Further, because coverage and reimbursement determinations are made on a payer-by-payer basis, obtaining acceptable coverage and reimbursement from one payer does not guarantee that we will obtain similar acceptable coverage or reimbursement from another payer. This process could delay the market acceptance of any product for which we may receive marketing approval and could have a negative effect on our future revenues and operating results. If we are unable to obtain coverage of, and adequate reimbursement and payment levels for, any products for which we may receive marketing approval from third-party payers, 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.

Furthermore, in many countries, particularly the countries in the European Union, the pricing of prescription drugs is subject to government control. In some non-U.S. jurisdictions, the proposed pricing for a drug must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the European Union provides options for Member States to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A Member State may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. We may face competition for any product for which we may receive marketing approval from lower-priced products in any country that has placed price controls on pharmaceutical products. In addition, there may be importation of foreign products that compete with products for which we may receive marketing approval, which could negatively impact our profitability.

2.5 INVESTMENTS, TURNOVER & COMPLETED PROJECTS

A. Investments

Investments in property, plant and equipment are limited due to the nature of our business. In the past, we mainly invested in laboratory & building infrastructure (leasehold improvements), office equipment, laboratory equipment, and IT equipment, all of which are being depreciated over their expected useful life as appropriate.

For the preceding three business years, the Company's investments in property, plant and equipment can be outlined as follows (for details, please consult the Annual Financial Statements referenced elsewhere in this Prospectus as well as the section entitled "Financial Statements" beginning on page 97):

<table>
<thead>
<tr>
<th>Purchase of Property, Plant and Equipment</th>
<th>In million CHF</th>
<th>Total Switzerland Other Jurisdictions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2020</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>2019</td>
<td>0.5</td>
<td>0.5</td>
</tr>
<tr>
<td>2018</td>
<td>0.3</td>
<td>0.3</td>
</tr>
</tbody>
</table>

Since December 31, 2020 until the date of this Prospectus, the Company has made no significant investments into property, plant & equipment and, at the date of this Prospectus, has no current plans to do so. The Company has no
contractual obligations or firm undertakings that would result in a significant capitalization of assets, such as purchase of plant, property and equipment.

With regard to investments in the further development of our products (which we consider operating expenses), reference is made to the Annual Financial Statements. The forecast for the Company's operating expenses in 2021 amounts to CHF 28 million to 32 million.

**B. Revenue**

The Company has one operating segment focusing on the research and development and prospective commercialisation of drugs addressing high unmet medical needs.

For the preceding three business years, the Company's revenues can be outlined as follows (for details, please consult the Annual Financial Statements referenced elsewhere in this Prospectus):

In the following table, revenue from contracts is disaggregated based on location of the customer.

<table>
<thead>
<tr>
<th>Revenue by location</th>
<th>In CHF</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Switzerland</td>
<td>14'271'000</td>
<td>6'403'163</td>
</tr>
<tr>
<td>Rest of Europe</td>
<td>6'568</td>
<td>142'432</td>
</tr>
<tr>
<td>United States</td>
<td>0</td>
<td>7'100</td>
</tr>
<tr>
<td>Asia</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>14'277'568</td>
<td>6'545'595</td>
</tr>
</tbody>
</table>

The vast majority of the revenue in 2020 represents the upfront payment received from Fosun Pharma.

**C. Completed Projects**

For ongoing and planned research projects, including for those which have been resolved and for which the Company has made commitments, reference is made to the section "Portfolio and Pipeline" beginning on page 53. All research projects described therein are substantially domestic, other than those relating to (i) ColiFin®, (ii) the AMPT discovery platform and (iii) the Anti-Persisters platform.

In the preceding three business years, the Company has completed the following projects, all of which were substantially domestic:

The Company has initiated and subsequently closed two Phase 3 trials for intravenous (IV) injection formulation of Murepavadin for the treatment of patients with nosocomial pneumonia in 2019. These two trials were PRISM-UDR clinical trial, a Phase 3 study for murepavadin (POL7080) for the treatment of hospital-acquired (HABP) and ventilator-associated bacterial pneumonia (VABP) due to Pseudomonas aeruginosa and PRISM-MDR Phase 3 trial which enrolled patients with nosocomial pneumonia. After their first patient enrollment in March and April 2019, the Company has decided to close both studies in July 2019 due to findings of a rise of creatinine concentration in the serum of patients indicating a higher than expected frequency of acute kidney injury. There was no increase in the incidence of mortality in the murepavadin arm compared to the control arm - the 28 days mortality rates were 30.0% in the murepavadin arm and 37.5% in the control arm. The decision to stop the PRISM trials applies only to the intravenous murepavadin formulation and does not impact the further development of the murepavadin inhaled program. Based on the data of the inhaled murepavadin preclinical program suggesting significantly higher safety margins (at least 5-10 times) versus the intravenous formulation, the Company continues its clinical development program which is currently in Phase 1.

In recent years, the Company conducted preclinical experiments for balixafortide in different combinations and tumors in oncology with various leading academic institutions including preclinical experiments in metastatic breast cancer in combination with nab-paclitaxel. Following closure of the Phase 3 FORTRESS study in advanced breast cancer in combination with eribulin, additional oncology and non-oncology indications for balixafortide will be evaluated, both alone and in collaboration with Fosun Pharma, who owns China rights.
The Company has identified a novel potent and selective CXCR4 antagonist to start non-clinical research and preclinical development for the treatment of haematological malignancies. Pharmacological in vitro and in-vivo data generated in collaboration with leading academic centre in Switzerland (IOR Bellinzona). In vitro studies demonstrate good potential of compound on top of standard of care in several liquid cancers. Experiments in several hematologic cancer types and combinations are planned. The compound remains undisclosed until relevant patent application is filed.
2.6 SHARE CAPITAL AND VOTING RIGHTS

CAPITAL STRUCTURE AND SHARES

This summary contains certain information in relation to the share capital of the Company and the Shares, as well as a brief description of certain significant provisions of the Articles and Swiss law as will be applicable to the Company as from the date of this Prospectus. This description does not purport to be complete and is qualified in its entirety by the Articles, the relevant excerpt from the commercial register and its underlying documents (Belege) as well as the laws of Switzerland in effect on the date of this Prospectus. Unless otherwise noted, the summary below is based on the versions of those documents that are in effect at the date of this Prospectus.

A. Capital structure

1. Ordinary, authorised and conditional capital as per December 31, 2020

The Company’s capital structure as at the balance sheet date for the annual financial statements (December 31, 2020) was as follows:

<table>
<thead>
<tr>
<th>Article # according to Articles</th>
<th>Share category</th>
<th>Number of Shares in such category</th>
<th>Aggregate Nominal Value of such Shares (CHF 2 each)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>Issued capital</td>
<td>11'208'408</td>
<td>22'416'816</td>
</tr>
<tr>
<td>3a</td>
<td>Authorized capital</td>
<td>5'531'603</td>
<td>11'063'206</td>
</tr>
<tr>
<td>3b</td>
<td>Conditional capital for Bonds and Similar Debt Instruments</td>
<td>2'076'821</td>
<td>4'153'642</td>
</tr>
<tr>
<td>3c</td>
<td>Conditional Share Capital for Employee Benefit Plans</td>
<td>840'227*</td>
<td>1'680'454*</td>
</tr>
</tbody>
</table>

* Numbers take into account the 145'201 registered shares with a nominal value of CHF 2 each issued from the Company’s conditional share capital in connection with the exercise of stock options and convertible bonds prior to December 31, 2020 which had not been registered in the commercial register and for which the Articles had not formally been updated at such date.

2. Changes in share capital (historic, as per commercial register)

<table>
<thead>
<tr>
<th>Date of Share Issuance Registration</th>
<th>New Nominal Share Capital in Swiss Francs</th>
<th>Number of Shares issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>November 6, 1996</td>
<td>100'000</td>
<td>1'000 Shares at CHF 100 each</td>
</tr>
<tr>
<td>April 8, 1997</td>
<td>200'000</td>
<td>2'000 Shares at CHF 100 each</td>
</tr>
<tr>
<td>August 26, 1999</td>
<td>1'140'000</td>
<td>11'400 Shares at CHF 100 each</td>
</tr>
<tr>
<td>September 6, 2000</td>
<td>1'875'000</td>
<td>18'750 Shares at CHF 100 each</td>
</tr>
<tr>
<td>December 18, 2000</td>
<td>2'079'000</td>
<td>20'790 Shares at CHF 100 each</td>
</tr>
<tr>
<td>March 15, 2001</td>
<td>2'215'000</td>
<td>22'150 Shares at CHF 100 each</td>
</tr>
<tr>
<td>May 3, 2001</td>
<td>3'015'000</td>
<td>30'150 Shares at CHF 100 each</td>
</tr>
<tr>
<td>April 7, 2003</td>
<td>3'415'000</td>
<td>34'150 Shares at CHF 100 each</td>
</tr>
<tr>
<td>May 10, 2004</td>
<td>3'815'000</td>
<td>38'150 Shares at CHF 100 each</td>
</tr>
<tr>
<td>March 30, 2006</td>
<td>4'129'200</td>
<td>41'292 Shares at CHF 100 each</td>
</tr>
<tr>
<td>May 29, 2006</td>
<td>4'637'700</td>
<td>46'377 Shares at CHF 100 each</td>
</tr>
<tr>
<td>April 27, 2007</td>
<td>4'692'500</td>
<td>46'925 Shares at CHF 100 each</td>
</tr>
<tr>
<td>August 9, 2007</td>
<td>5'885'100</td>
<td>58'851 Shares at CHF 100 each</td>
</tr>
<tr>
<td>April 8, 2008</td>
<td>5'914'400</td>
<td>59'144 Shares at CHF 100 each</td>
</tr>
<tr>
<td>June 16, 2009</td>
<td>6'000'800</td>
<td>60'008 Shares at CHF 100 each</td>
</tr>
<tr>
<td>October 30, 2009</td>
<td>6'302'900</td>
<td>63'029 Shares at CHF 100 each</td>
</tr>
<tr>
<td>April 6, 2010</td>
<td>6'497'100</td>
<td>64'971 Shares at CHF 100 each</td>
</tr>
<tr>
<td>May 21, 2010</td>
<td>6'665'000</td>
<td>66'650 Shares at CHF 100 each</td>
</tr>
<tr>
<td>August 27, 2010</td>
<td>6'943'100</td>
<td>69'431 Shares at CHF 100 each</td>
</tr>
<tr>
<td>December 3, 2010</td>
<td>7'362'900</td>
<td>73'629 Shares at CHF 100 each</td>
</tr>
<tr>
<td>April 4, 2011</td>
<td>7'616'900</td>
<td>76'169 Shares at CHF 100 each</td>
</tr>
<tr>
<td>October 25, 2011</td>
<td>7'884'600</td>
<td>78'846 Shares at CHF 100 each</td>
</tr>
<tr>
<td>April 20, 2012</td>
<td>7'914'100</td>
<td>79'141 Shares at CHF 100 each</td>
</tr>
<tr>
<td>May 15, 2012</td>
<td>8'370'600</td>
<td>83'706 Shares at CHF 100 each</td>
</tr>
<tr>
<td>December 14, 2012</td>
<td>8'566'800</td>
<td>85'668 Shares at CHF 100 each</td>
</tr>
<tr>
<td>March 20, 2013</td>
<td>8'582'000</td>
<td>85'820 Shares at CHF 100 each</td>
</tr>
</tbody>
</table>
March 22, 2013 ................................................................. 8'660'100 86'601 Shares at CHF 100 each
May 14, 2013 .................................................................. 8'987'200 89'872 Shares at CHF 100 each
September 2, 2013 .......................................................... 9'201'700 92'017 Shares at CHF 100 each
October 1, 2013 ............................................................... 9'340'100 93'401 Shares at CHF 100 each
October 30, 2013 .............................................................. 9'728'200 97'282 Shares at CHF 100 each
March 7, 2014 .................................................................. 10'044'400 100'444 Shares at CHF 100 each
June 14, 2014 .................................................................. 10'482'000 104'820 Shares at CHF 100 each
July 25, 2014 ..................................................................... 10'869'600 108'696 Shares at CHF 100 each
December 23, 2014 .......................................................... 11'424'200 114'242 Shares at CHF 100 each
April 26, 2017 .................................................................. 11'836'264 5'918'132 Shares at CHF 2 each
August 22, 2017 ............................................................... 13'071'034 6'535'517 Shares at CHF 2 each
December 12, 2017 .......................................................... 13'365'922 6'682'961 Shares at CHF 2 each
March 20, 2018 ................................................................ 13'397'286 6'698'643 Shares at CHF 2 each
May 15, 2018 .................................................................... 21'555'186 10'777'593 Shares at CHF 2 each
July 10, 2018 .................................................................... 21'711'502 10'855'751 Shares at CHF 2 each
October 12, 2018 .............................................................. 22'069'396 11'034'698 Shares at CHF 2 each
April 3, 2019 .................................................................... 22'093'004 11'046'502 Shares at CHF 2 each
April 6, 2020 ..................................................................... 22'126'414 11'063'207 Shares at CHF 2 each
May 6, 2021 ..................................................................... 22'496.32 11'224'816 Shares at CHF 0.02 each
June 14, 2021.................................................................... 224'496.32 11'224'816 Shares at CHF 0.02 each

3. Issued share capital

As at the date of this Prospectus, the Company's share capital amounts to CHF 950'638.76, divided into 47'531'938 Shares, all of which are registered shares and have a nominal value of CHF 0.02 each. Thereof, 46'375'777 Shares have already been recorded in the commercial register.

The Shares are fully paid in. Each Share carries one vote.

No other changes in the Company's share capital are planned or have been decided as at the date of this Prospectus, except as set forth in Company's authorized share capital and conditional share capital (described below).

4. Authorised share capital

At the extraordinary general meeting of shareholders of October 28, 2021, the Company’s shareholders resolved among other things to increase the authorised capital to 20'530'008 Shares, subject to completion of the Capital Increase.

As of the date of this Prospectus, Article 3a of the Articles reads as follows (English translation of the authoritative German version):

"Article 3a Authorized Share Capital

The Board of Directors is authorized to increase the share capital, at any time until October 27, 2023, by a maximum amount of CHF 410'600.16 by issuing a maximum of 20'530'008 registered shares with a par value of CHF 0.02 each, to be fully paid up. An increase of the share capital (i) by means of an underwriting (ii) by a subsidiary in view of and related to any of the below mentioned transactions allowing an exclusion of the preemptive rights and (iii) in partial amounts shall be permissible.

The Board of Directors shall determine the time of the issuance, the issue price, the manner in which the new registered shares have to be paid up, the date from which the registered shares carry the right to dividends, the conditions for the exercise of the preemptive rights and the allotment of preemptive rights that have not been exercised. The Board of Directors may allow the preemptive rights that have not been exercised to expire, or it may place with third parties such rights or registered shares, the preemptive rights of which have not been exercised, at market conditions or use them otherwise in the interest of the Company.

The Board of Directors is authorized to withdraw or limit the pre-emptive rights of the shareholders and to allot them to third parties: (a) if the issue price of the new registered shares is determined by reference to the market price; or (b) for the acquisition of an enterprise, part of an enterprise or participations, or for the financing or refinancing of any of such acquisition; or (c) for purposes of broadening the shareholder constituency of the Company in certain financial or
investor markets, for purposes of the participation of strategic partners, or in connection with the listing of new registered shares on domestic or foreign stock exchanges; or (d) for purposes of granting an over-allotment option (Greenshoe) of up to 15% of the number of registered shares offered in a base-tranche in a placement or sale of registered shares to the respective initial purchaser(s) or underwriter(s); or (e) for raising of capital (including private placements) in a fast and flexible manner which probably could not be reached without the exclusion of the statutory pre-emptive right of the existing shareholders.

The purchase of registered shares out of authorized capital increase and any transfers of registered shares shall be subject to the restrictions specified in Article 4 of the Articles of Association.”

5. Conditional share capital

At the extraordinary general meeting of shareholders of October 28, 2021, the Company’s shareholders resolved among other things to increase the conditional capital for bonds and similar debt instruments to 10'199'256 Shares, subject to completion of the Capital Increase.

As of the date of this Prospectus, Article 3b of the Articles reads as follows (English translation of the authoritative German version):

“Article 3b Conditional Capital for Bonds and Similar Debt Instruments

The share capital of the Company shall be increased by a maximum amount of CHF 203'985.12 through the issuance of a maximum of 10'199'256 registered shares, payable in full, each with a nominal value of CHF 0.02 through the exercise of conversion and/or option rights granted in connection with bonds or similar instruments, issued or to be issued by the Company or by subsidiaries of the Company, including convertible debt instruments.

Shareholders’ subscription rights are excluded. Shareholders’ advance subscription rights with regard to the new bonds or similar instruments may be restricted or excluded by decision of the Board of Directors in order to finance or refinance the acquisition of companies, parts of companies or holdings, or new investments planned by the Company, or in order to issue convertible bonds or similar instruments on the international capital markets or through private placement. If advance subscription rights are excluded, then (1) the instruments are to be placed at market conditions, (2) the exercise period is not to exceed ten years from the date of issue of option rights and twenty years for conversion rights and (3) the conversion or exercise price for the new shares is to be set at least in line with the market conditions prevailing at the date on which the instruments are issued.

The purchase of registered shares through the exercise of conversion or option rights and any transfers of registered shares shall be subject to the restrictions specified in Article 4 of the Articles of Association.”

As of the date of this Prospectus, Article 3c of the Articles reads as follows (English translation of the authoritative German version, no change expected with implementation of Capital Increase):

“Article 3c Conditional Share Capital for Employee Benefit Plans

The share capital of the Company shall be increased by an amount not exceeding CHF 16'804.54 through the issue of a maximum of 840'227 registered shares, payable in full, each with a nominal value of CHF 0.02, in connection with the exercise of option rights granted to any employee of the Company or a subsidiary, and any consultant, members of the Board of Directors, or other person providing services to the Company or a subsidiary.

Shareholders’ subscription rights shall be excluded with regard to these shares. These new registered shares may be issued at a price below the current market price. The Board of Directors shall specify the precise conditions of issue including the issue price of the shares.

The purchase of registered shares in connection with employee participation and any further transfers of registered shares shall be subject to the restrictions specified in Article 4 of the Articles of Association.”

At the extraordinary general meeting of shareholders of October 28, 2021, the Company’s shareholders resolved among other things to create a new conditional capital for employee benefit plans in the amount of 2'053'001 Shares, subject to completion of the Capital Increase.
As of the date of this Prospectus, Article 3d of the Articles reads as follows (English translation of the authoritative German version):

“Article 3d  Conditional Share Capital for Employee Benefit Plans

The share capital of the Company shall be increased by an amount not exceeding CHF 41'060.02 through the issue of a maximum of 2'053'001 registered shares, payable in full, each with a nominal value of CHF 0.02, in connection with the exercise of option rights granted to any employee of the Company or a subsidiary, and any consultant, members of the Board of Directors, or other person providing services to the Company or a subsidiary.

Shareholders' subscription rights shall be excluded with regard to these shares. These new registered shares may be issued at a price below the current market price. The Board of Directors shall specify the precise conditions of issue including the issue price of the shares.

The purchase of registered shares in connection with employee participation and any further transfers of registered shares shall be subject to the restrictions specified in Article 4 of the Articles of Association.”

6. Participation certificates and profit sharing certificates

The Company has not issued any non-voting equity securities, such as participation certificates (Partizipationsscheine) or profit sharing certificates (Genuss scheine), and the Company does not have any preference shares (Vorzugsaktien).

7. Treasury Shares

As of the date of this Prospectus, the Company holds no treasury shares.

8. Cross-shareholdings

As of the date of this Prospectus, there are no cross-shareholdings of the Company that exceed 5% of the holdings of capital or voting rights on both sides.

9. Convertible bonds, debt instruments and options

There are no outstanding debt instruments convertible into the Company’s securities as of the date of this Prospectus other than equity-linked financing arrangement with the French company IRIS as further outlined under “—Material Agreements” beginning on page 63. Pursuant to the financing arrangement, IRIS will receive shares to be created from the Company's conditional capital based on an interest-free mandatory convertible bonds program. The total gross amount raised under the contract is CHF 19.3 million to be drawn over the period of two years. IRIS is committed to buy on a monthly basis over a period of two years twenty-four tranches of CHF 800’000 of unsecured zero-coupon mandatory convertible bonds.

For descriptions on the rights to acquire Shares that are expected to be outstanding as of the date of this Prospectus see “—Incentive and equity-based plans” beginning on page 49.

B. Description of Shares, Articles and Swiss Law

1. Shares

The Shares are registered shares with a nominal value of CHF 0.02 each and are fully paid in and non-assessable. The Shares rank pari passu in all respects with each other, including in respect of entitlements to dividends, to a share in the liquidation proceeds in the case of a liquidation of the Company and to preemptive rights.

2. Form of the Shares

The Capital Increase Shares are issued in uncertificated form in accordance with article 973c CO as uncertificated securities (Wertrechte). In connection with the Capital Increase, the Capital Increase Shares have been entered into the main register of the SIS and, consequently, constitute intermediated securities (Bucheffekten) within the meaning of the FISA. In accordance with article 973c CO, the Company maintains a register of uncertificated securities (Wertrechthebuch).
According to the Articles, the Company may issue its registered shares in the form of single certificates, global certificates and uncertificated securities. Subject to applicable law, the Company may convert its registered shares from one form into another form at any time and without the approval of its shareholders. No shareholder has the right to request a conversion of the registered shares issued in one form into another form. Each shareholder may, however, at any time request a written confirmation from the Company of the registered shares held by such shareholder, as reflected in the share register maintained by the Company (the “Share Register”). Any such confirmation is not a negotiable instrument.

3. Voting rights

Each Share carries one vote at the general meeting of shareholders of the Company. Voting rights may be exercised only after a shareholder has been recorded in the Share Register as a shareholder with voting rights up to a specific qualifying day (the “Record Date”) designated each time by the Board. Acquirers of Shares will be recorded in the Share Register as shareholders with the right to vote, provided that they expressly declare that they acquired the registered shares in their own name and for their own account and fulfill certain other requirements (see “—Transfer of Shares and transfer restrictions” beginning on page 89).

4. General meeting of shareholders

Under Swiss law and the Articles, an annual general meeting of shareholders must be held within six months after the end of a company’s financial year. As of the date of this Prospectus, this means, in the case of the Company, on or before June 30.

In general meetings of shareholders, except as described below, each shareholder has equal rights, including equal voting rights. According to the Articles, each Share is entitled to one vote (provided that its holder or usufructuary is recorded in the Share Register as a shareholder with voting rights as of the relevant Record Date).

The annual general meeting of shareholders of the Company is convened by the Board or, if necessary, by the Company’s auditors. Extraordinary general meetings may be held when deemed necessary by the Board or the Company’s auditors. Furthermore, extraordinary general meetings must be convened upon resolution of a general meeting of shareholders or upon written request by one or more shareholders who represent an aggregate of at least 10% of the Company’s share capital registered in the commercial register, provided that such request specifies the agenda items and the proposals or, in case of elections, the names of the proposed candidates. One or more shareholders representing at least 5% of the Company’s share capital registered in the commercial register have the right to request that a specific proposal be put on the agenda for the next general meeting. A general meeting of shareholders of the Company is convened at least 20 calendar days prior to such meeting by publishing a notice of the meeting in the Swiss Official Gazette of Commerce (Schweizerisches Handelsamtsblatt) (the “SOGC”). The Board may designate additional means of publication.

Pursuant to Swiss law and the Articles, shareholders’ resolutions generally require the approval of a simple majority of the votes cast regardless of abstentions, blank or invalid ballots unless otherwise required by Swiss law or the Articles. The resolutions requiring the approval of a simple majority of the votes passed include, inter alia, amendments to the Articles (subject to exceptions), the election and removal of the Chairman and the members of the Board, the independent voting rights representative and the auditors, approval of the annual report and the financial statements, approval of dividends (if any), approval of the aggregate amounts of compensation of the members of the Board and the Executive Management, releasing the members of the Board and the Executive Management from liability for matters disclosed to the general meeting of shareholders, and ordering an independent investigation into specific matters proposed to the general meeting (Sonderprüfung).

A resolution passed at a general meeting of shareholders with a qualified majority of at least two-thirds of the votes represented and the absolute majority of the nominal share capital represented at such meeting (a “Qualified Majority”) is required by law and/or the Articles for: (i) modifications of the Company’s purpose; (ii) the creation of shares with preferential voting rights; (iii) restrictions of the transferability of registered shares and the easing or lifting of such restrictions; (iv) an authorised or conditional share capital increase; (v) a share capital increase by conversion of equity surplus, against contributions in kind or for purposes of an acquisition of assets, or the granting of special benefits; (vi) the limitation or exclusion of preemptive rights of shareholders; (vii) the relocation of the registered office of the Company; and (ix) the dissolution of the Company. The Qualified Majority requirement and, in some instances, other qualified majority requirements, apply by law to a merger (Fusion), demerger (Spaltung) or conversion (Umwandlung) of the Company. The introduction or abolition of any provision of the Articles providing for a higher majority requirement than is prescribed by law must be adopted by such majority.
Shareholders of the Company may elect to be represented by proxy at general meetings of shareholders by the independent voting rights representative (see “—Compensation “beginning on page 48), by their legal representative(s), or, by means of a written proxy, by any other proxy, who need not be a shareholder.

5. Preemptive rights and advance subscription rights

Under Swiss law, any share issue, whether for cash or non-cash consideration, is subject to the prior approval of the shareholders at a general meeting of shareholders. Shareholders have certain preemptive rights (Bezugsrechte) to subscribe for new issues of shares and advance subscription rights (Vorwegzeichnungsrechte) to subscribe for convertible or warrant-bearing bonds or other financial instruments in proportion to the nominal amount of shares held. A resolution adopted at a general meeting of shareholders by a Qualified Majority may limit or exclude preemptive rights in certain limited circumstances. According to the Articles, the Board is authorised to limit or withdraw preemptive rights and advance subscription rights in connection with share issues out of its authorised and conditional share capital (see “—Authorised share capital” and “—Conditional share capital” beginning on page 85). At the extraordinary general meeting of shareholders of October 28, 2021, the Company’s shareholders resolved on an ordinary capital increase for which the preemptive rights were excluded in favour of the holders of EnBiotix capital stock.

6. Dividends and other distributions

See “Dividends and Other Distributions” beginning on page 147.

7. Transfer of Shares and transfer restrictions

So long as and to the extent that the Shares are intermediated securities (Bucheffekten) within the meaning of the FISA, (i) any transfer of Shares is effected by a corresponding entry in the securities deposit account of a bank or a depository institution, (ii) no Shares can be transferred by way of assignment, and (iii) a security interest in any Shares cannot be granted by way of assignment.

The Company maintains the Share Register and enters the full name, address and nationality (in the case of legal entities, the company name and registered office) of the shareholders and usufructuaries therein. A person recorded in the Share Register must notify the share registrar of any changes of address. Until such notification occurs, all written communication from the Company to persons entered in the Share Register are deemed to have been validly made if sent to the relevant address recorded in the Share Register.

Any person who acquires Shares may submit a request to the Company to be entered into the Share Register as a shareholder with voting rights, provided such person expressly declares to the Company that it has acquired and holds such Shares in its own name and for its own account. Any such person that does not expressly state in his or her application to the Company that the relevant Shares were acquired for his or her own account (any such person, a “Nominee”) may be entered in the Share Register as a shareholder with voting rights with regard to up to 2% of the share capital recorded in the commercial register.

The Board may, after having heard the concerned registered shareholder or Nominee, cancel entries in the Share Register that were based on false or misleading information with retroactive effect as of the date of entry.

The restrictions on registration also apply to shares that are subscribed or acquired by exercising a subscription, option or conversion right. After the publication or dispatch of the invitations to the general meeting up to the day after the general meeting, no entries will be made in the share register, unless the Board of Directors announces another deadline.

Any acquirer of Shares who is not registered in the Share Register as a shareholder with voting rights may not vote at or participate in any general meeting of shareholders of the Company, but will still be entitled to dividends and other rights with financial value with respect to such Shares.

8. Ordinary capital increase, authorised and conditional share capital

Pursuant to Swiss law and the Articles, the share capital of a company may be increased against cash contributions by a resolution passed at a general meeting of shareholders by an absolute majority of the votes represented. A capital increase against contributions in kind or at the exclusion of the preemptive rights (Bezugsrechte) of the shareholders or by way of a reclassification of reserves into share capital requires a resolution passed by a Qualified Majority. Furthermore,
under the CO, the shareholders of a company may authorise, by passing a resolution with a Qualified Majority, the issuance of shares up to a specified aggregate nominal amount, but not more than 50% of the existing share capital, in the form of:

(a) authorised share capital (genehmigtes Kapital) to be utilised by the board of directors within a period not exceeding two years from the approval given in the general meeting of shareholders; and/or

(b) conditional share capital (bedingtes Kapital) for the purpose of issuing shares, inter alia, (i) to grant conversion rights or warrants to holders of convertible bonds, or (ii) to grant rights to employees of a company or affiliated companies to subscribe for new shares.

9. Ownership of Shares by non-Swiss persons

Except for the limitation on voting rights described above applicable to shareholders generally, and subject to government sanctions (see next subsection), there is no limitation under Swiss law or the Articles on the right of non-Swiss residents or nationals to own Shares or to exercise voting rights attached to the Shares applicable to stock corporations of the type of and conducting a business as the Company.

10. Foreign investment and exchange control regulations in Switzerland

Other than in connection with government sanctions imposed on certain persons from the Republic of Iraq, the Islamic Republic of Iran, Lebanon, Yemen, Libya, Sudan, the Republic of South Sudan, Burundi, the Democratic Republic of Congo, Somalia, Guinea-Bissau, Syria, Myanmar (Burma), Zimbabwe, Belarus, Guinea, the Republic of Mali, Venezuela, Nicaragua, the Democratic People’s Republic of Korea (North Korea) and the Central African Republic, persons and organisations with connections to Osama bin Laden, the “Al-Qaeda” group or the Taliban, certain persons in connection with the assassination of Rafik Hariri, and certain measures in connection with the prevention of circumvention of international sanctions in connection with the situation in the Ukraine, there are currently no government laws, decrees or regulations in Switzerland that restrict the export or import of capital, including, but not limited to, Swiss foreign exchange controls on the payment of dividends, interest or liquidation proceeds, if any, to non-resident holders of the Shares.

11. Borrowing power

Neither Swiss law nor the Articles generally restrict the Company’s power to borrow and to raise funds. The decision to borrow funds is made by or under direction of the Board, with no shareholders’ resolution being required.

12. Conflicts of interest, management transactions

There is no explicit general provision on conflicts of interest in the CO. However, the CO requires directors and senior management of a company to safeguard the interests of such company and, in this connection, imposes a duty of loyalty and duty of care on the company’s directors and officers. This rule is generally understood to disqualify directors and senior officers of a company from participating in decisions that directly affect them. A company’s directors and officers are personally liable to the company for a breach of this rule. In addition, the CO contains provisions under which directors and all persons engaged in the management of a company are liable to the company, each shareholder and the company’s creditors for losses caused by an intentional or negligent breach of their duties. Furthermore, the CO contains a provision under which payments made to any shareholders or directors of a company or any person associated with any such shareholder or director, other than payments made at arm’s length, must be repaid to the company if such shareholder or director was acting in bad faith. In addition, if, in connection with entering into a contract (except relating to daily business matters of up to CHF 1’000), a company is represented by the person with whom it is entering into the contract, such contract must be in writing.

According to Swiss law, listed companies are obliged to disclose the total amount of all compensation and loans granted to current or former members of the board of directors and executive management. In addition, compensation paid, and loans made, to persons closely related to the members of the board of directors or executive management must be disclosed. The compensation paid, and loans granted, to every member of the board of directors must be disclosed individually (including the name and function of the member). In the case of the executive management, the highest amount awarded must be disclosed (including the recipient and his or her function within the company). All of these disclosures must be made in the company’s compensation report. See also “—Compensation” beginning on page 48.
The shares of a company held by members of its board of directors and executive management or persons closely related to such members must be disclosed in the notes to the company’s annual financial statement.

The Directive on Information Relating to Corporate Governance issued by the SIX Swiss Exchange also addresses conflict of interest issues. See “—Corporate Governance Directive” on page 149.

13. Purchases of own Shares

Swiss law limits the right of the Company to purchase and hold its own shares in treasury. The Company or its subsidiaries may purchase Shares only if and to the extent that (a) the Company has freely distributable reserves in the amount of the purchase price, and (b) the aggregate nominal value of all Shares held by the Company does not exceed 10% of the Company’s share capital (20% in specific circumstances). Furthermore, the Company must present the acquired Shares on its statutory balance sheet as a negative item in its equity. For tax implications in case of cancellation of own shares or exceeding thresholds, see “Tax Considerations” beginning on page 152.

Shares held by the Company or its subsidiaries do not carry any rights to vote at general meetings of shareholders, but are entitled to the economic benefits, including dividends, preemptive rights (Bezugsrechte) in the case of share capital increases and advance subscription rights (Vorwegzeichnungsrechte), attached to the Shares generally.

In addition, selective share repurchases are only permitted under certain circumstances. In particular, publicly announced repurchases of listed shares are subject to certain restrictions promulgated by the Swiss Takeover Board (the regulatory body for takeover bids in Switzerland) under the Federal Act on Financial Market Infrastructures and Market Conduct in Securities and Derivatives Trading of June 19, 2015 (the “FMIA”), and the implementing ordinances enacted thereunder. Within these limitations, as is customary for Swiss companies, the Company may purchase and sell its own Shares from time to time.

14. Duration and liquidation

The Articles do not limit the Company’s duration. Under Swiss law, the Company may be dissolved at any time, by way of liquidation or in the case of a merger in accordance with the Merger Act, based on a resolution of a general meeting of shareholders, which must be passed by a Qualified Majority. Dissolution and liquidation by court order is possible if, among other things, (a) the Company becomes bankrupt or (b) shareholders holding at least 10% of the Company’s share capital so request for important reasons. Under Swiss law, any surplus arising out of a liquidation (after the settlement of all claims of all creditors) is distributed in proportion to the paid-up nominal value of shares held. This surplus is subject to Swiss federal withholding tax, except if paid out of qualifying reserves from capital contributions (Reserven aus Kapitaleinlagen). See “Tax Considerations” beginning on page 152.

15. Reporting and disclosure of major shareholdings

Under the FMIA and its implementing ordinances, persons who directly, indirectly or in concert with other parties acquire or dispose of Shares or coordinate their voting behavior or are granted the power to exercise the voting rights attached to Shares at their own discretion (“delegated voting rights”) or acquire or dispose of purchase or sale rights relating to Shares, and thereby 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), must report such acquisition or disposal to the Company and the SIX Swiss Exchange in writing within four trading days. The person or entity subject to the reporting obligation is the beneficial owner. Special rules apply to the disclosure obligation of investment funds. Within two trading days after the receipt of such notification, the Company must publish such information through SIX Swiss Exchange’s electronic reporting and publishing platform. For purposes of calculating whether a threshold has been reached or crossed, shares, delegated voting rights and acquisition rights or obligations (“Purchase Positions”) on the one hand and sale rights or obligations (“Sale Positions”) on the other hand may not be netted. Rather, the Purchase Positions and the Sale Positions must be accounted for separately and may each trigger disclosure obligations if the respective positions reach one of the thresholds. In addition, actual share ownership and delegated voting rights must be reported separately from other Purchase Positions if they reach or cross one of the thresholds.

Furthermore, under the CO, the Company must disclose the identity of shareholders and shareholder groups acting in concert who hold more than 5% of the Company’s voting rights in the notes to the financial statements as published in the Company’s annual report.

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16. **Obligation to make a mandatory takeover offer**

Pursuant to the FMIA, any person that acquires shares of a company whose shares are listed on a Swiss stock exchange, whether directly or indirectly or acting in concert with third parties, and, as a result, exceeds the threshold of 33\(\frac{1}{3}\)% of the voting rights (whether exercisable or not) of such company, must submit a public tender offer to acquire 100% of the listed equity securities of such company. A company’s articles of association may waive this requirement or raise the relevant threshold to up to 49% (“opting-out” and “opting-up” respectively). The Articles do not contain an opting-out or opting-up provision.

An exemption from the mandatory offer rule may be granted by the Swiss Takeover Board or the Swiss Financial Market Supervisory Authority FINMA in certain circumstances. If no exemption is granted, the mandatory tender offer must be made pursuant to the rules set forth in the FMIA and its implementing ordinances.

There is no obligation to make a public tender offer under the FMIA and its implementing ordinances if the voting rights in question are acquired as a result of a gift, succession or partition of an estate, a transfer based upon matrimonial property law or execution proceedings. However, such acquisitions have to be notified to the Swiss Takeover Board.

Since May 15, 2018, the Shares have been traded on the SIX Swiss Stock exchange. The Company has to date not been subject to any public tender offers pursuant to the provisions of the FMIA and its implementing ordinances.

On October 1, 2021, the Company filed a request with the Swiss Takeover Board to issue a confirmation regarding the absence of an obligation of the Company and EnBiotix shareholders to make a mandatory takeover offer for the Shares in connection with the Transaction. The Board supported this proposal in its opinion dated October 5, 2021, and the Swiss Takeover Board issued its confirmation on October 13, 2021.

17. **Cancellation of remaining equity securities**

Under the FMIA, any offeror who has made a tender offer for equity securities of a listed Swiss company, and who, as a result of such offer, holds more than 98% of the voting rights of such company, may petition the court to cancel such company’s remaining equity securities. The petition must be filed against the target company within three months after the expiration of the offer period. The remaining shareholders of the target company may join in the proceedings. If the court orders cancellation of the remaining equity securities, the target company must reissue and deliver such equity securities to the offeror against payment of the offer consideration for the benefit of the holders of the cancelled equity securities.

18. **Squeeze-out merger**

The Merger Act allows a squeeze-out of minority shareholders by way of a squeeze-out merger. With the approval of at least 90% of all shareholders of the target company, the target company may be merged into another company and the minority shareholders of the target company may be compensated in cash or other consideration (e.g., securities from another company) instead of receiving shares in the surviving company. It is unclear and controversial whether the 90% approval relates to the total number of votes represented by all shares of the target company outstanding or to the total number of shareholders of the target company entitled to vote.

19. **Shareholders’ inspection rights**

A shareholder may, upon application to the Company, inspect the minutes of a general meeting of shareholders. In accordance with Swiss law, the Company makes its annual report and the auditors’ report available for inspection by shareholders at its registered address at least 20 days prior to each annual general meeting of shareholders. Any shareholder may request a copy of these reports in advance of or after the annual general meeting. In addition, at a general meeting of shareholders, a shareholder may request information from the Board concerning the business and operations of the Company and may request information from the Company’s auditors concerning the performance and results of their audit of the financial statements. The Company may refuse to provide such information to a shareholder if, in its opinion, the disclosure of the requested information would reveal confidential business secrets or infringe other protected interests of the Company.
20. Shareholders’ rights to bring derivative actions

According to the CO, an individual shareholder may bring an action, in its own name and for the benefit of the Company, against the Company’s directors, officers or liquidators for the recovery of any losses the Company has suffered as a result of the intentional or negligent breach by such directors, officers or liquidators of their duties.

21. Compensation Ordinance

The below summarises certain key provisions of the Compensation Ordinance. The Articles of the Company implement the respective requirements.

a. Severance Pay, Advance Payments and Transaction Bonuses

The Compensation Ordinance prescribes certain types of compensation arrangements with members of a Swiss public company’s board of directors, executive management and advisory board, including severance payments, forms of advance compensation, transaction bonuses and certain other types of compensation and benefits not expressly provided for by a company’s articles of association.

The Compensation Ordinance broadly prohibits severance payments in any form. In addition, excessive termination notice periods in employment contracts (i.e., longer than one year) and long-term employment contracts for a fixed term of for more than one year are viewed as types of prohibited severance payments. However, post-employment non-competition covenants and consultancy agreements are not subject to the Compensation Ordinance’s severance pay prohibition, unless as a result of their terms they are deemed to be disguised severance payments.

The Compensation Ordinance also restricts certain forms of advance compensation. The decisive element in distinguishing prohibited advance payments from certain types of other advance payments, such as signing bonuses, is the point in time at which such payment is made. Consequently, signing bonuses compensating benefits and other entitlements that executives forfeit from their previous employers continue to be permissible whereas genuine prepayments of salary (i.e., if the contractual salary is paid in advance) are not permitted.

The Compensation Ordinance also prohibits certain types of transaction bonuses and certain other types of compensation and benefits not expressly provided for by the company’s articles of association.

b. Shareholder Approval of Compensation for Board of Directors, Executive Management and advisory board

The Compensation Ordinance requires Swiss public companies to vote on the compensation of the board of directors, executive management and advisory board. Swiss public companies are required to specify in their articles of association the mechanism for say-on-pay votes, subject to certain minimum requirements. These minimum requirements provide that the say-on-pay vote must be (i) held annually, (ii) binding and (iii) separate for the members of the board of directors, the members of the executive management and the members of the advisory board (if any). Companies are required to specify in their articles of association the mechanism for such say-on-pay votes.

c. Articles of Association

The Compensation Ordinance requires that the articles of association of a Swiss public company contain provisions regarding (i) the maximum number of positions that the members of the board of directors, executive management and advisory board may hold on the board or executive management of other companies that are neither controlled by the company nor control the company, (ii) the maximum duration of and/or the notice period under compensation arrangements with members of the board of directors, executive management and advisory board (which must not, in either case, exceed one year), (iii) the duties and responsibilities of a company’s compensation committee and (iv) the particulars of the say-on-pay vote of the annual general meeting of shareholders.

d. Election of the members of the Board of Directors, the Chairperson, the Members of the Compensation Committee and the Independent Voting Rights Representative

The Compensation Ordinance requires that the members of the board of directors, its chairperson, the members of the compensation committee (who must be members of the board of directors) and one or several independent voting rights representatives be elected by the general meeting of shareholders on an individual basis for a term ending at the next annual general meeting. Re-election is permitted.
e. **Independent Voting Rights Representative**

The Compensation Ordinance prohibits the representation of shareholders by corporate proxies (i.e., officers or other company representatives) as well as by proxies of deposited shares. The Compensation Ordinance requires the board of directors to ensure that the shareholders are able to electronically grant proxies and instruct the independent voting rights representative on both (i) agenda items included in the invitation to the general meeting of shareholders and (ii) new motions that were not disclosed in the invitation to the general meeting. The independent voting rights representative is required to exercise the voting rights granted by shareholders only in accordance with shareholder instructions. Further, absent express voting instructions, the independent voting rights representative is required to abstain from voting.

**CAPITALIZATION AND INDEBTEDNESS**

The following table sets forth the capitalization and indebtedness and certain other balance sheet information as of June 30, 2021 of the Company on a consolidated basis. This information should be read in conjunction with the Company's Annual Consolidated Financial Statements contained and included by reference in this Prospectus, in particular the section on "Unaudited Pro Forma Financial Information" beginning on page 133 which lists certain material transactions after June 30, 2021.

<table>
<thead>
<tr>
<th></th>
<th>As at June 30, 2021 (unaudited)</th>
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</thead>
<tbody>
<tr>
<td><strong>Total assets</strong></td>
<td>26'047</td>
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<tr>
<td>Current liabilities</td>
<td>19'039</td>
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<tr>
<td>Of which guaranteed/secured</td>
<td>-</td>
</tr>
<tr>
<td>Non-current liabilities</td>
<td>13'107</td>
</tr>
<tr>
<td>Of which guaranteed/secured</td>
<td>-</td>
</tr>
<tr>
<td><strong>Total liabilities</strong></td>
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<td>Share capital</td>
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<tr>
<td>Additional paid-in capital</td>
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<td>Treasury shares</td>
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<td>Cumulative translation differences</td>
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<td>Other reserves</td>
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<td>Accumulated deficit</td>
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<td><strong>Total equity</strong></td>
<td>(6'099)</td>
</tr>
<tr>
<td><strong>Total capitalization (liabilities plus equity)</strong></td>
<td>26'047</td>
</tr>
</tbody>
</table>

As of the date of this Prospectus, there have been no changes to the table above, other than (i) as a result of ongoing normal operating activities of the Company, (ii) as otherwise described in this Prospectus, in particular in Section 2.8 "Financial Statements", and (iii) any changes that would not have a material adverse effect on the Company.

**PRINCIPAL SHAREHOLDERS**

A. **Disclosures registered with the Disclosure Office of SIX Swiss Exchange**

To the Company's knowledge as at the date of this Prospectus, the following individuals and entities hold purchase positions (Shares and rights to acquire Shares) corresponding to at least 3% of the issued share capital of the Company after the Transaction pursuant to article 120 et seqq. FMIA. The Company is not aware of any sales positions exceeding 3% following the closing of the Transaction. Investors should consult the official disclosure notifications of significant shareholders as published on https://www.ser-ag.com/de/resources/notifications-market-participants/significant-shareholders.html#/ for further information.

The percentages set forth in the table below are required to be calculated on the basis of the 46'375'777 Shares recorded in the commercial register as of the date of this Prospectus (total outstanding: 47'531'938 Shares).
<table>
<thead>
<tr>
<th>Direct holder</th>
<th>Shares</th>
<th>% of voting rights</th>
<th>Other purchase positions</th>
<th>% of voting rights</th>
<th>Aggregate % of voting rights(1)</th>
<th>Sale positions</th>
<th>% of voting rights</th>
</tr>
</thead>
<tbody>
<tr>
<td>Apeiron Holdings Limited (US)(2)</td>
<td>7,295,494</td>
<td>15.73%</td>
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<td>—</td>
<td>15.73%</td>
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<td>RLG Corp. (US)</td>
<td>6,110,092</td>
<td>13.18%</td>
<td>—</td>
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<td>13.18%</td>
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<td>Vectura Group plc (UK)</td>
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<td>Trustees of Boston University (US)</td>
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<td>—</td>
<td>4.40%</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Sanford Biosciences, LLC (US)(3)</td>
<td>1,963,193</td>
<td>4.23%</td>
<td>—</td>
<td>—</td>
<td>4.23%</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>James Collins</td>
<td>1,962,237</td>
<td>4.23%</td>
<td>—</td>
<td>—</td>
<td>4.23%</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Jeffrey D. Wager</td>
<td>1,864,082</td>
<td>4.02%</td>
<td>—</td>
<td>—</td>
<td>4.02%</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Cystic Fibrosis Foundation (US)</td>
<td>1,509,988</td>
<td>3.26%</td>
<td>—</td>
<td>—</td>
<td>3.26%</td>
<td>—</td>
<td>—</td>
</tr>
</tbody>
</table>

(1) Percentage of the aggregate of the Shares and other purchase positions.

(2) Apeiron Holdings Limited is beneficially owned by Jeffrey D. Wager, Boston, MA.

B. **Lock-Up**

In connection with an investment by Vectura Group plc in EnBiotix prior to the Transaction, certain former Enbiotix shareholders (including Jeffrey D. Wager and Dennis Ausiello, Directors of the Company) will be subject to a 6 month lock-up commencing on the closing of the Transaction with respect to certain transactions in Shares and Share-based instruments, the counterparty being Vectura Group plc.
2.7 INFORMATION POLICY

The Company releases its annual financial results in the form of an annual report. Its annual report is published in print and electronic form within four months after the December 31 balance sheet date. In addition, results for the first half of each financial year are released in electronic form within four months after the June 30 balance sheet date. The Company’s annual report and half-year results will be announced via press releases and media and investor conferences in person or via telephone.

From the date of this Prospectus, copies of all information and documents pertaining to press releases, media conferences, investor updates and presentations at analyst and investor presentation conferences can be downloaded from the Company’s website at http://www.polyphor.com or obtained from the Company upon request at Spexis AG (formerly Polyphor Ltd), Hegenheimermattweg 125, CH-4123 Allschwil, Switzerland (telephone number: +41 (0)61 567 16 00, facsimile: +41 (0)61 567 16 01 or email: IR@polyphor.com).

The Company publishes price-sensitive information as required by the SIX Listing Rules. The Company’s ad-hoc reports and press releases may be retrieved at https://www.polyphor.com/news-adhoc/. Persons that wish to be included in the Company’s distribution list with respect to ad hoc notices may fill in the online form on the same website.

Management transaction of members of the Board or the Executive Management in Shares of the Company and certain financial instruments are published according to the Directive on the Disclosure of Management Transactions (the DMT) of March 20, 2018 (as amended) on https://www.ser-ag.com/de/resources/notifications-market-participants/management-transactions.html#. Disclosure notifications of significant shareholders are published on https://www.ser-ag.com/de/resources/notifications-market-participants/significant-shareholders.html#/


According to article 42 of the articles of association of the Company, shareholder communications and notices to the shareholders shall be made by publication in the Swiss Official Gazette of Commerce or sent by mail or e-mail to the addresses registered in the share register.

Weblinks

The Company’s website: http://www.polyphor.com

Email distribution list (push system): http://www.polyphor.com/news

2.8 FINANCIAL STATEMENTS

For the financial statements of Polyphor, reference is made to published Annual Consolidated Financial Statements as well as the unaudited condensed consolidated financial statements (see also “Important Information about the Prospectus” beginning on page 3), copies of which can be obtained, free of charge, from the registered office of the Company and are also available on the Company's website at www.polyphor.com. The financial statements of EnBiotix as well as certain pro forma financial information of the Company in light of the Transaction are included below.
Independent auditor’s report on the audit of the consolidated financial statements

Opinion
In accordance with the terms of our engagement, we have audited the consolidated financial statements of EnBiotix Inc. and its subsidiary (the Group), which comprise the consolidated statement of financial position as at 31 December 2020 and the consolidated income statement, the consolidated statement of comprehensive income, consolidated statement of changes in shareholders’ equity and consolidated statement of cash flows for the year then ended, and notes to the consolidated financial statements, including a summary of significant accounting policies.

In our opinion, the accompanying consolidated financial statements give a true and fair view of the consolidated financial position of the Group as at 31 December 2020, and its consolidated financial performance and its consolidated cash flows for the year then ended in accordance with International Financial Reporting Standards (IFRS).

Basis for opinion
We conducted our audit in accordance with International Standards on Auditing (ISAs) and Swiss Auditing Standards. Our responsibilities under those standards are further described in the Auditor’s responsibilities for the audit of the consolidated financial statements section of our report.

We are independent of the Group in accordance with the Code of Ethics for Professional Accountants issued by the International Ethics Standards Board for Accountants (IESBA Code) and the requirements of the Swiss audit profession, and we have fulfilled our other ethical responsibilities in accordance with these requirements and the IESBA Code.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

Responsibilities of the Board of Directors for the consolidated financial statements
The Board of Directors is responsible for the preparation of the consolidated financial statements that give a true and fair view in accordance with IFRS and for such internal control as the Board of Directors determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, the Board of Directors is responsible for assessing the Group’s ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the Board of Directors either intends to liquidate the Group or to cease operations, or has no realistic alternative but to do so.
Auditor's responsibilities for the audit of the consolidated financial statements

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs and Swiss Auditing Standards will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements.

A further description of our responsibilities for the audit of the consolidated financial statements is located at the website of EXPERTsuisse: http://www.expertsuisse.ch/en/audit-report-for-public-companies. This description forms part of our auditor's report.

Ernst & Young Ltd

Elisa Alfieri
(Qualified Signature)
Licensed audit expert
(Auditor in charge)

Martin Mattes
(Qualified Signature)
Licensed audit expert

Enclosure
- Consolidated financial statements

- 99 -
Financial Report
with consolidated financial statements as at December 31, 2020 of
EnBiotix, Inc., Boston
### EnBiotix, Inc., Boston

### Consolidated statement of financial position in CHF

<table>
<thead>
<tr>
<th>Notes</th>
<th>December 31, 2020</th>
<th>December 31, 2019</th>
<th>January 1, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Assets</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Current assets</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>5</td>
<td>294'142</td>
<td>411'040</td>
</tr>
<tr>
<td>Other accounts receivable</td>
<td>6</td>
<td>11'542</td>
<td>50'097</td>
</tr>
<tr>
<td>Prepaid expenses</td>
<td>1</td>
<td>1'835</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total current assets</strong></td>
<td></td>
<td>307'519</td>
<td>461'137</td>
</tr>
<tr>
<td><strong>Non-current assets</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Loans</td>
<td>6</td>
<td>33'294</td>
<td>35'369</td>
</tr>
<tr>
<td><strong>Total non-current assets</strong></td>
<td></td>
<td>33'294</td>
<td>35'369</td>
</tr>
<tr>
<td><strong>Total assets</strong></td>
<td></td>
<td>340'813</td>
<td>496'506</td>
</tr>
<tr>
<td><strong>Liabilities and shareholders’ equity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Current liabilities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade accounts payable</td>
<td>7</td>
<td>106'149</td>
<td>125'330</td>
</tr>
<tr>
<td>Other accounts payable</td>
<td>7</td>
<td>3'050</td>
<td>147</td>
</tr>
<tr>
<td>Current portion of debt</td>
<td>9</td>
<td>3'322'058</td>
<td>2'568'737</td>
</tr>
<tr>
<td>Current portion of preferred shares</td>
<td>10</td>
<td>1'134'245</td>
<td>948'828</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>8</td>
<td>2'076'859</td>
<td>1'963'358</td>
</tr>
<tr>
<td><strong>Total current liabilities</strong></td>
<td></td>
<td>6'704'761</td>
<td>5'606'603</td>
</tr>
<tr>
<td><strong>Non-current liabilities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-current portion of debt</td>
<td>9</td>
<td>0</td>
<td>83'595</td>
</tr>
<tr>
<td>Preferred shares</td>
<td>10</td>
<td>4'904'855</td>
<td>5'248'331</td>
</tr>
<tr>
<td><strong>Total non-current liabilities</strong></td>
<td></td>
<td>4'904'855</td>
<td>5'332'126</td>
</tr>
<tr>
<td><strong>Total liabilities</strong></td>
<td></td>
<td>11'609'616</td>
<td>10'938'729</td>
</tr>
<tr>
<td><strong>Shareholders’ equity</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Share capital</td>
<td>11</td>
<td>6'463</td>
<td>6'463</td>
</tr>
<tr>
<td>Additional paid-in capital</td>
<td></td>
<td>427'672</td>
<td>427'672</td>
</tr>
<tr>
<td>Cumulative translation differences</td>
<td></td>
<td>1'164'128</td>
<td>153'500</td>
</tr>
<tr>
<td>Retained earnings</td>
<td></td>
<td>-12'849'086</td>
<td>-11'029'858</td>
</tr>
<tr>
<td><strong>Total shareholders’ equity</strong></td>
<td></td>
<td>-11'288'803</td>
<td>-10'442'223</td>
</tr>
<tr>
<td><strong>Total liabilities and shareholders’ equity</strong></td>
<td></td>
<td>340'813</td>
<td>496'506</td>
</tr>
</tbody>
</table>
EnBiotix, Inc., Boston

Consolidated income statement for the year ended December 31, 2020
in CHF

<table>
<thead>
<tr>
<th>Notes</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other income</td>
<td>4</td>
<td>5,233</td>
</tr>
<tr>
<td>Research and development</td>
<td>13</td>
<td>-558,976</td>
</tr>
<tr>
<td>General and administrative</td>
<td>12</td>
<td>-717,399</td>
</tr>
<tr>
<td>Operating loss</td>
<td>-1,224,541</td>
<td>-1,080,959</td>
</tr>
<tr>
<td>Financial income</td>
<td>14</td>
<td>26,146</td>
</tr>
<tr>
<td>Financial expenses</td>
<td>14</td>
<td>-705,547</td>
</tr>
<tr>
<td>Net foreign exchange gain/loss</td>
<td>14</td>
<td>52,637</td>
</tr>
<tr>
<td>Net loss for the period</td>
<td>-1,851,305</td>
<td>-2,019,304</td>
</tr>
</tbody>
</table>

Net loss per share, (basic)            | 17     | -0.25   | -0.32 |
Net loss per share, (diluted)           | 17     | -0.28   | -0.32 |

Consolidated statement of comprehensive income for the year ended December 31
in CHF

<table>
<thead>
<tr>
<th>Notes</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net loss for the period</td>
<td>-1,851,305</td>
<td>-2,019,304</td>
</tr>
</tbody>
</table>

Other comprehensive loss that may be reclassified to profit or loss in subsequent periods:
Cumulative translation differences         | 992,626 | 153,500 |

Other comprehensive income                | 992,626 | 153,500 |
Total comprehensive loss                  | -858,677 | -1,865,804 |
EnBiotix, Inc., Boston

Consolidated statements of changes in shareholders’ equity for the year ended December 31, 2020
in CHF

<table>
<thead>
<tr>
<th>Share Capital</th>
<th>Additional paid-in capital</th>
<th>Cumulative translation differences</th>
<th>Retained earnings</th>
<th>Total Equity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance as of January 1, 2019</td>
<td>6'672</td>
<td>330'252</td>
<td>0</td>
<td>9'272'256</td>
</tr>
</tbody>
</table>

Net loss for the period: 0 0 0 -2'019'304 -2'019'304
Other comprehensive income: 0 0 153'566 0 153'566
Total comprehensive loss: 0 0 153'566 -2'019'304 -1'865'738

Issuance of share capital (note 11): 391 97'520 0 0 97'911
Equity component of issued preferred shares: 0 0 0 250'040 250'040
Share-based compensation (note 12): 0 0 0 11'962 11'962

Balance as of December 31, 2019: 6'463 427'872 153'566 -11'929'658 -10'442'223

Balance as of January 1, 2020: 6'463 427'872 153'566 1'162'958 10'442'223

Net loss for the period: 0 0 0 -1'861'305 -1'861'305
Other comprehensive income: 0 0 992'629 0 992'629
Total comprehensive loss: 0 0 992'629 -1'861'305 -868'672
Share-based compensation (note 12): 0 0 0 32'087 32'087

Balance as of December 31, 2020: 6'463 427'872 1'140'128 -12'849'066 -11'268'803
EnBiotix, Inc., Boston

Consolidated statement of cash flows for the year ended December 31, 2020
in CHF

<table>
<thead>
<tr>
<th>Notes</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net loss for the period</td>
<td>-1,351,300</td>
<td>-2,019,304</td>
</tr>
<tr>
<td>Adjustments for</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Net finance cost</td>
<td>14</td>
<td>639,401</td>
</tr>
<tr>
<td>- Share-based compensation</td>
<td>12</td>
<td>32,997</td>
</tr>
<tr>
<td>- Net foreign exchange (gain)/loss</td>
<td>14</td>
<td>-52,837</td>
</tr>
<tr>
<td>Changes in</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Trade and other receivables</td>
<td></td>
<td>38,470</td>
</tr>
<tr>
<td>- Prepaid expenses</td>
<td></td>
<td>-19,133</td>
</tr>
<tr>
<td>- Trade and other payables</td>
<td></td>
<td>53,363</td>
</tr>
<tr>
<td>- Accrued expenses</td>
<td></td>
<td>328,330</td>
</tr>
<tr>
<td>Net cash from operating activities</td>
<td></td>
<td>-774,264</td>
</tr>
</tbody>
</table>

Cash flows from financing activities

| Proceeds from issue of share capital | 11 | 0 | 49,000 |
| Proceeds from convertible notes | 9 | 630,525 | 525,220 |
| Proceeds from preferred shares | 10 | 0 | 99,900 |
| Transaction cost of preferred shares | 10 | 0 | -10,266 |
| Net cash from financing activities | 630,525 | 149,704 |

Net increase/(decrease) in cash equivalents | -82,769 | 388,423 |

Cash and cash equivalents at 1 January | 411,040 | 346,660 |

Effect of movements in exchange rates on cash and cash equivalents | -32,129 | -9,065 |

Cash and cash equivalents as at end of period | 294,142 | 411,040 |
EnBiotix, Inc., Boston

Notes to the Consolidated Financial Statements as of December 31, 2020

1. General information

EnBiotix, Inc. ("EnBiotix" or the "Company" or the "Corporation"), and together with its subsidiary, a wholly owned German limited liability company, EnBiotix GmbH, Leipzig, "the Group") is a late clinical stage, US specialty Pharma Company.

The Corporation was originally incorporated under the name Anagenix Therapeutics, Inc. The date of filing of the original Certificate of Incorporation of the Corporation with the Secretary of State of the State of Delaware was August 10, 2010. The Corporation filed its Amended & Restated Certificate of Incorporation on March 13, 2013, Second Amended & Restated Certificate of Incorporation on November 14, 2014 and Third Amended & Restated Certificate of Incorporation on August 21, 2019.

The Corporation is a late clinical-stage respiratory therapeutics company initially advancing first-line labelled products for chronic, recurrent and life-threatening pulmonary infections and has developed over the past years engineered antibiotics deploying novel systems and synthetic biology technologies. These technologies enable the development of both novel antibiotics and potentiators of existing antibiotics which have the potential to transform their spectrum of activity and resistance profile. With drug-resistant and drug-tolerant infections rapidly becoming a global health crisis, EnBiotix's product pipeline addresses a wide range of acute and chronic infections to significantly impact the lives of patients.

The Corporation has in-licensed ColiFin® from PARI Pharma GmbH located in Starnberg, Germany, a global leader in nebulized therapies, for worldwide rights ex-Europe. Approved in Europe since 2010 as a front-line therapy for lung infections in CF, ColiFin® has a proven safety and efficacy track record which the Corporation is leveraging initially towards the U.S. market. On May 9, 2020 the Corporation received FDA approval for their clinical phase III trial of ColiFin®.

In addition to the lead development candidate the Corporation owns 5 proprietary development platforms.

- Anti-Persister platform (Boston)
- Linear Peptide Antibiotics (LPA) platform (Leipzig)
- Engineered Bacteriophage platform (Boston)
- Tunable Target Degradation platform (Boston)
- Mine-AI Systems Biology platform (Boston)

The legal domicile of the Company is: EnBiotix, Inc.
197 West Springfield Street
Boston, Massachusetts 02118
United States of America

The Company is privately held by various investors.

2. Summary of significant accounting policies

2.1 Basis of preparation and adoption of IFRS

The consolidated financial statements as of December 31, 2020 are the first set of consolidated financial statements prepared by the Group. The Group has prepared an opening statement of financial position as at January 1, 2019 in accordance with IFRS and has applied all accounting policies effective as at December 31, 2020, its first reporting date under IFRS, consistently for all periods presented.
As the Group is not transitioning from a previous GAAP, no reconciliations of equity as of January 1 and December 31, 2019 respectively and other comprehensive income for the period ended December 31, 2019 are presented in these consolidated financial statements.

The consolidated financial statements have been prepared on a historical cost basis and are presented in Swiss Francs (CHF), rounded to the nearest Swiss Franc. Due to rounding, numbers presented throughout this report may not add up precisely to the totals provided. All ratios and variances are calculated using the underlying amount rather than the presented rounded amount.

The consolidated financial statements of EnBiotix have been prepared under the going concern assumption. The Company has typically limited financial resources and is raising cash in regular intervals in the form of debt and/or preferred shares. The Company expects to be able to finance its operations also in the foreseeable future.

The consolidated financial statements were authorised for issue by the Company’s Board of Directors on November 18, 2021.

2.2 Functional and presentation currency
These consolidated financial statements are presented in Swiss Francs (CHF) as they will be used as basis for the intended merger with Polyphor AG, Allschwil/Switzerland. The functional currency of the parent and its subsidiary are the local currencies US Dollars (USD) and Euro (EUR), which are the currencies of the jurisdictions in which the entities operate (USA and Germany).

2.3 Consolidation
The consolidated financial statements include the Company and its subsidiary. Control exists when the investor is exposed, or has rights, to variable returns from its investment with the investee and has the ability to affect those returns through its power over the investee. Control is normally evidenced when the Company owns, either directly or indirectly, more than 50% of the voting rights or potential voting rights of a company's share capital that are currently exercisable. Subsidiaries are consolidated from the date on which effective control is transferred to the Group and are deconsolidated from the date control ceases.

All inter-company balances, transactions and unrealized gains on transactions have been eliminated in the consolidated financial statement. Unrealized losses are also eliminated unless the transaction provides evidence of an impairment of the asset transferred.

The following entities are within the scope of consolidation:

<table>
<thead>
<tr>
<th>Company</th>
<th>Registered</th>
<th>Currency</th>
<th>Nominal Capital</th>
<th>Equity Interest</th>
</tr>
</thead>
<tbody>
<tr>
<td>EnBiotix, Inc.</td>
<td>USA</td>
<td>USD</td>
<td>6'463</td>
<td></td>
</tr>
<tr>
<td>EnBiotix GmbH</td>
<td>Germany</td>
<td>EUR</td>
<td>25'000</td>
<td>100%</td>
</tr>
</tbody>
</table>

2.4 Future changes in accounting policies
The accounting policies adopted in the preparation of the consolidated financial statements are those which are effective as of December 31, 2020. The Group has not early adopted any other standard, interpretation or amendment that has been issued but is not yet effective. It is not expected that such standards have a material impact on the consolidated financial statements of EnBiotix.
2.5 Use of judgement and estimates

The preparation of the consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of income, expenses, assets and liabilities, and the accompanying disclosures, and the disclosure of contingent liabilities. Uncertainty about these assumptions and estimates could result in outcomes that require a material adjustment to the carrying amount of the affected assets or liabilities in future periods.

Judgement

The Company has issued various share options and financial instruments with conversion features with no fixed maturity date. The Company has assessed on January 1, 2019 and thereafter that an exit event (IPO, merger, sale) is expected to happen at the end of 2022. This assumption has an impact on the valuation of many instruments in the financial statements.

Estimates and assumptions

The key assumptions at the reporting date that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year relate to the following items:

- The Company has issued preferred shares to investors. While these preferred shares have been recorded as equity in the local financial statements, they qualify as liabilities under IFRS. The conversion feature was bifurcated from the liability and recorded in equity.
- EnBioex has issued various share-based payments to mostly employees. These options differ and often have features including graded vesting schemes that are fixed in time or vest upon a specific event. Management made assumptions on these features in the valuation of the instruments.

2.6 Foreign currency translation

Both companies in the Group use their functional currency, and items in the financial statements of each entity are measured using that functional currency.

Foreign currency transactions are translated in the functional currency at the exchange rates prevailing at the date of the transaction. Foreign exchange gains and losses resulting from the settlement of such transactions, as well as from the translation of monetary assets and liabilities denominated in foreign currencies are recognized in the income statement.

Upon consolidation, assets and liabilities of the subsidiaries reporting in foreign currency are translated into Swiss Francs using the exchange rate at the reporting date. Their income statements are translated at the average yearly exchange rates of the reporting year.

The exchange rates for the most significant foreign currencies are as follows:

<table>
<thead>
<tr>
<th>Income statement in CHF average rates</th>
<th>Statement of financial position in CHF year-end rates</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2020</td>
</tr>
<tr>
<td>1 USD</td>
<td>0.9207</td>
</tr>
<tr>
<td>1 EUR</td>
<td>1.0859</td>
</tr>
</tbody>
</table>

2.7 Financial assets

Financial assets are classified, at initial recognition, and subsequently measured at amortised cost or fair value through profit or loss.

The classification of financial assets at initial recognition depends on the financial asset's contractual cash flow characteristics and the Group's business model for managing them. The Group initially measures a financial asset at its fair value plus, in the case of a financial asset not
at fair value through profit or loss, transaction costs. Trade receivables, if any, are measured at the transaction price determined under IFRS 15.

In order for a financial asset to be classified and measured at amortised cost, it needs to be held to collect contractual cash flows that are solely payments of principal and interest (SPPI) on the principal amount outstanding. This assessment is referred to as the SPPI test and is performed at an instrument level.

EnBiOrx financial assets at amortised cost comprise cash and cash equivalents, other accounts receivable and loans. Subsequently to initial recognition, these financial instruments are carried at amortised cost using the effective interest method and are subject to an impairment assessment applying the expected credit loss (ECL) model. ECLs 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.

Financial assets are derecognised when the rights to receive the cash flows from the financial assets have expired or been transferred and EnBiOrx has transferred substantially all risks and rewards of ownership.

2.8 Grants

Grants received from governmental and other organisations are recognised in the statement of financial position initially as accrued income when there is reasonable assurance that it will be received and that the Group will comply with the conditions attached to it. Grants that compensate the company for expenses incurred are recognized as other operating income on a systematic basis in the same periods in which the expenses are incurred.

2.9 Provisions

Provisions are recognised when the Group has a present obligation (legal or constructive) as a result of a past event, it is probable that an outflow of resources embodying economic benefits will be required to settle the obligation and a reliable estimate can be made of the amount of the obligation.

2.10 Financial liabilities

All financial liabilities are recognised initially at fair value and, in the case of loans and borrowings and payables, net of directly attributable transaction costs. The Group’s financial liabilities include trade and other payables and interest-bearing debt (incl. preferred shares).

After initial recognition, interest-bearing loans and borrowings are subsequently measured at amortised cost using the effective interest method. Gains and losses are recognised in the income statement when the liabilities are derecognised as well as through the effective interest rate amortisation process.

Derivatives embedded in financial liabilities which are not closely related to the host are bifurcated at the inception of the financing facility but recorded together with the host contract as a financial liability.

The preferred shares contain a conversion feature that meets the definition of an equity instrument. The convertible element is bifurcated at inception, credited to equity and the loan is thereafter recorded at amortized cost using the effective interest method.

A financial liability is derecognised when the obligation under the liability is discharged, cancelled or expires. When an existing financial liability is replaced by another from the same lender on substantially different terms, or the terms of an existing liability are substantially modified, such an exchange or modification is treated as the derecognition of the original liability and the recognition of a new liability. The difference in the respective carrying amounts is recognised in the income statement.
If the contractual cashflows of a modified financial debt instrument are not substantially different from the cashflows of the original debt instrument, the financial debt instrument is not derecognised. However, the amortised cost of the instrument is adjusted to the net present value of the revised cashflows discounted at the original effective interest rate with the difference recognised in the profit or loss.

2.11 Share capital
The costs of an equity transaction are accounted for as a deduction from equity. Equity transaction costs are comprised of only those incremental external costs directly attributable to the equity transaction which would otherwise have been avoided.

2.12 Research and development
Research and development ("R&D") expenses are charged to the income statement when incurred. EnBiotox considers that the regulatory and other uncertainties inherent in the development of its product candidates preclude it from capitalizing development costs.
Costs of applying for patents for internally developed products, costs of defending existing patents and costs of challenging patents held by third parties where these are considered invalid, are considered part of development expense and expensed as incurred.

2.13 Employee benefit costs
Wages, salaries, social security contributions, paid annual leave, sick leave and other benefits are paid or accrued undiscounted in the year in which the associated services are rendered by employees of the Group. Legal or constructive obligations such as bonus are recognized for the amount expected to be paid in the year in which the services are provided and are presented under other liabilities.

2.14 Share-based compensation
The Group's share-based compensation plans qualify as equity-settled plans and the fair value is determined at the grant date. The fair value of the employee services received in exchange for the grant of shares or share options is recognized as an expense over the relevant vesting period in line with the graded vesting patterns of the awards. The same approach is used for grants to non-employees as the terms and conditions are comparable to those granted to employees. At each reporting date, the Group revises its estimates of the number of options that are expected to become exercisable. It recognizes the impact of the revision of original estimates, if any, in the income statement and a corresponding adjustment to equity.
In the year the options are exercised the proceeds received net of any directly attributable transaction costs are credited to share capital (nominal value) and additional paid-in capital.

2.15 Taxation
Income tax expense comprises current and deferred tax. It is recognized in the income statement except to the extent that it relates to items recognized directly in equity or in other comprehensive income.

Current income tax
Current income tax assets and liabilities for the current and prior periods are measured at the amount expected to be recovered from or paid to the taxation authorities. The tax rates and tax laws used to compute the amount are those that are enacted or substantively enacted by the balance sheet date. Current tax assets and liabilities are offset only if certain criteria are met.
Deferred income taxes

Deferred tax is recognised in respect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for tax purposes. Deferred income tax assets and liabilities are offset when there is a legally enforceable right to offset current tax assets against current tax liabilities and when the deferred income taxes relate to the same fiscal authority.

Deferred tax assets are recognised for unused tax losses, unused tax credits and deductible temporary differences to the extent that it is probable that future taxable profits will be available against which they can be used. Future taxable profits are determined based on business plans for the Group and the reversal of temporary differences. Deferred tax assets are reviewed at each reporting date and are reduced to the extent that it is no longer probable that the related tax benefit will be realised; such reductions are reversed when the probability of future taxable profits improves.

Unrecognised deferred tax assets are reassessed at each reporting date and recognised to the extent that it has become probable that future taxable profits will be available against which they can be used.

Deferred tax is measured at the tax rates that are expected to be applied to temporary differences when they reverse, using tax rates enacted or substantively enacted at the reporting date. The measurement of deferred tax reflects the tax consequences that would follow from the manner in which the Group expects, at the reporting date, to recover or settle the carrying amount of its assets and liabilities. Deferred tax assets and liabilities are offset only if certain criteria are met.

3. Segment information

The Group has one operating segment focusing on the research and development and prospective commercialisation of respiratory therapeutics addressing high unmet medical needs.

The Group has not yet recorded any revenue up to 2020.

4. Other income

Other income only consists of government grants received:

<table>
<thead>
<tr>
<th></th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grants</td>
<td>52'334</td>
<td>82'283</td>
</tr>
<tr>
<td>Total</td>
<td>52'334</td>
<td>82'283</td>
</tr>
</tbody>
</table>

In August 2017, EnBiOtx GmbH received a non-dilutive grant ("Förderung durch die Sächsische Aufbau Bank") in Leipzig (Germany) in connection with the EFRE (European Fund for regional Development). The SAB issued a non-repayable grant of up to 65.0% of the eligible costs as a project claim for proportional financing (partial financing) up to a maximum amount of EUR 380,534. The amount can only be used for work associated with the project "Evaluation of Oncocin peptides as a new class of antibiotics for the treatment of ventilator-associated nosocomial pneumonia and Application of Oncocin peptides for inhalation through the lung infection model". The initial grant period was extended from July 31, 2019 until December 31, 2020. In the period from August 1, 2017 until December 31, 2020, the company has to finance the project with matching funds with a total amount of EUR 204,903. The Project "Evaluation of Oncocin peptides as a new class of antibiotics for the treatment of ventilator-associated nosocomial pneumonia" has been performed in collaboration with the University of Leipzig, Prof. Dr. Rolf Hoffmann, Institut für Bioanalytische Chemie. The Company and the University of Leipzig entered into a collaboration agreement in November 2017. The parties agreed that each party covers its own cost.
The project research project has been completed on December 31, 2020. A final report has been submitted to the SAB on March 31, 2021. EnBiotix GmbH expects in the 4th Quarter 2021 a final payment in the amount of EUR 3,400 once the final report has been accepted by the SAB.

In 2020, EnBiotix, Inc. has received a loan that was forgiven in January 2021 and recorded as other income in 2020 (CHF 42'444) as the criteria to record it as other income was already met in 2020.

5. Cash and cash equivalents

Cash is held with banks in the USA and in Germany in local currencies.

6. Other accounts receivable

The other receivables consist mainly of amounts due from government grants (see note 4). They are due within 30-180 days and bear no interest.

No bad debt provision was recognized on these receivables as management estimates that no allowance is necessary as of December 31, 2020 and 2019.

7. Trade accounts payable and other liabilities

<table>
<thead>
<tr>
<th></th>
<th>2020</th>
<th>2019</th>
<th>January 1, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade accounts payable</td>
<td>168'149</td>
<td>125'533</td>
<td>134'566</td>
</tr>
<tr>
<td>Other accounts payable</td>
<td>3'050</td>
<td>147</td>
<td>4'086</td>
</tr>
<tr>
<td>Total at December 31</td>
<td>171'199</td>
<td>125'680</td>
<td>138'652</td>
</tr>
</tbody>
</table>

Trade accounts payable are non-interest bearing and usually settled within 30 to 60 days.

8. Accrued expenses

Accrued expenses relate primarily to employee expenses, licence fees and other operating expenses. The employee expenses are non-financial liabilities. Other operating expenses (financial) include accruals for patents, energy costs, clinical costs, IT expenses and third party contractors/advisors.

<table>
<thead>
<tr>
<th></th>
<th>2020</th>
<th>2019</th>
<th>January 1, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Accrued salary Jeffrey O. Vilas</td>
<td>1'316'003</td>
<td>1'444'298</td>
<td>1'229'200</td>
</tr>
<tr>
<td>Other operating expenses</td>
<td>792'756</td>
<td>51'038</td>
<td>50'685</td>
</tr>
<tr>
<td>Total at December 31</td>
<td>2'108'759</td>
<td>1'495'336</td>
<td>1'279'885</td>
</tr>
</tbody>
</table>
9. Debt

<table>
<thead>
<tr>
<th></th>
<th>2020</th>
<th>2019</th>
<th>January 1, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Current portion of debt</td>
<td>3,322,658</td>
<td>2,568,726</td>
<td>3,839,224</td>
</tr>
<tr>
<td>Non-current portion of debt</td>
<td>0</td>
<td>83,565</td>
<td>84,440</td>
</tr>
<tr>
<td><strong>Total at end of period</strong></td>
<td><strong>3,322,658</strong></td>
<td><strong>2,652,332</strong></td>
<td><strong>3,923,644</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>2020</th>
<th>2019</th>
<th>January 1, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fair Value of embedded derivatives in host contract</td>
<td>25,906</td>
<td>13,483</td>
<td>10,917</td>
</tr>
<tr>
<td>as of statement date</td>
<td>0</td>
<td>15,668</td>
<td>10,517</td>
</tr>
</tbody>
</table>

The Group has issued various loans, of which the majority contains embedded derivatives that meet the definition of a derivative based on IFRS requirements. Interests on all loans are accrued and have not been paid in the years above and are therefore shown in line with the classification of the debt instrument itself.

As a general rule, for the measurement of embedded derivatives, the Company has assessed, that a conversion (IPO or sale) shall take place at December 31, 2002.

Two convertible notes ("junior/senior convertible notes") amounting to USD 2'340'000, USD 2'090'000 and USD 3'450'000 as of December 31, 2020, 2019 and 2018, respectively were issued. These loans are split into a junior and a senior tranche as follows (nominal amount):

<table>
<thead>
<tr>
<th></th>
<th>2020</th>
<th>2019</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>USD</td>
<td>USD</td>
<td>USD</td>
</tr>
<tr>
<td>Junior notes</td>
<td>1'080'000</td>
<td>1'080'000</td>
<td>2'800'000</td>
</tr>
<tr>
<td>Senior notes</td>
<td>1'290'000</td>
<td>1'240'000</td>
<td>850'000</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>2'240'000</td>
<td>2'320'000</td>
<td>3'650'000</td>
</tr>
<tr>
<td><strong>in CHF</strong></td>
<td>2'065'848</td>
<td>2'029'181</td>
<td>3'392'592</td>
</tr>
</tbody>
</table>

Convertible loans amounting to USD 1'990'000 were converted together with accrued interest of USD 248'187 into preferred shares (series B) of the Company in 2019. Additional tranches were issued in 2019 (USD 540'000) and in 2020 (USD 290'000). Embedded derivatives are separately recorded at the issue date and thereafter measured at fair value through profit and loss, but discounted together with the host contract. Both notes can be converted into series B preferred shares of the Company. The conversion ratio is the lesser of the share price (series B) or an assumed pre-money valuation of the company of USD 15 million, divided by the outstanding securities on a fully-diluted basis.
The main features of the notes are as follows:

- Junior tranche: the notes carry an interest of 8% (compound) and are due on July 31, 2022. In case of an acquisition, the loans need to be repaid plus a premium of 25%. If an IPO takes place, the investors have the right to convert the loan into common shares. The junior note is subordinated.

- Senior tranche: the notes carry an interest of 14% (compound) and are due on July 31, 2022. In case of an acquisition, the loans need to be repaid plus a premium of 25%. If an IPO takes place, the investors have the right to convert the loan into common shares. The note is subordinated, but senior to the junior note. The senior debt is collateralized with receivables, inventory and intangibles of the Company.

An additional tranche ("additional tranche of convertible note") amounting to USD 500'000 (CHF 407'423 excl. embedded derivative) was issued in 2020 with the same terms as the senior tranche, except that the maturity date is July 31, 2023. The fair value of the embedded derivative at the issue date amounted to USD 42'300, was separately measured and is thereafter fair valued through profit and loss (CHF 22'376 as of December 31, 2020). However, the embedded derivative is disclosed together with the host contract as debt.

In addition, the Company issued a convertible note ("additional convertible note") amounting to USD 78'930 on May 8, 2016 with a maturity date of May 8, 2021. The note carries interest of 8%. The note is converted into common shares upon a qualified financing or a sale of the Company. The holder of the note has the right to convert the note into common shares of the Company at maturity.

Finally, the Company issued a fixed-term loan bearing interest of 6% denominated in USD. The loan is repayable on demand.

10. Preferred shares

The Company has issued 3 different types of preferred shares:

- Series-A preferred shares issued in 2014, 2015 and 2016 have a privileged dividend of 5% since issuance which accumulate, but do not carry a compound element. The dividend has to be paid upon a deemed liquidity or redemption event and have preference over dividends paid to common shareholders. Such a dividend is paid in case of a liquidation or winding-up or a similar event, incl. a merger or a sale of the company. Additionally, the holder of Series-A preferred shares have the right to convert the shares into common shares at a price of USD 1.32 on a fully diluted basis. The preferred shares can be redeemed on November 30, 2024, 2025 and 2026 in equal tranches if not converted by then. Considering the assumption of an IPO or a sale, the preferred shares Series-A are accounted for using an effective interest rate of 5.96% until the expected maturity.

- Series-B preferred shares were issued in 2019 (converted from convertible loans, see note 9 above). Series-B preferred shares carry a privileged dividend of 5% under the same terms as Series-A preferred shares. The conversion price is USD 1.00 and the effective interest rate amounts to 9.26% until the expected maturity.

- Series-C preferred shares were issued in 2019, have a privileged dividend of 6% and otherwise have the same terms and conditions as the other preferred shares. The conversion price is USD 3.88 and the effective interest rate amounts to 7.35% until the expected maturity.

As for all outstanding notes, the same assumption regarding an IPO or sale as of December 31, 2022 was applied which has an impact on the privileged dividend and the overall cost of all preferred shares. While the preferred shares are generally non-current in nature, the unpaid accumulated privileged dividend is shown as a current liability.
11. Share capital

At December 31, 2020 the Company’s share capital consisted of 6'568'172 Common Shares with a nominal value of USD 0.001 each.

No dividends were declared or paid by the Company for the year under review (2019: nil).

<table>
<thead>
<tr>
<th>Shares</th>
<th>Total</th>
<th>Nominal</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Shares</td>
<td>Value in USD</td>
</tr>
<tr>
<td>Shares at January 1, 2019</td>
<td>6'174.172</td>
<td>6.174</td>
</tr>
<tr>
<td>Shares at January 1, 2019</td>
<td>6'174.172</td>
<td>6.174</td>
</tr>
<tr>
<td>Capital Increase</td>
<td>394'990</td>
<td>394</td>
</tr>
<tr>
<td>Shares at December 31, 2019</td>
<td>6'568.172</td>
<td>6.568</td>
</tr>
<tr>
<td>Shares at January 1, 2020</td>
<td>6'568.172</td>
<td>6.568</td>
</tr>
<tr>
<td>Shares at December 31, 2020</td>
<td>6'568.172</td>
<td>6.568</td>
</tr>
</tbody>
</table>

12. Share-based payment arrangements

The Company has historically offered 3 different types of share-based payment arrangements to employees, Board members and consultants determined to provide similar services as employees and therefore treated as employees.

- Restricted shares awards (RSA) were offered including vesting conditions of up to 48 months. The Company has a call option over unvested shares and can buy them back at the original issue price prior to any vesting. Most of the RSA are fully vested as of the transition date to IFRS (January 1, 2019) and only 63'621 shares have not vested as of that date. As RSA were sold at fair market value (FMV), no related expense has been recorded in any year. As the call option over unvested shares meets the condition of an equity instrument, such call options are not remeasured at year-end.

- Non-qualified shares options ("NQSO") have been granted. The options include vesting conditions and have different terms as described below.

- Incentive shares options ("ISO") have been granted including vesting conditions.

As NQSO and ISO are identical for accounting purposes, they are treated the same way and are not distinguished or disclosed separately. Overall, 12 grants have been granted to employees, consultants and Board members (all to be treated as employees in the context of IFRS 2) that have been measured according to IFRS 2, share-based payments, leading to an expense of CHF 11'662 in 2019 and CHF 32'097 in 2020.

As with other instruments, the Company made a general assumption that an IPO or sale takes place on December 31, 2022, and, therefore, the expected life has been assumed to be December 31, 2022.

Options granted in 2017/18

Two awards (employee share options, "ESOP") were made in 2018 and 1 in 2017 to employees under different terms and conditions prior to the adoption of IFRS.

The fair value of the share options had been determined at the grant date based on a valuation report prepared by a third party. All unvested options have a graded straight-line vesting scheme over a specific period whereas certain options vested immediately.

The tables below show the assumptions applied to value the share-based payment arrangements for 2017/18:
### Stock options, conditions and assumptions

#### ESOP2017/18

<table>
<thead>
<tr>
<th>Nature of arrangement</th>
<th>Grant of stock options 2018</th>
<th>Grant of stock options 2016</th>
<th>Grant of stock options 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grant date</td>
<td>01.02.2018</td>
<td>01.02.2016</td>
<td>01.11.2017</td>
</tr>
<tr>
<td>Number of options granted</td>
<td>0</td>
<td>0</td>
<td>42,500</td>
</tr>
<tr>
<td>Exercise price (USD)</td>
<td>0.23</td>
<td>0.23</td>
<td>0.3</td>
</tr>
<tr>
<td>Share price at date of grant (USD)</td>
<td>0.23</td>
<td>0.23</td>
<td>0.23</td>
</tr>
<tr>
<td>Vesting period (months)</td>
<td>12</td>
<td>42</td>
<td>50</td>
</tr>
<tr>
<td>Vesting type</td>
<td>graded</td>
<td>graded</td>
<td>graded</td>
</tr>
<tr>
<td>Immediate vesting</td>
<td>3,333</td>
<td>3,125</td>
<td>2,425</td>
</tr>
<tr>
<td>Settlement</td>
<td>Shares</td>
<td>Shares</td>
<td>Shares</td>
</tr>
<tr>
<td>Expected volatility (%)</td>
<td>69.86%</td>
<td>69.86%</td>
<td>69.86%</td>
</tr>
<tr>
<td>Expected option life at grant date (months)</td>
<td>59</td>
<td>59</td>
<td>60</td>
</tr>
<tr>
<td>Risk-free interest rate (p.a.) (%)</td>
<td>7% 7% 7%</td>
<td>7% 7% 7%</td>
<td>7% 7% 7%</td>
</tr>
<tr>
<td>Expected dividend</td>
<td>Zero</td>
<td>Zero</td>
<td>Zero</td>
</tr>
<tr>
<td>Estimated fair value of option at grant date (USD)</td>
<td>0.1354</td>
<td>0.1354</td>
<td>0.1220</td>
</tr>
<tr>
<td>Estimated fair value of option at grant date (CHF)</td>
<td>0.1345</td>
<td>0.1345</td>
<td>0.1211</td>
</tr>
</tbody>
</table>

**Valuation model:** Black-Scholes-Merton

#### Options granted in 2019

During 2019 the Group established additional awards to 5 employees, consultants and Board members.

The fair value of the share options had been determined at the grant date based on a valuation report prepared by a third party. Two awards have a graded straight-line vesting scheme over a specific period whereas certain options vested immediately. Other options vest upon a defined milestone event (transaction or FDA approval) which in all cases is expected to be on December 31, 2022.

The tables below show the assumptions applied to value the share-based payment arrangements for 2019:

#### ESOP2019

<table>
<thead>
<tr>
<th>Nature of arrangement</th>
<th>Grant of stock options 2018</th>
<th>Grant of stock options 2016</th>
<th>Grant of stock options 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of options granted</td>
<td>25,000</td>
<td>10,000</td>
<td>25,000</td>
</tr>
<tr>
<td>Exercise price (USD)</td>
<td>0.19</td>
<td>0.93</td>
<td>0.49</td>
</tr>
<tr>
<td>Share price at date of grant (USD)</td>
<td>0.49</td>
<td>0.46</td>
<td>0.46</td>
</tr>
<tr>
<td>Vesting period (months)</td>
<td>milestone</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Vesting type</td>
<td>cliff</td>
<td>graded</td>
<td>graded</td>
</tr>
<tr>
<td>Immediate vesting</td>
<td>0</td>
<td>7,960</td>
<td>0</td>
</tr>
<tr>
<td>Settlement</td>
<td>Shares</td>
<td>Shares</td>
<td>Shares</td>
</tr>
<tr>
<td>Expected volatility (%)</td>
<td>78.72%</td>
<td>79.99%</td>
<td>79.99%</td>
</tr>
<tr>
<td>Expected option life at grant date (months)</td>
<td>36.5</td>
<td>37</td>
<td>37</td>
</tr>
<tr>
<td>Risk-free interest rate (p.a.) (%)</td>
<td>1.03%</td>
<td>1.01%</td>
<td>1.01%</td>
</tr>
<tr>
<td>Expected dividend</td>
<td>Zero</td>
<td>Zero</td>
<td>Zero</td>
</tr>
<tr>
<td>Estimated fair value of option at grant date (USD)</td>
<td>0.2668</td>
<td>0.321</td>
<td>0.321</td>
</tr>
<tr>
<td>Estimated fair value of option at grant date (CHF)</td>
<td>0.25</td>
<td>0.32</td>
<td>0.32</td>
</tr>
</tbody>
</table>

**Valuation model:** Black-Scholes-Merton

#### Options granted in 2020

During 2020 the Group established additional share grants to 4 employees, consultants and Board members.

The fair value of the share options had been determined at the grant date based on a valuation report prepared by a third party. All options have a graded straight-line vesting scheme over a specific period whereas certain options vested immediately except for one which can be exercised in case of three specific non-market milestones.
The tables below show the assumptions applied to value the share-based payment arrangements for 2020:

### ESOP2020

**Stock options, conditions and assumptions**

<table>
<thead>
<tr>
<th>Nature of arrangement</th>
<th>Grant of stock options</th>
<th>Grant of stock options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grant date or earliest vesting start</td>
<td>01.01.2020</td>
<td>01.09.2020</td>
</tr>
<tr>
<td>Number of options granted</td>
<td>205,000</td>
<td>120,000</td>
</tr>
<tr>
<td>Exercise price (USD)</td>
<td>0.59</td>
<td>0.59</td>
</tr>
<tr>
<td>Share price at date of grant (USD)</td>
<td>0.59</td>
<td>0.59</td>
</tr>
<tr>
<td>Exercise date</td>
<td>31.12.2022</td>
<td>31.09.2024</td>
</tr>
<tr>
<td>Vesting period (months)</td>
<td>milestone</td>
<td>48</td>
</tr>
<tr>
<td>Vesting type</td>
<td>cliff</td>
<td>graded</td>
</tr>
<tr>
<td>Settlement</td>
<td>Shares</td>
<td>Shares</td>
</tr>
<tr>
<td>Expected volatility (%)</td>
<td>74.73%</td>
<td>55.12%</td>
</tr>
<tr>
<td>Expected option life at grant date (months)</td>
<td>26</td>
<td>48</td>
</tr>
<tr>
<td>Risk-free interest rate p.a. (%)</td>
<td>1.62%</td>
<td>0.11%</td>
</tr>
<tr>
<td>Expected dividend</td>
<td>Zero</td>
<td>Zero</td>
</tr>
<tr>
<td>Estimated fair value of option at grant date (USD)</td>
<td>0.2670</td>
<td>0.2627</td>
</tr>
<tr>
<td>Estimated fair value of option at grant date (CHF)</td>
<td>0.2608</td>
<td>0.2479</td>
</tr>
<tr>
<td>Valuation model</td>
<td>Black-Scholes-Merton</td>
<td>Black-Scholes-Merton</td>
</tr>
</tbody>
</table>

The movements in the number of all shares options are as follows:

<table>
<thead>
<tr>
<th>Block option movements</th>
<th>Options (number)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Balance outstanding December 31, 2018</td>
<td>27,100</td>
</tr>
<tr>
<td>Granted</td>
<td>62,500</td>
</tr>
<tr>
<td>Balance outstanding December 31, 2019</td>
<td>140,000</td>
</tr>
<tr>
<td>Granted</td>
<td>140,000</td>
</tr>
<tr>
<td>Balance outstanding December 31, 2020</td>
<td>300,500</td>
</tr>
</tbody>
</table>

The weighted average fair value of shares options granted for employees during the year was USD 0.27 (2019: USD 0.31).

The following table applies to all shares options outstanding at December 31, 2020:

<table>
<thead>
<tr>
<th>Options (number)</th>
<th>Weighted average remaining contractual life (months)</th>
<th>Exercisable options (number)</th>
</tr>
</thead>
<tbody>
<tr>
<td>300,500</td>
<td>29.3</td>
<td>192,896</td>
</tr>
</tbody>
</table>

The following table applies to all shares options outstanding at December 31, 2019:

<table>
<thead>
<tr>
<th>Options (number)</th>
<th>Weighted average remaining contractual life (months)</th>
<th>Exercisable options (number)</th>
</tr>
</thead>
<tbody>
<tr>
<td>165,000</td>
<td>29.3</td>
<td>77,393</td>
</tr>
</tbody>
</table>

17
13. Expenses by nature – additional details

The following tables show the Group’s expenses for employee benefits:

<table>
<thead>
<tr>
<th></th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CHF</td>
<td>CHF</td>
</tr>
<tr>
<td>Wages and salaries</td>
<td>79,563</td>
<td>63,918</td>
</tr>
<tr>
<td>Social security cost</td>
<td>12,338</td>
<td>83,795</td>
</tr>
<tr>
<td>Share-based payments</td>
<td>22,006</td>
<td>11,962</td>
</tr>
<tr>
<td>Total net operating expenses</td>
<td>114,907</td>
<td>159,675</td>
</tr>
</tbody>
</table>

Employee expenses have been charged to:

<table>
<thead>
<tr>
<th></th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research and development</td>
<td>12,304</td>
<td>82,896</td>
</tr>
<tr>
<td>General and administrative</td>
<td>111,209</td>
<td>60,379</td>
</tr>
<tr>
<td>Total</td>
<td>123,507</td>
<td>748,275</td>
</tr>
</tbody>
</table>

14. Financial Result

Financial income

The financial income recognized during the period under review comprises interest income from loans granted to unpaid share capital increases. Financial income includes fair value changes of derivatives in 2020 amounting to CHF 2,496,4 (2019: nil).

Financial expenses

The financial expenses recognized during the period under review comprise interest on preferred shares and convertible notes.

<table>
<thead>
<tr>
<th></th>
<th>2020 CHF</th>
<th>2019 CHF</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interest expense on preferred shares</td>
<td>421,155</td>
<td>281,966</td>
</tr>
<tr>
<td>Other interest expense</td>
<td>284,121</td>
<td>347,310</td>
</tr>
<tr>
<td>Fair value changes of derivatives</td>
<td>271</td>
<td>232</td>
</tr>
<tr>
<td>Total at December 31</td>
<td>705,547</td>
<td>629,207</td>
</tr>
</tbody>
</table>

15. Income taxes and deferred taxes

As the Group companies do not generate profits, no current income taxes have been charged to the Group. The Group has the following unrecognized tax loss carry-forwards available:

<table>
<thead>
<tr>
<th>Tax loss carry-forwards</th>
<th>December 31, 2020</th>
<th>December 31, 2019</th>
<th>January 1, 2019</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>CHF 8,686,830</td>
<td>CHF 8,136,964</td>
<td>CHF 6,334,747</td>
</tr>
</tbody>
</table>

Deferred tax assets (not recognized in the statement of financial position) consist mainly of tax losses in the US which begin to expire in 2030. Tax losses in Germany do not expire and amount to CHF 307,303, CHF 284,874 and CHF 229,261 for the years ended 2020, 2019 and as of January 1, 2019, respectively.

Preferred shares are recorded in equity in the local US accounts and as a liability in these IFRS financial statements. However, no potential deferred tax asset is recognized at inception as this temporary difference falls under the so-called initial recognition exemption at inception. Differences recognized thereafter due to accrued interest however are shown in the table above.

The Group’s expected tax rate is 28% for the period under review (2019: 29%), which is the expected statutory tax rate of EntBiotix, Inc.
The following table shows the reconciliation between expected and effective taxes: expenses not deductible for tax purposes consist primarily of share-based payment expenses and non-deductible expenses in the US.

<table>
<thead>
<tr>
<th>Income tax reconciliation</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CHF</td>
<td>CHF</td>
</tr>
<tr>
<td>Net income/(loss) before taxes</td>
<td>-1'851'305</td>
<td>-2'019'304</td>
</tr>
<tr>
<td>Tax expense/(income) at applicable tax rate (29%)</td>
<td>-536'878</td>
<td>-585'598</td>
</tr>
<tr>
<td>Tax effect of non-deductible expenses</td>
<td>9'361</td>
<td>7'504</td>
</tr>
<tr>
<td>Tax effect of unrecognised US tax credit</td>
<td>6'354</td>
<td>16'035</td>
</tr>
<tr>
<td>Effect of unrecognised deferred taxes on tax losses, carry-forwards</td>
<td>-1'819'690</td>
<td>-559'786</td>
</tr>
<tr>
<td>Effect of unrecognised deferred taxes on temporary differences</td>
<td>142'693</td>
<td>9'378</td>
</tr>
<tr>
<td>Other effects</td>
<td>-3'180</td>
<td>-7'099</td>
</tr>
<tr>
<td>Effective tax income/(expenses)</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Effective tax rate</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

16. Commitments

The Company did not enter into any contracts resulting in capital commitments.

17. Earnings per share (EPS)

Basic and diluted earnings per share have been computed based upon the weighted average number of registered shares outstanding. Basic earnings per share excludes any dilutive effects of options, warrants, convertible notes and preferred shares. Outstanding employee shares options to purchase registered share, convertible notes and preferred shares are not included in the computation of the diluted earnings per share as the effect would have been anti-dilutive.

For the period ending

<table>
<thead>
<tr>
<th>Basic and diluted earnings</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CHF</td>
<td>CHF</td>
</tr>
<tr>
<td>Net loss attributable to the ordinary shareholders</td>
<td>-1'851'305</td>
<td>-2'019'304</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Weighted average number of shares</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>shares</td>
<td>shares</td>
</tr>
<tr>
<td>Weighted average number of ordinary shares (basic)</td>
<td>6'568'172</td>
<td>6'342'716</td>
</tr>
<tr>
<td>Weighted average number of ordinary shares (diluted)</td>
<td>6'568'172</td>
<td>6'342'716</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Earnings per share</th>
<th>2020</th>
<th>2019</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CHF</td>
<td>CHF</td>
</tr>
<tr>
<td>Basic earnings per share</td>
<td>-0.26</td>
<td>-0.32</td>
</tr>
<tr>
<td>Diluted earnings per share</td>
<td>-0.26</td>
<td>-0.32</td>
</tr>
</tbody>
</table>
18. Non-cash transactions

In 2019, two non-cash transactions were made that are not shown in the consolidated cash flow statement:

- Convertible loans were converted into series B preferred shares amounting to CHF 2'133'130 (USD 2'148'165)
- A capital increase of common shares amounting to CHF 48'161 (USD 48'500) was made. However, the amount was not paid but granted as a loan.


EnBiotx is a late stage biotech company with R&D activities in the US and Germany. The Group is exposed to limited financial risks, mainly foreign exchange rate, credit liquidity risk, and interest rate risk. EnBiotx’s overall financial risk management program focuses on ensuring capital protection (measured in CHF) to ensure that the funds provided by its investors will be available for the primary purpose to ensure going concern.

As a consequence, it is EnBiotx’s policy to reduce material exposures to foreign currencies, to invest liquidity in cash and other liquid instruments, and to limit its financial counterparties to highly rated financial institutions.

19.1 Foreign exchange risk

EnBiotx’s exposure to foreign exchange risk is not material as both entities are investing in local R&D activities. Moreover, none of the entities hold material assets or liabilities that are denominated in a foreign currency.

19.2 Interest rate risk

EnBiotx is financed with different instruments that are all classified as liabilities under IFRS. Interest rates are all fixed until maturity and any changes in interest rates therefore do not have an impact on the Group.

19.3 Credit and Counterparty risk

Credit risk is the risk of financial loss to the Group if a customer or counterparty to liquidity or of a financial instrument fails to meet its contractual obligations. As at December 31, 2020 the Group has no significant credit and counterparty risk.

EnBiotx currently holds its cash deposits and handles its financial transactions solely with highly rated financial institutions.

19.4 Liquidity risk

EnBiotx regularly raises funds through preferred shares and convertible loans to finance its operations. The cash position is typically not high as the company only raises funds for the near future.

<table>
<thead>
<tr>
<th></th>
<th>2019 CHF</th>
<th>Increase</th>
<th>Interest</th>
<th>FX effect</th>
<th>FV change of derivative</th>
<th>2020 CHF</th>
</tr>
</thead>
<tbody>
<tr>
<td>cash</td>
<td>2'652'332</td>
<td>695'325</td>
<td>241'142</td>
<td>-279'627</td>
<td>-24'714</td>
<td>3'332'658</td>
</tr>
<tr>
<td>preferred shares</td>
<td>6'197'359</td>
<td>0</td>
<td>421'158</td>
<td>-579'410</td>
<td>0</td>
<td>6'099'100</td>
</tr>
<tr>
<td>Total</td>
<td>8'847'691</td>
<td>695'325</td>
<td>262'298</td>
<td>-858'037</td>
<td>-24'714</td>
<td>9'301'758</td>
</tr>
</tbody>
</table>

Reference is made to note 20 for the explanation of the non-cash transactions for financial instruments.
Other include issuance cost of preferred shares and the equity component of the convertible element.

The maturity analysis of contractually agreed cash flows (principal and interest) of the Group’s financial liabilities is as follows:

### Maturity of financial liabilities

<table>
<thead>
<tr>
<th>(CHF)</th>
<th>Carrying amount</th>
<th>contractual cash flows</th>
<th>1 to 3 months</th>
<th>4 to 12 months</th>
<th>2-5 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>Trade accounts payable</td>
<td>168'149</td>
<td>168'149</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Other accounts payable</td>
<td>3'050</td>
<td>3'050</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>7'597'755</td>
<td>7'597'755</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Current and non-current debt</td>
<td>3'322'659</td>
<td>66'608</td>
<td>300'351</td>
<td>4'008'097</td>
<td></td>
</tr>
<tr>
<td>Current and non-current preferred shares</td>
<td>6'039'100</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td><strong>Total as per December 31, 2020</strong></td>
<td><strong>10'292'712</strong></td>
<td><strong>1'021'562</strong></td>
<td><strong>390'351</strong></td>
<td><strong>4'008'097</strong></td>
<td></td>
</tr>
</tbody>
</table>

| Trade accounts payable | 125'533 | 125'533 | 0 | 0 |
| Other accounts payable | 147 | 147 | 0 | 0 |
| Accrued expenses | 515'098 | 515'098 | 0 | 0 |
| Current and non-current debt | 2'952'332 | 69'983 | 209'949 | 343'269 |
| Current and non-current preferred shares | 6'197'359 | 0 | 0 | 0 |
| **Total as per December 31, 2019** | **9'490'469** | **710'760** | **209'949** | **343'269** |

Preferred shares do not have contractual cash flows; they include a preferred dividend that only has to be paid if common shareholders receive a dividend. Consequently, the table includes cash flows other than for preferred shares.

20. **Categories of financial instruments and fair value disclosures**

The following table shows the carrying amounts and fair values of financial assets and financial liabilities. The carrying amounts are a reasonable approximation of their fair values.

<table>
<thead>
<tr>
<th>For the period ended December 31, 2020</th>
<th>(CHF)</th>
<th>Financial assets at amortized costs</th>
<th>Financial liabilities at FV at %</th>
<th>Other liabilities at amortized costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assets</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>294'142</td>
<td>294'142</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Other accounts receivable</td>
<td>115'42</td>
<td>115'42</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Loans and rent deposit</td>
<td>30'54</td>
<td>30'54</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>339'128</td>
<td>339'128</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Liabilities</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade accounts payable</td>
<td>168'149</td>
<td>0</td>
<td>0</td>
<td>168'149</td>
</tr>
<tr>
<td>Other accounts payable</td>
<td>3'050</td>
<td>0</td>
<td>0</td>
<td>3'050</td>
</tr>
<tr>
<td>Debt (current and non-current)</td>
<td>3'322'659</td>
<td>0</td>
<td>29'344</td>
<td>3'322'659</td>
</tr>
<tr>
<td>Preferred shares (current and non-current)</td>
<td>6'039'100</td>
<td>0</td>
<td>0</td>
<td>6'039'100</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>7'597'755</td>
<td>0</td>
<td>0</td>
<td>7'597'755</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>10'292'712</td>
<td>0</td>
<td>29'344</td>
<td>10'292'712</td>
</tr>
<tr>
<td></td>
<td>Book value (CHF)</td>
<td>Financial assets at amortized costs</td>
<td>Financial liabilities at FY/PL</td>
<td>Other liabilities at amortized costs</td>
</tr>
<tr>
<td>----------------</td>
<td>------------------</td>
<td>------------------------------------</td>
<td>-------------------------------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td><strong>Assets</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>411,540</td>
<td>411,540</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Other accounts receivable</td>
<td>30,000</td>
<td>30,000</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Loans and net deposits</td>
<td>20,206</td>
<td>20,206</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>461,746</td>
<td>461,746</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td><strong>Liabilities</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade accounts payable</td>
<td>125,533</td>
<td>0</td>
<td>0</td>
<td>125,533</td>
</tr>
<tr>
<td>Other accounts payable</td>
<td>147</td>
<td>0</td>
<td>0</td>
<td>147</td>
</tr>
<tr>
<td>Debt (current and non-current)</td>
<td>2,982,332</td>
<td>0</td>
<td>19,817</td>
<td>2,992,149</td>
</tr>
<tr>
<td>Preferred shares (current and non-current)</td>
<td>619,250</td>
<td>0</td>
<td>0</td>
<td>619,250</td>
</tr>
<tr>
<td>Accounts expenses</td>
<td>11,058</td>
<td>0</td>
<td>0</td>
<td>11,058</td>
</tr>
<tr>
<td>Total</td>
<td>9,660,469</td>
<td>0</td>
<td>13,897</td>
<td>9,674,362</td>
</tr>
</tbody>
</table>

The table above analyses recurring fair value measurement for financial assets and financial liabilities. These fair value measurements are categorized into different levels in the fair value hierarchy based on the input and techniques used. The different levels have been defined as follows:

- **Level 1**: quoted prices (unadjusted) in active markets for identical assets or liabilities
- **Level 2**: inputs other than quoted prices included within level 1 that are observable for the asset or liability, either directly (i.e. as prices) or indirectly (i.e. derived from prices)
- **Level 3**: inputs for the asset or liability that are not based on observable market data (unobservable inputs).

The derivatives listed above are level 3 fair values.

The carrying amounts approximately reflect fair values of the financial instruments except for the following debt:

<table>
<thead>
<tr>
<th></th>
<th>Book value (USD)</th>
<th>Book value (CHF)</th>
<th>Fair value (CHF)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Liabilities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Convertible loans</td>
<td>2,878,300</td>
<td>2,878,300</td>
<td>3,020,834</td>
</tr>
<tr>
<td>Preferred shares</td>
<td>8,480,257</td>
<td>9,039,100</td>
<td>3,483,322</td>
</tr>
<tr>
<td>Total</td>
<td>11,358,557</td>
<td>11,489,350</td>
<td>6,483,322</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>Book value (USD)</th>
<th>Book value (CHF)</th>
<th>Fair value (CHF)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Liabilities</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Convertible loans</td>
<td>2,090,000</td>
<td>2,090,000</td>
<td>2,367,609</td>
</tr>
<tr>
<td>Preferred shares</td>
<td>6,357,066</td>
<td>6,917,358</td>
<td>3,703,766</td>
</tr>
<tr>
<td>Total</td>
<td>8,447,066</td>
<td>9,277,418</td>
<td>6,071,375</td>
</tr>
<tr>
<td>As of January 1, 2019</td>
<td>Book value</td>
<td>Book value (USD)</td>
<td>Fair value (CHF)</td>
</tr>
<tr>
<td>Liabilities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Convertible loans</td>
<td>3,450,000</td>
<td>3,450,000</td>
<td>3,941,583</td>
</tr>
<tr>
<td>Preferred shares</td>
<td>3,309,427</td>
<td>3,254,555</td>
<td>1,531,326</td>
</tr>
<tr>
<td>Total</td>
<td>6,759,427</td>
<td>6,704,555</td>
<td>5,472,909</td>
</tr>
</tbody>
</table>

21. **Transactions with related parties**

**Key management**

Key management includes the Executive Management and the Board of Directors. It consists of 1 member of Executive Management and 4 members of the Board of Directors, for both years. Also the share based payment expenses of CHF 6'023 in 2020 and CHF 6'227 in 2019 relates to key management.
22. Events after the reporting period

The convertible note amounting to USD 78’930 with a maturity date of May 8, 2021 was not paid back. Instead, the Company is renegotiating the terms with the lender. No formal agreement has been reached as of today.

On September 1, 2021 EnBiotech Inc. and Polyphor Ltd. entered into a merger agreement pursuant to which Polyphor Ltd. acquires all of the outstanding capital stock of EnBiotech Inc. in exchange for shares of Polyphor Ltd.’s common stock. The transaction is subject to a number of closing conditions, satisfactory completion of due diligence and satisfactory assessment of tax consequences as well as approval by Polyphor Ltd. and EnBiotech Inc. shareholders who voted positively for the merger on October 28, 2021. Upon completion of the merger, former EnBiotech Inc. equity holders (including investors of the planned financing round) are expected to own approximately 74-77% of Polyphor Ltd.’s common stock. Polyphor’s current shareholders are expected to own approximately 22-26% of Polyphor Ltd.’s issued common shares following the closing of the merger. Following closing, which is expected in the first half of December 2021, Polyphor Ltd. will be renamed into Speex Ltd., and is expected to trade under a new ticker symbol on the Swiss Stock Exchange.

In parallel to the merger Polyphor Ltd. and EnBiotech Inc. closed on September 10, 2021 a purchase agreement of Inhaled Murepavadin by EnBiotech Inc. As a result of the closing of the transaction, EnBiotech Inc. issued 2’599’655 of common shares of EnBiotech Inc. (15.4% fully diluted of EnBiotech Inc.) as compensation based on an agreed valuation of USD 10 million.

In September 2021 EnBiotech Inc. established a wholly owned subsidiary EnBiotech Switzerland GmbH with a capital of 20,000 CHF which owns the Murepavadin IP rights.

Under the existing convertible notes agreement as described in the Note 9 ("junior/senior convertible notes") above the Company has received additional capital in 2021 amounting to USD 975,000 in different tranches until November 18, 2021.
B. Financial Report with consolidated financial statements as at 30 June 2021 of EnBiotix, Inc., Boston/USA (unaudited)

EnBiotix, Inc., Boston

Interim consolidated statement of financial position in CHF

<table>
<thead>
<tr>
<th></th>
<th>June 30, 2021</th>
<th>December 31, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Current assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>18'115</td>
<td>294'142</td>
</tr>
<tr>
<td>Other accounts receivable</td>
<td>18'444</td>
<td>11'542</td>
</tr>
<tr>
<td>Prepaid expenses</td>
<td>2'156</td>
<td>1'835</td>
</tr>
<tr>
<td><strong>Total current assets</strong></td>
<td><strong>36'715</strong></td>
<td><strong>307'519</strong></td>
</tr>
<tr>
<td><strong>Non-current assets</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Loans</td>
<td>35'305</td>
<td>33'294</td>
</tr>
<tr>
<td><strong>Total non-current assets</strong></td>
<td><strong>35'305</strong></td>
<td><strong>33'294</strong></td>
</tr>
<tr>
<td><strong>Total assets</strong></td>
<td><strong>72'020</strong></td>
<td><strong>340'813</strong></td>
</tr>
</tbody>
</table>

| **Liabilities and shareholders' equity** |       |                   |
| **Current liabilities**                 |       |                   |
| Trade accounts payable                  | 377'048 | 168'149           |
| Other accounts payable                  | 139    | 3'050             |
| Current portion of debt                 | 3'749'377 | 3'322'658       |
| Current portion of preferred shares     | 1'324'387 | 1'134'245       |
| Accrued expenses                       | 2'170'127 | 2'076'659       |
| **Total current liabilities**           | **7'621'078** | **6'704'761**   |

| **Non-current liabilities**             |       |                   |
| Preferred shares                       | 5'199'705 | 4'904'855       |
| **Total non-current liabilities**       | **5'199'705** | **4'904'855**   |
| **Total liabilities**                   | **12'820'783** | **11'609'616** |

| **Shareholders' equity**                |       |                   |
| Share capital                           | 6'463 | 6'463             |
| Additional paid-in capital              | 427'672 | 427'672         |
| Cumulative translation differences      | 671'308 | 1'146'128       |
| Retained earnings                      | -12'849'066 | -12'849'066     |
| **Total shareholders' equity**          | -12'748'763 | -11'268'803     |
| **Total liabilities and shareholders' equity** | **72'020** | **340'813**     |
EnBiotix, Inc., Boston

Interim consolidated income statement for the 6 months ended June 30, 2021
in CHF

<table>
<thead>
<tr>
<th>Notes</th>
<th>June 30, 2021</th>
<th>June 30, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other income</td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td>Research and development</td>
<td>-322'893</td>
<td>-270'724</td>
</tr>
<tr>
<td>General and administrative</td>
<td>-272'203</td>
<td>-312'916</td>
</tr>
<tr>
<td>Operating loss</td>
<td>-555'086</td>
<td>-538'215</td>
</tr>
<tr>
<td>Financial income</td>
<td>582</td>
<td>619</td>
</tr>
<tr>
<td>Financial expenses</td>
<td>-421'242</td>
<td>-330'060</td>
</tr>
<tr>
<td>Net foreign exchange gain/(loss)</td>
<td>-10'962</td>
<td>-5'826</td>
</tr>
<tr>
<td>Net loss for the period</td>
<td>-1'016'708</td>
<td>-873'482</td>
</tr>
</tbody>
</table>

Net loss per share (basic) | 9 | -0.15 | -0.13 |
Net loss per share (diluted) | 9 | -0.15 | -0.13 |

Interim consolidated statement of comprehensive income for the 6 months ended June 30, 2021
in CHF

<table>
<thead>
<tr>
<th>Notes</th>
<th>June 30, 2021</th>
<th>June 30, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td>Net loss for the period</td>
<td>-1'016'708</td>
<td>-873'482</td>
</tr>
<tr>
<td>Other comprehensive loss that may be reclassified to profit or loss in subsequent periods:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cumulative translation differences</td>
<td>-474'220</td>
<td>252'711</td>
</tr>
<tr>
<td>Other comprehensive income</td>
<td>-474'220</td>
<td>252'711</td>
</tr>
<tr>
<td>Total comprehensive loss</td>
<td>-1'490'928</td>
<td>-620'771</td>
</tr>
</tbody>
</table>
## EnBiotix, Inc., Boston

### Interim consolidated statements of changes in shareholders’ equity for the 6 months ended June 30, 2021 in CHF

<table>
<thead>
<tr>
<th></th>
<th>Share Capital</th>
<th>Additional paid-in capital</th>
<th>Cumulative translation differences</th>
<th>Retained earnings</th>
<th>Total Equity</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Balance as of January 1, 2020</strong></td>
<td>6’463</td>
<td>427’672</td>
<td>153’500</td>
<td>.11’029’058</td>
<td>10’442’223</td>
</tr>
<tr>
<td>Net loss for the period</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>.873’482</td>
<td>.873’482</td>
</tr>
<tr>
<td>Other comprehensive income</td>
<td>0</td>
<td>0</td>
<td>252’711</td>
<td>0</td>
<td>252’711</td>
</tr>
<tr>
<td><strong>Total comprehensive loss</strong></td>
<td>0</td>
<td>0</td>
<td>252’711</td>
<td>0</td>
<td>252’711</td>
</tr>
<tr>
<td>Share-based compensation</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>23’005</td>
<td>23’005</td>
</tr>
<tr>
<td><strong>Balance as of June 30, 2020</strong></td>
<td>6’463</td>
<td>427’672</td>
<td>406’211</td>
<td>.11’860’335</td>
<td>11’038’989</td>
</tr>
<tr>
<td><strong>Balance as of January 1, 2021</strong></td>
<td>6’463</td>
<td>427’672</td>
<td>1’146’128</td>
<td>.12’849’066</td>
<td>11’268’803</td>
</tr>
<tr>
<td>Net loss for the period</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>.1’016’708</td>
<td>.1’016’708</td>
</tr>
<tr>
<td>Other comprehensive income</td>
<td>0</td>
<td>0</td>
<td>.474’220</td>
<td>0</td>
<td>.474’220</td>
</tr>
<tr>
<td><strong>Total comprehensive loss</strong></td>
<td>0</td>
<td>0</td>
<td>.474’220</td>
<td>0</td>
<td>.474’220</td>
</tr>
<tr>
<td>Share-based compensation</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>10’968</td>
<td>10’968</td>
</tr>
<tr>
<td><strong>Balance as of June 30, 2021</strong></td>
<td>6’463</td>
<td>427’672</td>
<td>671’908</td>
<td>.13’854’806</td>
<td>12’748’763</td>
</tr>
</tbody>
</table>
Interim consolidated statement of cash flows for the 6 months ended June 30, 2021
In CHF

<table>
<thead>
<tr>
<th>Notes</th>
<th>June 30, 2021</th>
<th>June 30, 2020</th>
</tr>
</thead>
</table>

**Net loss for the period**  
-10,167,086  
-873,482

**Adjustments for**
- Other non-cash items  
0  
44,436
- Net finance cost  
420,661  
329,441
- Share-based compensation  
10,968  
23,005
- Net foreign exchange gain/(loss)  
12,007  
5,826

**Changes in**
- Trade and other receivables  
4,747  
41,627
- Prepaid expenses  
-242  
0
- Trade and other payables  
200,645  
28,163
- Accrued expenses  
3,290  
90,363

**Net cash from operating activities**  
-376,126  
-396,493

**Cash flows from financing activities**
Proceeds from increases in debt  
87,058  
0

**Net cash from financing activities**  
87,058  
0

**Net increase/(decrease) in cash equivalents**  
-289,068  
-354,057

<table>
<thead>
<tr>
<th>Notes</th>
<th>June 30, 2021</th>
<th>June 30, 2020</th>
</tr>
</thead>
</table>

- **Cash and cash equivalents at 1 January**  
294,142  
411,040
- **Effect of movements in exchange rates on cash and cash equivalents**  
11,043  
33,352
- **Cash and cash equivalents as at end of period**  
161,115  
533,831
1. General information

EnBiotix, Inc. (“EnBiotix” or the “Company” or the “Corporation”), and together with its subsidiary, a wholly owned German limited liability company, EnBiotix GmbH, Leipzip, (“the Group”) is a late clinical stage, US specialty Pharma Company.

The Corporation was originally incorporated under the name Anagenix Therapeutics, Inc. The date of filing of the original Certificate of Incorporation of the Corporation with the Secretary of State of the State of Delaware was August 10, 2010. The Corporation filed its Amended & Restated Certificate of Incorporation on March 13, 2013, Second Amended & Restated Certificate of Incorporation on November 14, 2014 and Third Amended & Restated Certificate of Incorporation on August 21, 2019.

The Corporation is a late clinical-stage respiratory therapeutics company initially advancing front-line labelled products for chronic, recurrent and life-threatening pulmonary infections and has developed over the past years engineered antibiotics deploying novel systems and synthetic biology technologies. These technologies enable the development of both novel antibiotics and potentiators of existing antibiotics which have the potential to transform their spectrum of activity and resistance profile. With drug-resistant and drug-tolerant infections rapidly becoming a global health crisis, EnBiotix’s robust product pipeline addresses a wide range of acute and chronic infections to significantly impact the lives of patients.

The Corporation has in-licensed ColiFin® from PARI Pharma GmbH located in Starnberg, Germany, a global leader in nebulized therapies, for worldwide rights ex-Europe. Approved in Europe since 2010 as a front-line therapy for lung infections in CF, ColiFin® has a proven safety and efficacy track record which the Corporation is leveraging initially towards the U.S. market. On May 9, 2020 the Corporation received FDA approval for their clinical phase III trial of ColiFin®.

In addition to the lead development candidate the Corporation owns 5 proprietary development platform.

- Anti-Persister platform (Boston)
- Linear Peptide Antibiotics (LPA) platform (Leipzig)
- Engineered Bacteriophage platform (Boston)
- Tunable Target Degradation platform (Boston)
- Mine-AI Systems Biology platform (Boston)

The legal domicile of the Company is: EnBiotix, Inc.
197 West Springfield Street
Boston, Massachusetts 02118
United States of America

The Company is privately held by various investors.

2. Summary of significant accounting policies

2.1 Basis of preparation

The interim condensed consolidated financial statements for the six months ended June 30, 2021 have been prepared in accordance with IAS 34 Interim Financial Reporting.

The interim condensed consolidated financial statements do not include all the information and disclosures required in the annual financial statements, and should be read in conjunction with the Group’s annual consolidated financial statements as at December 31, 2020.

The interim condensed consolidated financial statements have been prepared on a historical cost basis and are presented in Swiss Francs (CHF), rounded to the nearest Swiss Franc. Due to rounding, numbers presented throughout this report may not add up precisely to the totals provided. All ratios and variances are calculated using the underlying amount rather than the presented rounded amount.

Considering the fact the EnBiotix is not yet generating revenues, there is no seasonality in its operations.
The interim condensed consolidated financial statements were authorised for issue by the Company’s Board of Directors on November 19, 2021.

2.2 New standards, interpretations and amendments adopted by the Group
The accounting policies adopted in the preparation of the interim condensed consolidated financial statements are consistent with those followed in the preparation of the Group’s annual consolidated financial statements for the year ended December 31, 2020, except for the adoption of amendments effective as of January 1, 2021 which do not have an impact on the interim condensed consolidated financial statements of the Group.

The Group has not early adopted any other standard, interpretation or amendment that has been issued but is not yet effective.

2.3 Use of judgement and estimates
The preparation of interim condensed consolidated financial statements requires management to make estimates and assumptions that affect the reported amounts of revenues, expenses, assets, liabilities and disclosure of contingent liabilities at the date of the interim condensed consolidated financial statements. If in the future such estimates and assumptions, which are based on management’s best judgment at the date of the interim consolidated financial statements, deviate from the actual circumstances, the original estimates and assumptions will be modified as appropriate during the period in which the circumstances change.

All judgments and estimates made by the Group are consistent with those presented in the annual consolidated financial statements as of December 31, 2020.

3. Segments
The Group has one operating segment focusing on the research and development and prospective commercialisation of respiratory therapeutics addressing high unmet medical needs.

The company has not yet recorded any revenue up to June 2021.

4. Other income
Other income recorded in June 30, 2020, relates to a grant that was received by EnBiotix, Inc.

5. Cash and cash equivalents
Cash is held with banks in the USA and in Germany in local currencies.
6. **Debt**

<table>
<thead>
<tr>
<th></th>
<th>June 30, 2021</th>
<th>December 31, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CHF</td>
<td>CHF</td>
</tr>
<tr>
<td>Current portion of debt</td>
<td>3'749’377</td>
<td>3'322’658</td>
</tr>
<tr>
<td>Total at end of period</td>
<td>3'749’377</td>
<td>3’322’658</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th></th>
<th>June 30, 2021</th>
<th>December 31, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>CHF</td>
<td>CHF</td>
</tr>
<tr>
<td>Fair value of embedded derivatives in host contract:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>23’762</td>
<td>25’907</td>
</tr>
<tr>
<td>of which non-current</td>
<td>23’762</td>
<td>25’907</td>
</tr>
</tbody>
</table>

The Group has issued various loans, of which the majority contains embedded derivatives that meet the definition of a derivative based on IFRS requirements. Interests on all loans are accrued and have not been paid in the years above and are therefore shown in line with the classification of the debt instrument itself.

As a general rule, for the measurement of embedded derivatives, the Company has assessed, that a transaction (IPO or sale) shall take place at December 31, 2022.

Two convertible loans amounting to USD 2’435’000 and USD 2’340’000 as of June 30, 2021 and December 31, 2020, respectively were issued. These loans are split into a junior and a senior tranche as follows:

<table>
<thead>
<tr>
<th></th>
<th>June 30, 2021</th>
<th>December 31, 2020</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>USD</td>
<td>USD</td>
</tr>
<tr>
<td>Junior notes</td>
<td>1’050’000</td>
<td>1’050’000</td>
</tr>
<tr>
<td>Senior notes</td>
<td>1’385’000</td>
<td>1’290’000</td>
</tr>
<tr>
<td>Total</td>
<td>2’435’000</td>
<td>2’340’000</td>
</tr>
<tr>
<td>in CHF</td>
<td>2’241’807</td>
<td>2’065’846</td>
</tr>
</tbody>
</table>

An additional tranche was issued in 2021 amounting to CHF 87’058 (USD 95’000). Embedded derivatives are separately recorded at the issue date and thereafter measured at fair value through profit and loss, but disclosed together with the host contract. Both notes can be converted into series B preferred shares of the Company. The conversion ratio is the lesser of the share price (series B) or an assumed pre-money valuation of the company of USD 15 million, divided by the outstanding securities on a fully-diluted basis.

The main features of the notes are as follows:

- **Junior tranche:** the notes carry an interest of 8% (compound) and are due on July 31, 2022. In case of an acquisition, the loans need to be repaid plus a premium of 25%. If an IPO takes place, the investors have the right to convert the loan into common stock. The junior note is subordinated.

- **Senior tranche:** the notes carry an interest of 14% (compound) and are due on July 31, 2022. In case of an acquisition, the loans need to be repaid plus a premium of 25%. If an IPO takes place, the investors have the right to convert the loan into common stock. The note is subordinated, but senior to the junior note. The senior debt is collateralized with receivables, inventory and intangibles of the Company.

An additional tranche amounting to USD 500’000 was issued in 2020 with the same terms as the senior tranche, except that the maturity date is July 31, 2023. The fair value of the embedded derivative at the issue date amounted to USD 42’300, was separately measured and is thereafter fair valued through profit and loss. However, the embedded derivative is disclosed together with the host contract as debt.

The Company moreover issued a convertible note amounting to USD 78’930 on May 8, 2016 with a maturity date of May 8, 2021. The note carries interest of 8%. The note is converted into common stock upon a qualified financing or a sale of the company. The holder of the note has the right to convert the note into common stock of the company at maturity. The note has not been redeemed as of today and negotiations with the lender are ongoing.

Finally, the Company issued a fixed-term loan bearing interest of 6% denominated in USD. The loan is repayable on demand.
7. **Preferred shares**

The Company has issued 3 different types of preferred shares:

- Series-A preferred shares issued in 2014, 2015 and 2016 have a privileged dividend of 5% since issuance which accumulate, but do not carry a compound element. The dividend has to be paid upon a deemed liquidity or redemption event and have preference over dividends paid to common shareholders. Such a dividend is paid in case of a liquidation or winding-up or a similar event, incl. a merger or a sale of the company. Additionally, the holder of Series-A preferred shares have the right to convert the shares into common shares at a price of USD 1.32 on a fully diluted basis. The preferred shares can be redeemed at November 30, 2024, 2025 and 2026 in equal tranches if not converted by then. Considering the assumption of an IPO or a sale, the preferred shares Series-A are accounted for using an effective interest rate of 5.96% until the expected maturity.
- Series-B preferred shares were issued in 2019 (converted from convertible loans, see note 9 above). Series-B preferred shares carry a privileged dividend of 5% under the same terms as Series-A preferred shares. The conversion price is USD 1.66 and the effective interest rate amounts to 9.26% until the expected maturity.
- Series-C preferred shares were issued in 2019, have a privileged dividend of 6% and otherwise have the same terms and conditions as the other preferred shares. The conversion price is USD 3.86 and the effective interest rate amounts to 7.35% until the expected maturity.

As for all outstanding notes, the same assumption regarding an IPO or sale as of December 31, 2022 was applied which has an impact on the privileged dividend and the overall cost of all preferred shares. While the preferred shares are generally non-current in nature, the unpaid accumulated privileged dividend is shown as a current liability.

8. **Share capital**

At June 30, 2020 the Company’s share capital consisted of 6'568'172 Common Shares with a nominal value of USD 0.001 each which is unchanged as compared to December 31, 2020.

No dividends were declared or paid by the Company for the periods under review.

9. **Earnings per share**

Basic and diluted earnings per share have been computed based upon the weighted average number of registered shares outstanding. Basic earnings per share excludes any dilutive effects of options, warrants and convertible loans. Outstanding employee stock options to purchase registered shares were not included in the computation of the diluted earnings per share as the effect would have been anti-dilutive.
10. Categories of financial instruments and fair value disclosure

The following table shows the carrying amounts and fair values of financial assets and financial liabilities. The carrying amounts are a reasonable approximation of fair values.

<table>
<thead>
<tr>
<th>For the period ended June 30, 2021 (CHF)</th>
<th>Book value</th>
<th>Financial assets at amortized costs</th>
<th>Financial liabilities at FVTPL</th>
<th>Other liabilities at amortized costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assets</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>16'115</td>
<td>16'115</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Other accounts receivable</td>
<td>18'444</td>
<td>18'444</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Loans</td>
<td>35'305</td>
<td>35'305</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>69'864</td>
<td>69'864</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Liabilities</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade accounts payable</td>
<td>377'048</td>
<td>0</td>
<td>0</td>
<td>377'048</td>
</tr>
<tr>
<td>Other accounts payable</td>
<td>126</td>
<td>0</td>
<td>0</td>
<td>126</td>
</tr>
<tr>
<td>Debt (current and non-current)</td>
<td>3'749'277</td>
<td>0</td>
<td>23'762</td>
<td>3'725'515</td>
</tr>
<tr>
<td>Preferred shares (current and non-current)</td>
<td>8'524'092</td>
<td>0</td>
<td>0</td>
<td>8'524'092</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>795'909</td>
<td>0</td>
<td>0</td>
<td>795'909</td>
</tr>
<tr>
<td>Total</td>
<td>11'446'025</td>
<td>0</td>
<td>23'762</td>
<td>11'422'263</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>For the period ended December 31, 2020 (CHF)</th>
<th>Book value</th>
<th>Financial assets at amortized costs</th>
<th>Financial liabilities at FVTPL</th>
<th>Other liabilities at amortized costs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Assets</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>294'142</td>
<td>294'142</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Other accounts receivable</td>
<td>11'542</td>
<td>11'542</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Loans and rent deposit</td>
<td>33'204</td>
<td>33'204</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Total</td>
<td>339'878</td>
<td>339'878</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Liabilities</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Trade accounts payable</td>
<td>161'149</td>
<td>0</td>
<td>0</td>
<td>161'149</td>
</tr>
<tr>
<td>Other accounts payable</td>
<td>3'056</td>
<td>0</td>
<td>0</td>
<td>3'056</td>
</tr>
<tr>
<td>Debt (current and non-current)</td>
<td>3'322'688</td>
<td>0</td>
<td>25'607</td>
<td>3'322'688</td>
</tr>
<tr>
<td>Preferred shares (current and non-current)</td>
<td>0'039'100</td>
<td>0</td>
<td>0</td>
<td>0'039'100</td>
</tr>
<tr>
<td>Accrued expenses</td>
<td>795'755</td>
<td>0</td>
<td>0</td>
<td>795'755</td>
</tr>
<tr>
<td>Total</td>
<td>10'328'712</td>
<td>0</td>
<td>25'607</td>
<td>10'328'712</td>
</tr>
</tbody>
</table>

The table above analyses recurring fair value measurement for financial assets and financial liabilities. These fair value measurements are categorized into different levels in the fair value hierarchy based on the input and techniques used. The different levels have been defined as follows:

- Level 1: quoted prices (unadjusted) in active markets for identical assets or liabilities
- Level 2: inputs other than quoted prices included within level 1 that are observable for the asset or liability, either directly (i.e. as prices) or indirectly (i.e. derived from prices)
- Level 3: inputs for the asset or liability that are not based on observable market data (unobservable inputs)
The derivatives listed above are level 3 fair values.

The carrying amounts approximately reflect fair values of the financial instruments except for the following debt:

<table>
<thead>
<tr>
<th>For the period ended June 30, 2021</th>
<th>Book value</th>
<th>Book value</th>
<th>Fair value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>USD</td>
<td>CHF</td>
<td>CHF</td>
</tr>
<tr>
<td>Liabilities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Convertible loans</td>
<td>2'935'000</td>
<td>2'702'137</td>
<td>3'802'926</td>
</tr>
<tr>
<td>Preferred shares</td>
<td>7'086'320</td>
<td>6'524'091</td>
<td>3'684'222</td>
</tr>
<tr>
<td>Total</td>
<td>10'021'320</td>
<td>9'226'228</td>
<td>7'287'149</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>For the period ended December 31, 2020</th>
<th>Book value</th>
<th>Book value</th>
<th>Fair value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>USD</td>
<td>CHF</td>
<td>CHF</td>
</tr>
<tr>
<td>Liabilities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Convertible loans</td>
<td>2'840'000</td>
<td>2'507'266</td>
<td>3'020'634</td>
</tr>
<tr>
<td>Preferred shares</td>
<td>6'840'537</td>
<td>6'039'100</td>
<td>3'483'929</td>
</tr>
<tr>
<td>Total</td>
<td>9'680'537</td>
<td>8'546'365</td>
<td>6'484'562</td>
</tr>
</tbody>
</table>

11. **Events after the reporting period**

The convertible note amounting to USD 78’930 with a maturity date of May 8, 2021 was not paid back. Instead, the Company is renegotiating the terms with the lender. No formal agreement has been reached as of today.
C) Unaudited Pro Forma Financial Information

The unaudited pro forma financial information in this Prospectus (“Unaudited Pro Forma Financial Information”, including the “Unaudited Pro Forma Statements of Income” and the “Unaudited Pro Forma Statement of Financial Position” and the "Notes to the Unaudited Pro Forma Financial Information”) has been prepared assuming that 100 per cent of the shares of EnBiotix were tendered in the Transaction (actual: 99.6 per cent, with the remainder presumed to follow shortly) and to illustrate the effect of such acquisition of 100 per cent of the shares of EnBiotix by Polyphor, as if they had been completed on January 1, 2020. The Unaudited Pro Forma Financial Information was prepared on the basis of a number of assumptions as outlined in “Note 1: Description of the Transaction and basis of preparation” of the Notes to the Unaudited Pro Forma Financial Information beginning on page 138.

The information presented below should be read in conjunction with the information contained in the sections entitled “Forward-Looking Statements” and “Risk Factors”, beginning on pages 5 and 12 respectively as well as information included elsewhere in this Prospectus.

The Unaudited Pro Forma Financial Information is not necessarily indicative of the results of operations in future periods or of the future financial position of the merged company and there can be no assurance that the trends indicated by the Unaudited Pro Forma Financial Information (or by the separate financial statements of Polyphor and EnBiotix) are representative of the future results or performance of the merged company. Accordingly, future results and financial position may differ significantly from those portrayed by the Unaudited Pro Forma Financial Information.

Background

Context of the publication of the Unaudited Pro Forma Financial Information

On August 31, 2021, the Boards of Directors of Polyphor Ltd (“Polyphor”) and EnBiotix Inc (“EnBiotix”) unanimously approved the intention to combine the two groups (the “Merger”).

On October 28, 2021 the Merger was approved by the Extraodinary Shareholder Meeting of Polyophor and EnBiotix respectively.

The Merger was completed on December 29, 2021 and structured as an exchange offer filed by Polyphor for 99.6% of the outstanding shares of EnBiotix (with the remainder presumed to follow shortly) on the basis of a 1.744 for 1 exchange ratio. An EnBiotix shareholder tendering 1 EnBiotix share to the exchange offer received 1.744 newly issued registered shares of Polyphor.

Presented Unaudited Pro Forma Financial Information

The Unaudited Pro Forma Financial Information has been prepared in Swiss Francs (CHF) and reflects the Merger of Polyphor and EnBiotix under the acquisition method as if the Merger had occurred as at January 1, 2020. For accounting purposes, EnBiotix is deemed the acquirer in accordance with IFRS 3 - Business Combinations. The Unaudited Pro Forma Financial Information consists of the following information:

- a pro forma statement of income for the six month period then ended June 30, 2021
- a pro forma statement of financial position as at June 30, 2021,
- a pro forma statement of income for the year ended December 31, 2020,
- a pro forma statement of financial position as at December 31, 2020, and
- explanatory notes.

The Unaudited Pro Forma Financial Information has been compiled and should be read in conjunction with the respective following documents:

- the audited consolidated financial statements as at and for the year ended December 31, 2020, of Polyphor prepared in accordance with IFRS,
- the interim condensed consolidated financial statements as at and for the six month period ended June 30, 2021, of Polyphor prepared in accordance with IAS 34,
- the audited consolidated financial statements as at and for the year ended December 31, 2020, of EnBiotix prepared in accordance with IFRS, and
- the interim condensed consolidated financial statements as at and for the six month period ended June 30, 2021, of EnBiotix prepared in accordance with IAS 34,

all of which are included elsewhere or incorporated by reference in this Prospectus.

The Unaudited Pro Forma Financial Information also reflects the impact of
- certain transactions leading up to and related to the merger, namely Polyphor's restructuring (reduction in force triggering an impairment of right of use assets, settlement gain and lower service costs on a recurring basis)
- the Asset Purchase Agreement (as defined below), and
- contractual change-of-control provisions (conversion of the EnBiotix convertible notes) that may result in a cash out impact and/or change of scope, to the extent the impact of such contractual arrangements is factually supportable and can be reasonably estimated at this stage.

With regard to the restructuring, in July 2021, the Company announced a restructuring of up to 29 positions to create operational efficiencies and reduce costs following the negative results of the FORTRESS study for balixafortide.

With regard to the asset purchase agreement, simultaneously to the merger agreement, Polyphor and EnBiotix have signed a definitive agreement where EnBiotix acquires Polyphor's inhaled murepavadin at an agreed valuation of USD 10'000'000 (CHF 9’146’000) in exchange for 2'599'655 of common shares of EnBiotix (the "Asset Purchase Agreement"). The closing of this agreement took place in September 2021 and prior to the expected closing of the merger. As the Asset Purchase Agreement has been entered into simultaneously with the merger agreement, the asset purchase has been considered as a pro forma adjustment as well.

The Unaudited Pro Forma Financial Information does not reflect any integration costs which may be incurred and it does not include any synergies as a result of the Merger.
C.1 Unaudited Pro Forma Statement of Income for the period ended June 30, 2021

<table>
<thead>
<tr>
<th>in CHF</th>
<th>Polyphor</th>
<th>Enbiotix</th>
<th>Impairment Right of use - Asset Note 3</th>
<th>Impact of organizational restructuring Note 4</th>
<th>Convertible Notes Enbiotix</th>
<th>Pro Forma Merged Company</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>June 30, 2021</td>
<td>June 30, 2021</td>
<td>Note 5</td>
<td>Note 6</td>
<td>Note 6</td>
<td></td>
</tr>
<tr>
<td>Polyphor library sales</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upfront and milestone payments</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total revenue</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Change in capitalized costs of Technology Platforms</td>
<td>972'429</td>
<td>0</td>
<td></td>
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<td></td>
<td></td>
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<tr>
<td>Other income</td>
<td>-22'164'467</td>
<td>-312'883</td>
<td>2'744'856</td>
<td>153'021</td>
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<td></td>
</tr>
<tr>
<td>Research and development</td>
<td>-413'881</td>
<td>78'512</td>
<td>3'951</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Marketing and sales</td>
<td>-2'963'515</td>
<td>-272'203</td>
<td>838'107</td>
<td>46'723</td>
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<td></td>
</tr>
<tr>
<td>General and administrative</td>
<td>-2'416'233</td>
<td>-585'086</td>
<td>3'653'475</td>
<td>203'676</td>
<td>0</td>
<td>-20'897'169</td>
</tr>
<tr>
<td>Net operating expenses</td>
<td>-24'169'233</td>
<td>-585'086</td>
<td>3'653'475</td>
<td>203'676</td>
<td>0</td>
<td>-20'897'169</td>
</tr>
<tr>
<td>Operating loss</td>
<td>-24'169'233</td>
<td>-585'086</td>
<td>3'653'475</td>
<td>203'676</td>
<td>0</td>
<td>-20'897'169</td>
</tr>
<tr>
<td>Financial income</td>
<td>20'345</td>
<td>582</td>
<td>20'927</td>
<td></td>
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<tr>
<td>Financial expenses</td>
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<td>-421'242</td>
<td>416'559</td>
<td></td>
<td>-443'250</td>
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<td>Net foreign exchange loss</td>
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<td></td>
<td>943'883</td>
<td></td>
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<tr>
<td>Net loss for the period</td>
<td>-23'632'610</td>
<td>-1'016'708</td>
<td>3'653'475</td>
<td>203'676</td>
<td>416'559</td>
<td>-20'375'609</td>
</tr>
<tr>
<td>Other comprehensive loss that may be reclassified to profit or loss in subsequent periods:</td>
<td>1'260'408</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cumulative translation differences</td>
<td>-1'647</td>
<td>-474'220</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Other comprehensive loss that will not be reclassified to profit or loss in subsequent periods:</td>
<td>1'258'761</td>
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<td></td>
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<tr>
<td>Remeasurement of pension liabilities</td>
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<td>-474'220</td>
<td>416'559</td>
<td></td>
<td>784'541</td>
<td></td>
</tr>
<tr>
<td>Other comprehensive income/ (loss)</td>
<td>1'258'761</td>
<td>-474'220</td>
<td>416'559</td>
<td></td>
<td>784'541</td>
<td></td>
</tr>
<tr>
<td>Total comprehensive loss</td>
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<td>-1'490'928</td>
<td>3'653'475</td>
<td>203'676</td>
<td>416'559</td>
<td>-19'591'067</td>
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<td>Net loss per share (basic)</td>
<td>-0.43</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Net loss per share (diluted)</td>
<td>-0.43</td>
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<td></td>
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<td></td>
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</tr>
<tr>
<td>Pro Forma weighted average of shares outstanding (Note 8)</td>
<td>47'657'953</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- 135 -
## C.2 Unaudited Pro Forma Statement of Financial Position as at June 30, 2021

<table>
<thead>
<tr>
<th></th>
<th>Polyphor</th>
<th>Enbiotix</th>
<th>Impact of organizational restructuring</th>
<th>Note 4</th>
<th>Note 5</th>
<th>Note 6</th>
<th>Note 7</th>
<th>Note 2</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Assets</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td><strong>Current assets</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cash and cash equivalents</td>
<td>17'915'280</td>
<td>16'115</td>
<td>10'201'400</td>
<td>28'132'795</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Trade accounts receivable</td>
<td>1'457</td>
<td></td>
<td></td>
<td>1'457</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other accounts receivable</td>
<td>447'757</td>
<td>18'444</td>
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<td>460'201</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Accrued income</td>
<td>136'047</td>
<td></td>
<td></td>
<td>136'047</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prepaid expenses</td>
<td>2'399'441</td>
<td>2'156</td>
<td></td>
<td>2'391'597</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total current assets</strong></td>
<td>20'909'983</td>
<td>36'715</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>10'201'400</td>
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<td>31'148'998</td>
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<tr>
<td><strong>Non-current assets</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Property, plant and equipment (PPE)</td>
<td>1'572'384</td>
<td></td>
<td></td>
<td>1'572'384</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Right-of-use asset</td>
<td>1'542'706</td>
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<td></td>
<td>1'542'706</td>
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<td></td>
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</tr>
<tr>
<td>Intangible assets</td>
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<td>9'146'000</td>
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<td>9'146'006</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Goodwill</td>
<td>0</td>
<td></td>
<td></td>
<td>14'941'751</td>
<td>14'941'751</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Technology Platforms</td>
<td>1'574'496</td>
<td></td>
<td></td>
<td>1'574'496</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rent deposit/Loans</td>
<td>447'356</td>
<td>35'305</td>
<td></td>
<td>482'661</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Total non-current assets</strong></td>
<td>5'136'978</td>
<td>35'305</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>14'941'751</td>
<td>0</td>
<td>29'280'034</td>
</tr>
<tr>
<td><strong>Total assets</strong></td>
<td>26'046'962</td>
<td>72'020</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>10'201'400</td>
<td>14'941'751</td>
<td>60'408'132</td>
</tr>
</tbody>
</table>

| **Liabilities and Shareholders’ equity** |          |          |                                        |        |        |        |        |        |
| **Current liabilities** |          |          |                                        |        |        |        |        |        |
| Trade accounts payable | 4'127'721 | 377'048  |                                        | 4'504'769 |
| Other accounts payable | 238'431   | 130     |                                        | 239'560 |
| Current lease liability | 754'147   |          |                                        | 754'147 |
| Current convertible notes (IRIS) | 2'947'500 |          |                                        | 2'947'500 |
| Deferred income | 6'577     |          |                                        | 6'577  |
| Current portion of debt | 271'418   | 3'749'377 |                                        | 4'020'795 |
| Current portion of preferred stock | 0 | 1'324'387 | -1'324'387 | 0 |
| Accrued expenses | 10'793'443 | 2'170'127 |                                        | 12'963'570 |
| **Total current liabilities** | 19'038'511 | 7'621'078 | 0                                      | 0      | -1'324'387 | 0      | 0      | 25'335'202 |
| **Non-current liabilities** |          |          |                                        |        |        |        |        |        |
| Pension liabilities | 7'008'147 |          |                                        | 4'435'499 |
| Non-current lease liability | 4'352'231 |          |                                        | 4'352'231 |
| Preferred stock | 5'199'705 |          |                                        | 5'199'705 |
| Non-current portion of debt | 1'887'076 |          |                                        | 1'887'076 |
| **Total non-current liabilities** | 13'107'444 | 5'199'705 | 2'634'698 | 0 | 9'146'000 | 0      | 0      | 10'472'746 |
| **Total liabilities** | 32'145'954 | 12'820'783 | 2'634'698 | 0 | 9'146'000 | 0      | 0      | 35'807'947 |
| **Shareholders’ equity** |          |          |                                        |        |        |        |        |        |
| Share capital | 231'128   | 6'463    |                                        | 202'012 | 131'205 | 382'355 | 955'199 |
| Additional paid-in capital | 359'428'615 | 427'672 | 9'146'000 | 6'322'080 | 10'070'198 | 14'559'796 | 40'903'796 |
| Other reserves | 10'425'603 | 0       |                                        | 10'425'603 |
| Cumulative translation differences | -1'053 | 671'908 |                                        | 670'855 |
| Accumulated deficit | -366'183'285 | -13'854'806 | 2'634'698 | -407'403'393 |
| **Total shareholders’ equity** | -6'999'993 | -12'748'763 | 2'634'698 | 9'146'000 | 4'524'092 | 10'291'400 | 14'941'751 | 24'600'185 |
| **Total liabilities and shareholders’ equity** | 26'046'962 | 72'020 | 0 | 9'146'000 | 0 | 10'201'400 | 14'941'751 | 60'408'132 |
### C.3 Unaudited Pro Forma Statement of Income for the period ended December 31, 2020

<table>
<thead>
<tr>
<th></th>
<th>Polyphor</th>
<th>Enbiotix</th>
<th>Impairment</th>
<th>Impact of organizational restructuring</th>
<th>Convertible Notes Enbiotix</th>
<th>Pro Forma Merged Company</th>
</tr>
</thead>
<tbody>
<tr>
<td>in CHF</td>
<td>2020</td>
<td>2020</td>
<td>Note 3</td>
<td>Note 4</td>
<td>Note 6</td>
<td></td>
</tr>
<tr>
<td>Polyphor library sales</td>
<td>6'568</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Upfront and milestone payments</td>
<td>14'271'000</td>
<td>14'271'000</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total revenue</td>
<td>14'277'568</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>14'277'568</td>
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<tr>
<td>Other income</td>
<td>1'020'437</td>
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<td>1'072'771</td>
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<tr>
<td>Research and development</td>
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<td>-558'976</td>
<td>406'645</td>
<td>759'376</td>
<td>-51'735'307</td>
<td></td>
</tr>
<tr>
<td>Marketing and sales</td>
<td>-771'134</td>
<td>10'446</td>
<td>19'520</td>
<td></td>
<td>-761'155</td>
<td></td>
</tr>
<tr>
<td>General and administrative</td>
<td>-4'572'680</td>
<td>-717'899</td>
<td>124'164</td>
<td>232'019</td>
<td>-4'834'397</td>
<td></td>
</tr>
<tr>
<td>Net operating expenses</td>
<td>-56'666'230</td>
<td>-1'224'541</td>
<td>541'256</td>
<td>1'011'415</td>
<td>0</td>
<td>-56'338'100</td>
</tr>
<tr>
<td>Operating loss</td>
<td>-42'388'862</td>
<td>-1'224'541</td>
<td>541'256</td>
<td>1'011'415</td>
<td>696'597</td>
<td>-42'060'832</td>
</tr>
<tr>
<td>Financial income</td>
<td>52'266</td>
<td>26'146</td>
<td></td>
<td></td>
<td>78'412</td>
<td></td>
</tr>
<tr>
<td>Financial expenses</td>
<td>-638'590</td>
<td>-705'547</td>
<td>696'597</td>
<td></td>
<td>-647'540</td>
<td></td>
</tr>
<tr>
<td>Net foreign exchange loss</td>
<td>-1'973'766</td>
<td>-52'637</td>
<td></td>
<td></td>
<td>-1'921'129</td>
<td></td>
</tr>
<tr>
<td>Net loss for the period</td>
<td>-44'948'752</td>
<td>-1'851'305</td>
<td>541'256</td>
<td>1'011'415</td>
<td>696'597</td>
<td>-44'550'790</td>
</tr>
</tbody>
</table>

**Other comprehensive loss that may be reclassified to profit or loss in subsequent periods:**
- Cumulative translation differences: 3'720 992'628 996'348
- **Other comprehensive loss that will not be reclassified to profit or loss in subsequent periods:**
  - Remeasurement of pension liabilities: 1'067'670 1'067'670
  - Other comprehensive income/loss: 1'071'390 992'628 0 0 0 2'064'018
  - **Total comprehensive loss:** -43'877'362 -858'677 541'256 1'011'415 696'597 -42'486'772

- Net loss per share (basic): -0.93
- Net loss per share (diluted): -0.93
- **Pro Forma weighted average number of shares outstanding (Note 8):** 47'657'953
### D) Notes to the Unaudited Pro Forma Financial Information

#### Note 1: Description of the Transaction and basis of preparation

### 1-a. Description of the Transaction

For purposes of preparing the Unaudited Pro Forma Financial Information, the Transaction as described in the background section of this Unaudited Pro Forma Financial Information and elsewhere in this Prospectus has been considered as if completed on January 1, 2020. In addition to that, certain transactions leading up to and related to the Merger have been considered in the preparation of the Unaudited Pro Forma Financial Information as well, namely Polyphor's restructuring (reduction in force triggering an impairment of right of use assets, settlement gain and lower service costs on a recurring basis) and the Merger related conversion of EnBiotix convertible notes and the Asset Purchase Agreement.

#### 1-b. Regulatory framework

This Unaudited Pro Forma Financial Information is presented pursuant to the SIX Directive Pro Forma Financial Information.
1-c. Historical financial information

Polyphor historical financial information under pro forma presentation

The historical financial information of Polyphor, is derived from the Polyphor audited consolidated financial statements as at and for the year ended December 31, 2020 and the Polyphor Interim condensed consolidated financial statements as at and for the six month period ended June 30, 2021 prepared in accordance with IAS 34, which are incorporated by reference in this Prospectus.

The consolidated financial statements of Polyphor as of and for the year ended December 31, 2020 prepared in accordance with IFRS, have been audited by Ernst & Young AG.

EnBiotix historical financial information under pro forma presentation

The historical financial information of EnBiotix is derived from the EnBiotix audited consolidated financial statements as at and for the year ended December 31, 2020 and EnBiotix Interim condensed consolidated financial statements as at and for the six month period ended June 30, 2021 prepared in accordance with IAS 34 and are included elsewhere in this Prospectus.

The consolidated financial statements of EnBiotix as of and for the year ended December 31, 2020 prepared in accordance with IFRS, have been audited by Ernst & Young AG.

1-d. Other sources of information

In addition to the audited historical financial information of Polyphor and EnBiotix described above, the Unaudited Pro Forma Financial Information has been prepared using other sources of information as follows:

- Polyphor provided, through an external actuary firm, the fair value of the pension liability relating to changes in scope described in Note 3 below,
- Combination Agreement signed on August 31, 2021 detailing the terms and conditions of the Merger, and
- Asset Purchase Agreement signed on August 31, 2021 and detailing the terms and conditions of Polyphor's sale of its inhaled murepavadin asset to EnBiotix.

1-e. Basis for preparation

The Unaudited Pro Forma Financial Information has been prepared in Swiss Francs and reflects the Merger of Polyphor and EnBiotix using the acquisition method as if the Merger of Polyphor and EnBiotix had been completed on January 1, 2020.

Due to rounding, numbers presented throughout this Unaudited Pro Forma Financial Information may not add up precisely to the totals provided.

The Unaudited Pro Forma Financial Information reflects a hypothetical situation and is presented exclusively for illustrative purposes, as such it does not provide for an indication of the results of operating activities or the financial position of the combined group that would have been obtained as of and for the six month period ended on June 30, 2021 or as of and for the year ended December 31, 2020 had the Merger been completed as at January 1, 2020. Similarly, it does not provide for an indication of the future results of operating activities or financial position of the merged company.

The unaudited pro forma adjustments are based upon information available as of December 20, 2021 and certain preliminary estimates and assumptions which are believed to be reasonable.

The Merger is treated as a business combination with EnBiotix being the accounting acquirer of Polyphor, applying the provisions of IFRS 3 – Business Combinations.

The Unaudited Pro Forma Financial Information has been prepared based upon the assumption that pursuant to the terms of the Combination Agreement every 1 outstanding share of EnBiotix common stock at the effective time of the Merger will be tendered to the offer for exchange into 1.744 registered shares of Polyphor.
Further, all of the outstanding EnBiotix stock options and other equity awards at the effective time of the Merger, whether vested or not vested, are converted into registered shares of Polyphor, determined by multiplying the number of shares subject to such award by the defined exchange ratio, at an exercise price determined by dividing the former exercise price by the defined exchange ratio.

The accelerated compensation impact in case of change of control will have no impact in the Statement of financial position in general as it will not trigger changes in equity, number of shares outstanding nor in cash and cash equivalent and therefore it has been deemed not relevant and hence has not been reflected in the Unaudited Pro Forma Financial Information.

The Unaudited Pro Forma Financial Information has been prepared reflecting preliminary purchase accounting, which is based on the reports from the valuation specialists as described in Note 2 below.

The excess of the consideration transferred over the fair value of the acquired Polyphor identifiable net assets is recorded as goodwill on a preliminary basis. Definitive valuations as of the date of completion of the Merger will be performed and the final purchase accounting will be finalized based upon valuations and other studies that will be performed with the services of outside valuation specialists after the effective date of the Merger and within 12 months following the completion of the Merger. Accordingly, the purchase accounting pro forma adjustments are preliminary and have been made solely for the purpose of preparing the Unaudited Pro Forma Financial Information and as such are hypothetical and subject to revision based on a final determination of fair value after the effective date of the Merger.

Only pro forma adjustments that are factually supportable and that can be estimated reliably at the date the Unaudited Pro Forma Financial Information is prepared have been taken into account. For instance, the Unaudited Pro Forma Financial Information does not reflect any restructuring or integration expenses that may be incurred in connection with the Merger.

The Unaudited Pro Forma Financial Information also reflects the impact of contractual change-of-control provisions or other Merger related agreements, that may result in a cash out impact and/or change of scope, to the extent the impact of such contractual arrangements is factually supportable and can be reasonably estimated at this stage.

The Unaudited Pro Forma Financial Information also does not reflect any cost savings potentially realizable from the elimination of certain expenses or from synergies that may be achieved from the Merger.

Subsequent to the effective date of the Merger, any transactions occurring between Polyphor and EnBiotix will be considered as intercompany transactions and be eliminated.

Note 2: The Merger and related pro forma adjustments

Consideration transferred and purchase accounting

The principles applied to account for the Merger of Polyphor and EnBiotix and are those defined in IFRS 3 – Business Combinations. The difference between the estimated consideration transferred for the Polyphor shares and the preliminary fair value of identifiable net assets of Polyphor is recognized as preliminary goodwill.

In consideration of the terms and characteristics of the Merger, EnBiotix has been determined to be the acquirer for accounting purposes. The effective date of the Merger was on December 29, 2021, at which date the fair value of the consideration transferred and the fair value of the acquired net assets of Polyphor has to be determined.

Consideration transferred

The consideration transferred is assumed to be equal to the number of Polyphor shares outstanding as at 31.08.2021 at the average closing share price of the 10 prior days of Polyphor on August 31, 2021, in accordance with the Combination Agreement.

For the purpose of the Unaudited Pro Forma Financial Information, the consideration transferred has therefore been determined on the basis of:

- the exchange ratio of 1.744 Polyphor shares for every 1 EnBiotix share exchanged,
• all outstanding EnBiotix shares being tendered for exchange in the offer as of December 29, 2021,
• the fair value of Polyphor shares issued in exchange for all outstanding EnBiotix shares of CHF 1.7498 per share corresponding to the average of the 10 previous days of Polyphor closing share prices as of August 31, 2021, i.e. on the announcement date of the amended terms of the Merger.

The following table details a preliminary estimate of the consideration transferred:

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount (CHF)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Polyphor shares as of 31.08.2021 (A)</td>
<td>11'786'179</td>
</tr>
<tr>
<td>Number of EnBiotix shares as of 31.08.2021 (B)</td>
<td>16'481'869</td>
</tr>
<tr>
<td>Exchange ratio into Polyphor shares (C)</td>
<td>1.7442</td>
</tr>
<tr>
<td>Number of Polyphor shares to be issued (D) = (B) x (C)</td>
<td>28'747'857</td>
</tr>
<tr>
<td>Polyphor share price 31.08.2021 (average of prior 10 trading days) (E)</td>
<td>1.7498</td>
</tr>
<tr>
<td>Fair value of Polyphor shares to be issued in exchange of EnBiotix shares (F) = (D) x (E)</td>
<td>50'303'000</td>
</tr>
<tr>
<td><strong>Total estimated consideration transferred (in CHF) (G) = (A) x (E)</strong></td>
<td><strong>20'623'456</strong></td>
</tr>
</tbody>
</table>

**Purchase accounting**

The Unaudited Pro Forma Financial Information reflects, a preliminary purchase accounting of the identifiable assets acquired and liabilities assumed of Polyphor as detailed in the table below:

<table>
<thead>
<tr>
<th>Description</th>
<th>Amount (CHF)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total estimated consideration transferred (in CHF).</td>
<td>20'623'456</td>
</tr>
<tr>
<td>Polyphor net assets as at June 30, 2021</td>
<td>(6'098'993)</td>
</tr>
<tr>
<td>Impact of organizational restructuring (Note 4)</td>
<td>2'634'698</td>
</tr>
<tr>
<td><strong>Polyphor net assets before acquisition</strong></td>
<td><strong>(3'464'295)</strong></td>
</tr>
<tr>
<td>Intangible - Asset Purchase Agreement (Note 5)</td>
<td>9'146'000</td>
</tr>
<tr>
<td><strong>Preliminary fair value of net assets acquired</strong></td>
<td><strong>5'681'705</strong></td>
</tr>
<tr>
<td><strong>Preliminary good will</strong></td>
<td><strong>14'941'751</strong></td>
</tr>
</tbody>
</table>

**Note 3: Impairment: Right-of-use asset**

At the end of June, Polyphor provided an update on the future of the FORTRESS study of balixafortide, which indicated that the right-of-use asset may be impaired due to an expected restructuring and reduction of around 20 employees (approx. 39%), resulting in idle office space.

The impairment test on the right-of-use asset led to an impairment charge of CHF 3’382’847 (approx. 69%) and the impact of such impairment is as follows,

- The Statement of Income for the period ending June 30, 2021 included a depreciation charge of CHF 394’044. The estimated depreciation charge following the impairment amounts to CHF 123’417 which results in a pro forma adjustment of CHF 270’628. In addition, the impairment charge of CHF 3’382’847 has been reversed considering the assumed Transaction date of January 1, 2020.
- The Statement of Financial Position for the period ending June 30, 2021 included an impairment adjustment of CHF 3’382’847. Therefore no further adjustments were made to the Pro Forma Statement of Financial Position ending June 30, 2021.
- The Statement of Income for the period ending December 31, 2020 included a depreciation charge of CHF 788’089. The estimated service fee following the restructuring amounts to CHF 246’833 which results in a pro forma adjustment of CHF 541’256.
- The Statement of Financial Position for the period ending December 31, 2020 did not include the impairment charge of CHF 3’382’847. Therefore an adjustments of CHF 3’382’847 was made to the Pro Forma Statement of Financial Position ending December 31, 2020.
Note 4: Impact of organizational restructuring

On June 28, 2021, Polyphor provided an update on the future of the FORTRESS study of balixafortide and announced initial restructuring steps.

The IAS19 charges reflect the impact of the restructuring and organizational changes.

The data and values of the insured people have been projected until November 30, 2021. The valuation date is November 30, 2021.

The results of former pension liabilities valuation as of June 30, 2021 have been disclosed in the Polyphor audited consolidated financial statements as at and for the year ended December 31, 2020 and Polyphor Interim condensed consolidated financial statements as at and for the six month period ended June 30, 2021.

The announcement of the restructuring took place in July 2021. For valuating the impact a list with all employees and their development within the period July 1, 2021 until November 30, 2021 was established by Polyphor. 13 employees were directly affected by the restructuring decision and quit the pension fund. 9 employees changed their occupancy degree but remain with Polyphor Ltd. Another 13 employees quit the company without being on the restructuring list within this period. Taking care of all these movement in the pension plan population, the actuarial calculation of the pension liability as of November 30, 2021 shows a net pension liability of CHF 4'433'449 and estimated annualised service cost of CHF 522'271.

The changes impacting the Unaudited Pro Forma Financial Information assume that the restructuring had taken place on January 1, 2020 and can be summarized as follows:

- The Statement of Income for the period ending June 30, 2021 included a service fee of CHF 464‘811. The estimated service cost following the restructuring amounts to CHF 261‘135 which results in a pro forma adjustment of CHF 203‘676.
- The pension liability in the statement of financial position as at June 30, 2021 has been adjusted to the amount of CHF 4‘433‘449 by CHF 2’634‘698.
- The Statement of Income for the period ending December 31, 2020 included a service fee of CHF 1’533‘686. The estimated service cost following the restructuring amounts to CHF 522‘271 which results in a pro forma adjustment of CHF 1’011‘415.
- The pension liability in the statement of financial position as at December 31, 2020 has been adjusted to the amount of CHF 4‘433‘449 by CHF 3‘895‘998.

Note 5: Asset Purchase agreement

Simultaneously to the merger agreement, Polyphor and EnBiotix have signed a definitive asset purchase agreement where EnBiotix acquires Polyphor's inhaled murepavadin at an agreed valuation of USD 10'000'000 (CHF 9'146'000) in exchange for 2'599'655 of common shares of EnBiotix (the "Asset Purchase Agreement"). The closing of this agreement took place in September 2021 and prior to the expected closing of the merger. As the Asset Purchase Agreement has been entered into simultaneously with the merger agreement, the asset purchase has been considered as a pro forma adjustment as well.

A translation into Swiss Francs has been presented in these pro forma figures for convenience purposes at an exchange rate of 0.9146 CHF/USD based on exchange rates on August 31, 2021.

Accordingly, the statement of financial position as of June 30, 2021 and December 31, 2020 reflect an intangible asset of CHF 9'146'000. There was no adjustment needed on the pro forma statements of income for the six month period ended June 30, 2021 and the year ended December 31, 2020, as the intangible asset is still under development.

Note 6: Convertible Notes EnBiotix

At the day of the merger all convertible notes were immediately converted into common stock of EnBiotix and exchanged for 1.744 registered Polyphor shares.
Convertible notes in the amount of CHF 6'524'092 at the end of June 30, 2021 and CHF 6'039’100 at the end of December 31, 2020 converted into 5'790’927 of Enbitix equivalent to 10’100’598 shares of Polyphor. The related financing cost including interest have been reversed.

A translation into Swiss Francs has been presented in these pro forma figures for convenience purposes at an exchange rate of 0.92066 CHF/USD based on exchange rates on June 30, 2021.

In addition, assuming that the conversion of the described notes had occurred already on January 1st 2020, the following adjustments were made in the presented pro forma financial information,

- The Statement of Income for the period ending June 30, 2021 included an interest charge of CHF 421’242. The estimated interest charge following the following the conversion of the notes amounts to CHF 4’683 which results in a pro forma adjustment of CHF 416’559.
- The Statement of Financial Position for the period ending June 30, 2021 included a carrying amount of CHF 6’524’092 in “Preferred Stock – Liability”. Therefore an adjustment of CHF 6’524’092 was made to the Pro Forma Statement of Financial Position ending June 30, 2021 to reflect the conversion of the notes into equity.
- The Statement of Income for the period ending December 31, 2020 included an interest charge of CHF 705’547. The estimated interest charge following the following the conversion of the notes amounts to CHF 8’950 which results in a pro forma adjustment of CHF 696’597.
- The Statement of Financial Position for the period ending December 31, 2020 included a carrying amount of CHF 6’039’100 in “Preferred Stock – Liability”. Therefore an adjustment of CHF 6’039’100 was made to the Pro Forma Statement of Financial Position ending December 31, 2020 to reflect the conversion of the notes into equity.

Note 7: Pre merger financing round of Enbiotix

On December 28, 2021 EnBiotix completed a financing round for a total consideration of USD 11’000’000 (CHF 10’201’400) of its common stock at a price of USD 3.00 per share. The common stock issued in connection with the this financing will exchanged for 1.744 registered shares of Polyphor.

A translation into Swiss Francs has been presented in these pro forma figures for convenience purposes at an exchange rate of 0.9274 CHF/USD based on exchange rates on November 19, 2021.

Note 8: EPS – Number of shares outstanding

The following table shows the number of shares outstanding used for the calculation of the E.P.S. in the Statement of Income for the periods ended June 30, 2021 and December 31, 2020:

| Number of shares                                      |  |
|-------------------------------------------------------|  |
| Polyphor shares outstanding on December 16, 2021       | 12’350’009 |
| Polyphor shares issued on December 16, 2021 to Enbiotix shareholders | 28’747’857 |
| Polyphor shares issued on December 16, 2021 to Enbiotix - pre merger financing | 6’560’087 |
| **Total number of shares outstanding**                | **47’657’953** |
To the Board of Directors of
Polyphor Ltd, Allschwil

Basle, 29 December 2021

Assurance report on the compilation of pro forma financial information included in a prospectus

We have completed our assurance engagement to report on the compilation of pro forma financial information of Polyphor Ltd (the Company) by the board of directors. The pro forma financial information consists of the pro forma balance sheet as at 31 December 2020 and as at 30 June 2021, the pro forma income statement for the 12 months period ended 31 December 2020 and the six months period ended 30 June 2021 and related notes as set out on pages 134 – 144 of the prospectus issued by the company. The applicable criteria on the basis of which the board of directors has compiled the pro forma financial information are specified in the Directive Pro-Forma Financial Information of the Prospectus Office of the SIX Exchange Regulation AG and described in the notes.

The pro forma financial information has been compiled by the Board of Directors to illustrate the impact of the merger with EnBiotix set out in Note 2 on the company’s financial position as at 31 December 2020 and as at 30 June 2021 and its financial performance for the period ended 31 December 2020 and 30 June 2021 as if the merger with EnBiotix had taken place at 1 January 2020. As part of this process, information about the company’s financial position and financial performance has been extracted by the board of directors from the company’s consolidated financial statements for the period ended 31 December 2020, on which an audit report has been published.

The Board of Directors’ responsibility for the pro forma financial information
The Board of Directors is responsible for compiling the pro forma financial information on the basis of the applicable criteria.

Independence and quality control
We have complied with the independence and other ethical requirements of the International Code of Ethics for Professional Accountants (including International Independence Standards) of the International Ethics Standards Board for Accountants (IESBA Code), which is founded on fundamental principles of integrity, objectivity, professional competence and due care, confidentiality and professional behavior.

The firm applies International Standard on Quality Control 1 and accordingly maintains a comprehensive system of quality control including documented policies and procedures regarding compliance with ethical requirements, professional standards and applicable legal and regulatory requirements.

Practitioner’s responsibilities
Our responsibility is to express an opinion, as required by the Directive Pro-Forma Financial Information of the Prospectus Office of the SIX Exchange Regulation AG, about whether the pro forma financial
information has been compiled, in all material respects, by the board of directors on the basis of the applicable criteria.

We conducted our engagement in accordance with International Standard on Assurance Engagements (ISAE) 3420, Assurance Engagements to Report on the Compilation of Pro Forma Financial Information Included in a Prospectus, issued by the International Auditing and Assurance Standards Board. This standard requires that the practitioner plan and perform procedures to obtain reasonable assurance about whether the board of directors has compiled, in all material respects, the pro forma financial information on the basis of the applicable criteria.

For purposes of this engagement, we are not responsible for updating or reissuing any reports or opinions on any historical financial information used in compiling the pro forma financial information, nor have we, in the course of this engagement, performed an audit or review of the financial information used in compiling the pro forma financial information.

The purpose of pro forma financial information included in a prospectus is solely to illustrate the impact of a significant event or transaction on unaudited financial information of the entity as if the event had occurred or the transaction had been undertaken at an earlier date selected for purposes of the illustration. Accordingly, we do not provide any assurance that the actual outcome of the event or transaction at 1 January 2020 would have been as presented.

A reasonable assurance engagement to report on whether the pro forma financial information has been compiled, in all material respects, on the basis of the applicable criteria involves performing procedures to assess whether the applicable criteria used by the board of directors in the compilation of the pro forma financial information provide a reasonable basis for presenting the significant effects directly attributable to the event or transaction, and to obtain sufficient appropriate evidence about whether:

- The related pro forma adjustments give appropriate effect to those criteria; and
- The pro forma financial information reflects the proper application of those adjustments to the unaudited financial information.

The procedures selected depend on the practitioner's judgment, having regard to the practitioner's understanding of the nature of the company, the event or transaction in respect of which the pro forma financial information has been compiled, and other relevant engagement circumstances.

The engagement also involves evaluating the overall presentation of the pro forma financial information.

We believe that the evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.
Opinion
In our opinion, the pro forma financial information has been compiled, in all material respects, on the basis of the applicable criteria and such basis is consistent with the accounting policies of Polyphor Ltd.

Ernst & Young Ltd

Elisa Alfieri  
(Qualified Signature)
Licensed audit expert  
(Auditor in charge)

Martin Mattes  
(Qualified Signature)
Licensed audit expert
2.9 DIVIDENDS AND OTHER DISTRIBUTIONS

Since its inception, the Company has paid no dividends or other distributions. The Company currently intends to retain all available funds to support operations and finance its research and development activities. Therefore, the Company does not anticipate paying dividends or other distributions over the coming years. As a result, investors in Shares will benefit in the foreseeable future only if the Shares appreciate in value. In order for the Company to declare and pay distributions, the distribution must be approved by shareholders holding an absolute majority of the Shares represented at the general meeting of shareholders. The Company’s board of directors (the “Board”) may propose distributions in the form of a dividend or in the form of a distribution of cash or property that is based upon a reduction of the Company’s share capital recorded in the commercial register.

Ordinary dividends may be paid only if the Company has sufficient distributable profits from previous years or freely distributable reserves to allow the distribution of a dividend, in each case, as presented on the Company’s annual statutory standalone balance sheet prepared in accordance with Swiss corporate law. In accordance with the requirements of Swiss law, the Company will retain at least 5% of annual group net income as general reserves for so long as these reserves amount to no less than 20% of the Company’s paid-in nominal share capital (article 671 CO). A confirmation by the Company’s auditors is required that a proposal made by the Board to shareholders regarding the appropriation of the Company’s available earnings conforms to the requirements of the CO and the Company’s articles of incorporation. Furthermore, in order for the Company to pay dividends to its shareholders out of reserves from capital contributions (Reserven aus Kapitaleinlagen), it is required that a general meeting of shareholders approves, by the absolute majority of votes represented at the meeting, the reclassification of such reserves from capital contributions (Reserven aus Kapitaleinlagen) to freely distributable reserves (to the extent permissible by the CO). As of December 31, 2020, the Company had reserves from capital contributions (Reserven aus Kapitaleinlagen) in the amount of CHF 309’060 thousand. A distribution of cash or property that is based upon a reduction of the Company’s share capital requires a special audit report confirming that the claims of the Company’s creditors remain fully covered by the Company’s assets despite the reduction in the share capital. After the general meeting of shareholders has approved the capital reduction, the Board has to give public notice of the capital reduction in the Swiss Official Gazette of Commerce (Schweizerisches Handelsamtsblatt) three times and notify the Company’s creditors that they may request, within two months after the third publication, satisfaction of or security for their claims.

All Shares are equally entitled to dividends and other distributions paid by the Company, if any. Dividends and other distributions of the Company, if any, will be declared and are expected to be paid in Swiss Francs. Holders of Capital Increase Shares will be entitled to any declared and paid dividends after delivery of such Shares to them. For further information on dividends and other distributions see “Dividends and other distributions” beginning on page 147.

Dividends paid on Shares are subject to Swiss federal withholding tax, except if paid out of qualifying reserves from capital contributions (Reserven aus Kapitaleinlagen). Distributions of cash or property that are based upon a share capital reduction are not subject to Swiss federal withholding tax. See “Tax Considerations” beginning on page 152 for a summary of certain Swiss tax consequences regarding dividends and other distributions to holders of the Shares.
3. INFORMATION ON THE SECURITIES

A. General information

For so long as any Shares remain listed on the SIX Swiss Exchange, the Company will be subject to the Listing Rules and any additional regulations enacted by the SIX Swiss Exchange.

The SIX Swiss Exchange (formerly known as the SWX Swiss Exchange AG) was founded in 1993 as the successor of the local stock exchanges in Zurich, Basel and Geneva. Full electronic trading in foreign equities and derivatives began in 1995. In 1996, the SIX Swiss Exchange introduced full electronic trading in Swiss equities, derivatives and bonds. In 2008, the SWX Swiss Exchange AG changed its name to SIX Swiss Exchange AG. The SIX Swiss Exchange has a single regulatory standard for the listing of equity securities, the Standard for Equity Securities, and two main sub-standards (“International Reporting” and “Swiss Reporting”). A listing in accordance with the International Reporting standard of SIX Swiss Exchange requires, inter alia, that (i) the articles of association of the issuer comply with applicable law, (ii) the operating and financial track record of the issuer extends over a period of at least three years, (iii) the issuer appoints auditors fulfilling the requirements pursuant to Articles 7 and 8 of the Federal Act on the Admission and Supervision of Auditors, (iv) the issuer’s equity capital amounts to at least CHF 2.5 million, (v) the total market value of the issuer’s initial public offering amounts to a minimum of CHF 25 million, (vi) the securities must have been validly issued at the time of listing, and (vii) 20% of the issuer’s outstanding share capital be placed in public hands.

B. General rules on securities trading

Trading on the SIX Swiss Exchange occurs through a fully integrated trading system covering the entire process from trade order through settlement. Trading in equity securities begins each business day at 9:00 am and continues until 5:20 pm CET or CEST (as applicable) at which time the closing auction starts, and continues until trading closes at 5:30 p.m. CET or CEST (as applicable), with a random close of trading within two minutes. From 5.30 p.m. to 5.40 p.m., trading at last (TAL, trading based on the official closing price) takes place. After the close of exchange trading, new orders can be entered or deleted until 10:00 pm CET or CEST (as applicable). From 6:00 am CET or CEST (as applicable) new entries and enquiries can be made until 9:00 am CET or CEST (as applicable). The system is not available between 10:00 pm and 6:00 am CET or CEST (as applicable). For the opening phase (starting at 9:00 am CET or CEST (as applicable)), the system closes the order book and starts opening procedures, establishes the opening prices and determines orders to be executed according to the matching rules. Closing auctions are held to determine the daily closing price for all equity securities traded on the SIX Swiss Exchange. At the start of the closing auction, the status of all equity order books changes from permanent trading to auction. The auction itself consists of a pre-opening period and the actual auction according to rules that are similar to the opening procedure.

Transactions take place through the automatic matching of orders. Each valid order of at least a round lot is entered and listed according to the price limit. A round lot of the shares is expected to consist of one share. In general, market orders (orders placed at best price) are executed first, followed by limit orders (orders placed at a price limit), provided that if several orders are listed at the same price, they are executed according to the time of entry. The SIX Swiss Exchange may provide for a duty to trade on the SIX Swiss Exchange in individual market segments. This duty obliges the participant, during trading hours, to execute orders on the order book only. The duty to trade on the SIX Swiss Exchange for Mid-/Small-Cap equity shares does apply to (i) orders with a market price of CHF 200’000 or more, (ii) collective orders, if the market price of the order is CHF 1’000’000 or more, or (iii) portfolio orders. Members of the SIX Swiss Exchange must observe the principle of best execution for any off-exchange transaction during the trading period. Transactions in shares effected by or through members of the SIX Swiss Exchange are subject to a stock exchange levy. This levy includes the reporting fee and is payable per trade and participant. The fee is defined individually for each trading segment.

Banks and broker-dealers doing business in Switzerland are required to report all transactions in listed securities traded on the SIX Swiss Exchange. Reporting occurs automatically for on order book transactions. Off-order book transactions during trading hours must be reported to the SIX Swiss Exchange within 1 minute. Transaction information is collected, processed and immediately distributed by the SIX Swiss Exchange. Transactions outside trading hours must be reported no later than the next opening. The SIX Swiss Exchange distributes a comprehensive range of information through various publications, including in particular the Swiss Market Feed. The Swiss Market Feed supplies SIX Swiss Exchange data in real time to all subscribers as well as to other information providers such as SIX Financial Information Ltd and Reuters.

A quotation may be suspended by the SIX Swiss Exchange if large price fluctuations are observed, or if important, price-sensitive information is about to be disclosed, or in other situations that might endanger fair and orderly trading.
Surveillance and monitoring is the responsibility of the SIX Swiss Exchange as the organiser of the market. The aim of such self-regulation is to ensure transparency, fair trading and an orderly market.

C. Clearing, payment and settlement

Clearing and settlement of securities listed on the SIX Swiss Exchange is made through SIS. Delivery against payment of exchange transactions usually occurs two trading days after the trade date.

D. Corporate Governance Directive

In Switzerland, two sets of rules are relevant with respect to corporate governance, specifically the SIX Swiss Exchange Directive on Information Relating to Corporate Governance entered into force on October 1, 2014, lastly amended effective as of October 1, 2021 (the “DCG”), and the Swiss Code of Best Practice for Corporate Governance of August 28, 2014, as amended (the “Swiss Code”). In addition, certain requirements on corporate governance were recently introduced through the Compensation Ordinance, see “—Compensation Ordinance” beginning on page 93.

The DCG is binding on all Swiss companies whose equity securities have their primary or main listing on SIX Swiss Exchange. The DCG requires issuers to disclose important information on the management and control mechanisms at the highest corporate level or to give specific reasons why this information is not disclosed.

The Swiss Code is issued by economiesuisse, the largest umbrella organization representing Swiss businesses. The Swiss Code is non-binding, but provides recommendations for good corporate standards in line with international business practices on a comply-or-explain basis.


The Directive on the Disclosure of Management Transactions issued by the SIX Swiss Exchange, entered into force on April 1, 2013 and was last amended effective as of May 1, 2018 (the “DMT”) requires issuers whose equity securities have their primary listing on the SIX Swiss Exchange to ensure that members of their board of directors and senior management disclose transactions they have made in the securities of their own company. Under the DMT, the relevant persons must disclose any such transaction to the issuer, and the issuer must forward such information to the SIX Swiss Exchange. Such transactions are subsequently published on a no names basis on the SIX Swiss Exchange’s website.

F. Ad-hoc Publicity

Under the Listing Rules, the Company is required to publish facts that are, with respect to the price of the Shares or other securities issued by the Company, potentially price-sensitive and that have arisen in the sphere of the Company’s business activities. Facts that are not known publicly and that, from an ex-ante perspective, are capable of leading to a significant price change are classified as potentially price-sensitive. Potentially price-sensitive facts include, but are not limited to, financial figures and reports, changes in key employee positions including changes affecting the composition of the Board or the Executive Management, mergers, takeovers, spin-offs, restructuring operations, changes in capital, takeover bids, changes in business operations (e.g., new sales partners, new and significant products, withdrawal or recall of a significant product, etc.), information on financial results (e.g., significant changes in earnings such as profit decrease/increase or profit warning, cessation of dividends, etc.), changes to the shareholder structure and financial restructuring. As a rule, the Company will be required to disclose any potentially price-sensitive fact immediately as soon as it has become aware of its material elements. Disclosure needs to be made to SIX (90 minutes ahead of time if published during trading hours), to no less than two electronic stock market information systems (such as Bloomberg, Reuters or Telekurs), to no less than two Swiss newspapers of nationwide distribution and, upon request, to all interested parties. Any public announcement which includes potentially price-sensitive facts has to be labelled as an ad hoc announcement pursuant to article 53 Listing Rules, and the Company is required to establish internal rules and procedures governing the process to decide when the publication of a potentially price-sensitive fact is postponed.
3.1 ISSUE PRICE AND VOLUME

The issue price of the Capital Increase Shares ("Issue Price") amounted to CHF 1.7498 and was based on the exchange mechanism foreseen in the merger agreement between the Company and EnBiotix whereby each EnBiotix shareholder tendering 1 EnBiotix share received 1.744 newly issued registered shares of the Company as further described in Section 2.8 "Financial Statements" beginning on page 97. The issue volume of the Capital Increase Shares ("Issue Volume") amounted to 35'150'961 Shares.

3.2 LEGAL BASIS

The Capital Increase Shares were issued out of an ordinary capital increase. At the extraordinary general meeting of shareholders held on October 28, 2021 the shareholders of the Company resolved to increase the Company's ordinary share capital by up to 39'462'967 Shares. On December 29, 2021, the Board executed the Capital Increase in the amount of 35'150'961 new shares, along with the relevant amendments to the articles of association (Feststellungs- und Statutenänderungsbeschluss) (the "Capital Increase"). The Capital Increase Shares were registered with the Commercial Register of the Canton of Basel-Landschaft, Switzerland, on December 30, 2021 and the First Day of Trading of the Capital Increase Shares is January 3, 2022.

3.3 RIGHTS

The Capital Increase Shares are fully fungible and rank pari passu in all respects with each other and with all other issued shares of the Company with a nominal value of CHF 0.02 each.

The Capital Increase Shares are issued as uncertificated securities (Wertrechte) within the meaning of article 973c CO, and established as intermediated securities (Bucheffekten) within the meaning of the Federal Act on Securities held with an Intermediary (Bucheffektengesetz) of October 3, 2008, as amended (the "FISA"). Since the Capital Increase Shares are issued in the form of uncertificated securities, no share certificates will be issued and no share certificates will be available for individual physical delivery.

3.4 PUBLICATION

According to the Articles, to the extent that personal notification is not mandated by law, all communications from the Company to its shareholders are validly made by publication in the Swiss Official Gazette of Commerce (Schweizerisches Handelsamtsblatt). Written communications by the Company to its shareholders may be sent by ordinary mail to the last address of the relevant shareholder recorded in the Share Register.

Any notices containing or announcing amendments or changes to this Prospectus will be announced through electronic media. Notices required under the Listing Rules will be published on the website of the SIX Swiss Exchange (currently: https://www.six-group.com/de/products-services/the-swiss-stock-exchange/market-data/news-tools/official-notices.html#/).

3.5 SECURITIES INFORMATION

The security numbers for the Shares are as follows: Swiss Security Number (Valorennummer): 10.621.379

International Security Identification Number (ISIN): CH0106213793

As of the date of this Prospectus, the SIX Swiss Exchange ticker symbol for the Shares is SPEX (formerly POLN).

3.6 INFORMATION ON THE ISSUANCE OF SHARES

A. Nature of the Issuance

The transaction described in this Prospectus consists of the issuance of Shares to the holders of EnBiotix's shares against contribution of such EnBiotix shares to Polyphor. 35'150'961 Shares with a nominal value of CHF 0.02 were issued at the Issue Price. The Capital Increase Shares were issued out of an ordinary capital increase and rank pari passu in all respects with each other and with all other Shares. The holders of EnBiotix Shares were required to sign an adherence declaration to the merger agreement between the Company and EnBiotix, thereby granting an authorized representative authority to sign on their behalf a contribution agreement for their respective portion of the EnBiotix Shares and a
subscription form for their respective portion of the Capital Increase Shares, thereby unconditionally tendering their EnBiotix Shares as a contribution in kind for their respective portion of the Capital Increase Shares. In addition, they were asked to complete an instruction form setting out the details of their securities account to which their respective portion of the Capital Increase Shares is to be transferred.

B. Amount and use of Proceeds

The Company received only shares of EnBiotix in the Transaction. However, EnBiotix closed a financing round in the amount of approximately USD 11m shortly prior to the closing of the Transaction, which will be used by the Company for the further development of its product pipeline and general corporate purposes.

C. Number of Shares after completion of the Transaction (as recorded in the commercial register)

With completion of the Transaction, the share capital of the Company consists of 47'531'938 Shares (of which 46'375'777 have already been recorded in the commercial register).

D. Listing and Trading

An application has been made to, and approval has been given by, the SIX Swiss Exchange to list the Capital Increase Shares and the Conditional Shares under the International Reporting Standard of the SIX Swiss Exchange. The listing of the Capital Increase Shares and the Conditional Shares will become effective, and trading in the Capital Increase Shares under the International Reporting Standard of the SIX Swiss Exchange commences, on the date of this Prospectus.

E. Voting Rights

Each Share carries one vote. See “Capital Structure and Shares” beginning on page 84.

F. Form of Capital Increase Shares

The Capital Increase Shares are issued as uncertificated securities (Wertrechte) within the meaning of article 973c of the CO and will be established as intermediated securities (Bucheffekten) within the meaning of the FISA. The Capital Increase Shares are registered in the main register (Hauptregister) maintained by SIS and will be credited to the securities account of each purchaser, and thus will become intermediated securities (Bucheffekten) within the meaning of the FISA.

G. Transfer Restrictions & Lock-Up

The Shares are subject to certain transfer restrictions as described in “Transfer of Shares and transfer restrictions” beginning on page 89. In addition, in connection with an investment by Vectura Group plc in EnBiotix prior to the Transaction, certain former Enbiotix shareholders (including Jeffrey D. Wager and Dennis Ausiello, Directors of the Company) will be subject to a 6 month lock-up commencing on the closing of the Transaction with respect to certain transactions in Shares and Share-based instruments, the counterparty being Vectura Group plc.

H. Dividends and Dividend Policy

All Capital Increase Shares are in principle entitled to dividends, if any, for the fiscal year 2021. The Capital Increase Shares carry the same entitlement to dividends and surplus arising from a liquidation, if any, as the existing Shares of the Company. For further details, see “Dividends and Other Distributions” beginning on page 147.

I. Listing Agent

VISCHER AG, as recognised representative according to article 43 of the Listing Rules, has filed on behalf of the Company the application for the listing of the Shares on the SIX Swiss Exchange according to the International Reporting Standard.

J. Paying Agent

As long as the Shares are listed on the SIX, distribution payments, if any, with respect to Shares held through a Swiss depositary bank will generally be effected via the SIS system.
4. TAX CONSIDERATIONS

The following summary does not purport to address all tax consequences of the Capital Increase, the acquisition, the ownership and sale or other disposition of Shares and does not take into account the specific circumstances of any particular investor. This summary is based on the tax laws, regulations and regulatory practices of Switzerland and the United States as in effect on the date hereof, which are subject to change (or subject to changes in interpretation), possibly with retroactive effect. This is not a complete analysis of the potential tax effects relevant to a decision to invest in Shares nor does the following summary take into account or discuss the tax laws of any jurisdiction other than Switzerland and the United States. It also does not take into account investors’ individual circumstances. This summary does not purport to be a legal opinion or to address all tax aspects that may be relevant to any particular holder of Shares.

Current and prospective shareholders are advised to consult their own tax advisers in light of their particular circumstances as to the Swiss and U.S tax laws, regulations and regulatory practices that could be relevant for them in connection with the Capital Increase, the acquiring, owning and selling or otherwise disposing of Shares and receiving dividends and similar cash or in-kind distributions on Shares (including dividends on liquidation proceeds and stock dividends) or distributions on Shares based upon a share capital reduction (Nennwertrückzahlungen) or reserves paid out of capital contributions (Reserven aus Kapitaleinlagen) and the consequences thereof under the tax laws, regulations and regulatory practices of Switzerland and the United States.

A. Swiss federal, cantonal and communal individual income tax and corporate income tax

1. **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, hereinafter, for the purposes of this section “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 dividends on liquidation proceeds and stock dividends) (hereinafter, for the purposes of this section, “Dividends”), distributions based upon a capital reduction on Shares (Nennwertrückzahlungen) and distributions paid out of reserves from capital contributions (Reserven aus Kapitaleinlagen), or capital gains realised on the sale or other disposition of Shares (see, however, “— Swiss federal withholding tax” beginning on page 153 for a summary of Swiss federal withholding tax on Dividends).

2. **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 (Nennwertrückzahlungen) and distributions paid out of qualifying reserves from capital contributions (Reserven aus Kapitaleinlagen), 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 (Nennwertrückzahlungen) and the distributions paid out of qualifying reserves from capital contributions (Reserven aus Kapitaleinlagen). Furthermore, the Swiss federal income tax on dividends, shares in profit, liquidation proceeds and pecuniary benefits from Shares (including bonus shares) is currently reduced to 70% of regular taxation (Teilbesteuerung), if the investment amounts to at least 10% of the total share capital of the issuer. On cantonal and communal level the same provisions regarding partial taxation apply, with income reduced to between 50% and 80% depending on the canton of residency. Capital gains resulting from the sale or other disposition of Shares are 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, hereinafter, for the purposes of this section, as “Resident Private Shareholders”). See “— Domestic Commercial Shareholders” beginning on page 152 for a summary of the taxation treatment applicable to Swiss resident individuals who, for income tax purposes, are classified as “professional securities dealers”.

3. **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 recognise Dividends, distributions based upon a capital reduction (Nennwertrückzahlungen) and distributions paid out of reserves
from capital contributions (Reserven aus Kapitaleinlagen) and capital gains or losses realised 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, hereinafter for the purposes of this section, as “Domestic Commercial Shareholders”). Domestic Commercial Shareholders who are corporate taxpayers may be eligible for dividend relief (Beteiligungsabzug) in respect of Dividends and distributions based upon a capital reduction (Nennwertrückzahlungen) and distributions paid out of reserves from capital contributions (Reserven aus Kapitaleinlagen) if the Shares held by them as part of a Swiss business have an aggregate market value of at least CHF 1 million or a shareholding of at least 10% in the total nominal share capital or give entitlement to at least 10% of the total profit and reserves of the Company. For Domestic Commercial Shareholders who are individual taxpayers, the Swiss federal individual income tax on dividends, shares in profit, liquidation proceeds and pecuniary benefits from the Shares (including bonus shares) is reduced to 70% of regular taxation (Teilbesteuerung), if the investment is held in connection with the conduct of a trade or business or qualifies as an opted business asset (gewillkürtes Geschäftsvermögen) according to Swiss tax law and amounts to at least 10% of the total share capital of the Company.

B. Swiss cantonal and communal private wealth tax and capital tax

1. Non-Resident Shareholders

Non-Resident Shareholders are not subject to Swiss cantonal and communal private wealth tax or capital tax.

2. 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.

C. Swiss Federal Withholding Tax

Dividends that the Company pays on the Shares are generally subject to Swiss federal withholding tax (Verrechnungssteuer) 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 share capital reduction (Nennwertrückzahlungen) and distributions paid out from qualifying reserves from capital contributions (Reserven aus Kapitaleinlagen) are not subject to Swiss federal withholding tax. Restrictions regarding the distribution from qualifying reserves from capital contributions (Reserven aus Kapitaleinlagen) apply for companies listed on a Swiss stock exchange market. The Company is listed on the SIX Swiss Exchange, therefore distributions from qualifying reserves from capital contributions (Reserven aus Kapitaleinlagen) are only excluded from Swiss federal withholding tax to the extent that other reserves are simultaneously distributed in the same amount, provided the Company has such other reserves. Exceptions may apply if the qualifying reserves from capital contributions (Reserven aus Kapitaleinlagen) stem from a cross-border transaction or if the Company does not have other reserves.

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 its individual income tax return as income or recognises the Dividend in its income statement as earnings, as applicable.

Non-Resident Shareholders may be entitled to a total or partial refund of the Swiss federal withholding tax if the country in which such recipient resides for tax purposes maintains a bilateral treaty for the avoidance of double taxation with Switzerland (“Tax Treaty”) and further conditions of such treaty are met. Non-Resident Shareholders should be aware that the procedures for claiming treaty benefits (and the time required for obtaining a refund) may differ from country to country. Non-Resident Shareholders should consult their own legal, financial or tax advisors regarding receipt, ownership, purchases, sale or other dispositions of Shares and the procedures for claiming a refund of the Swiss federal withholding tax.
D. Automatic Exchange of Information

Switzerland has concluded a multilateral agreement with the EU on the international automatic exchange of information (“AEOI”) in tax matters (the “AEOI Agreement”). This Agreement became effective as of January 1, 2017, and applies to all 28 member states as well as Gibraltar. Furthermore, on January 1, 2017, the multilateral competent authority agreement on the automatic exchange of financial account information and, based on such agreement, a number of bilateral AEOI agreements with other countries became effective. Based on this AEOI Agreement and the bilateral AEOI agreements and the implementing laws of Switzerland, Switzerland began to collect data in respect of financial assets, which may include Shares, held in, and income derived thereon and credited to, accounts or deposits with a paying agent in Switzerland for the benefit of residents in a member state or a treaty state from 2017, and will begin to exchange it from 2018. Switzerland has signed and is expected to sign further AEOI agreements with other countries, which have become effective on January 1, 2018 or, subject to ratification, will become effective at a later date. A list of the AEOI agreements of Switzerland in effect or signed and becoming effective can be found on the website of the State Secretariat for International Financial Matters.

E. 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 (Emissionsabgabe) on the consideration received by it for the issuance of the newly created Capital Increase Shares less certain costs incurred in connection with the issuance. The issuance and the delivery of the newly created Capital Increase Shares to the initial shareholders at the Offer Price is not subject to Swiss federal securities turnover duty (Umsatzabgabe).

Any other purchases or sales of Shares, whether by Resident Private Shareholders, Domestic Commercial Shareholders or Non-Resident Shareholders, may be subject to the Swiss federal securities turnover duty at a current rate of up to 0.15%, as well as the SIX turnover fee, both calculated on the purchase price or the sale proceeds, respectively, if (i) such transfer occurs through or with a Swiss or Liechtenstein bank or by or with involvement of another Swiss securities dealer as defined in the Swiss federal stamp tax act and (ii) no exemption applies.

The following categories of foreign institutional investors that are subject to regulations similar to that imposed by Swiss federal supervisory authorities are exempt from their portion (50%, i.e., 0.075%) of the Swiss federal securities turnover duty: foreign states and central banks, social security institutions, pension funds, collective investment schemes, certain life insurance companies and certain quoted non-Swiss quoted companies and their non-Swiss consolidated group companies. In addition, Swiss or foreign collective investment schemes as defined in the Swiss Collective Investment Law are also exempt from their portion of the Swiss federal securities turnover duty.

F. Other Swiss taxes on Capital Gains upon Disposal of Shares

1. Resident Private Shareholders

Resident Private Shareholders who hold Shares as part of their private assets (Privatvermögen) are generally exempt from Swiss federal, cantonal and communal taxes with respect to capital gains realised upon the sale or other disposal of Shares, unless such Resident Private Shareholders are qualified as professional securities dealers (Wertschriftenhändler) for income tax purposes. Under certain circumstances, share sale proceeds of a private individual may be recharacterized into (in certain cases partially) taxable investment income. Upon a repurchase of Shares by the Company, the portion of the repurchase price in excess of the nominal amount and the qualifying reserves from capital contributions (Reserven aus Kapitaleinlagen) may be classified as (in certain cases partially) taxable investment income if the Share repurchase constitutes a Partial Liquidation.

2. Domestic Commercial Shareholders

Capital gains realized by an individual on Shares that are held as part of his or her business assets (including capital gains realized by individuals, who, for income tax purposes, are classified as professional securities dealers) are subject to income taxation and social security contributions.

Capital gains upon the sale or other disposal of Shares realized by corporations resident in Switzerland for tax purposes or foreign corporations holding Shares as part of a Swiss permanent establishment are generally subject to ordinary profit taxation. For Domestic Commercial Shareholders who are individual taxpayers the Swiss federal individual income tax on a gain realized upon the disposal of Capital Increase Shares is currently reduced to 50% of regular taxation.
(Teilbesteuerung), if (i) the investment is held in connection with the conduct of a trade or business or qualifies as an opted business asset (gewillkürtes Geschäftsvermögen) according to Swiss tax law, (ii) the sold shares reflect an interest in the total share capital of the Company of at least 10% and (iii) were held for at least one year. On cantonal and communal level the same provisions regarding partial taxation apply, with income reduced to between 50 and 80% depending on the canton of residency. A Swiss corporation or cooperative, or non-Swiss corporation or cooperative holding Shares as part of a Swiss permanent establishment, may, under certain circumstances, benefit from taxation relief on capital gains realized upon the disposal of Shares (Beteiligungsabzug), provided such Shares were held for at least one year and the shareholder disposes of at least 10% of the total share capital or 10% of the total profit and reserves, respectively. In case of staggered sales, subsequent sales can be less than 10% of the total nominal share capital in order to qualify for the participation relief, provided the total remaining shareholding is less than 10% of the total share capital or the profit and reserves, respectively, and the fair market value of the Shares held as per the previous financial year-end prior to this sale amounts to at least 1 million Swiss francs.

3. Gift and Inheritance Taxes

The transfer of Shares may be subject to cantonal and/or communal gift, estate or inheritance taxes if the donor is, or the deceased was, resident for tax purposes in a canton levying such taxes.

G. Certain Material U.S. Federal Income Tax Consequences

1. Introductory Remarks

This section summarizes certain material U.S. federal income tax consequences relevant to the Transaction that are generally applicable to EnBiotix stockholders who hold their shares as capital assets. This discussion is included for general information purposes only and does not constitute, and is not, a tax opinion or tax advice to any particular EnBiotix stockholders. This summary is based on the provisions of the Internal Revenue Code of 1986, as amended (the “Code”), existing Treasury Regulations promulgated thereunder, judicial decisions, administrative rulings and other legal authorities, all as of the date hereof and all of which are subject to change, possibly with retroactive effect which could alter the tax consequences to the holders of EnBiotix capital stock, and all of which are subject to differing interpretations. No ruling from the Internal Revenue Service (the “IRS”), nor any opinion of counsel will be requested concerning the U.S. federal income tax consequences of the Transaction. As a result, neither EnBiotix nor the Company can assure prospective investors that the tax consequences described in this summary will not be challenged by the IRS or will be sustained by a court if challenged by the IRS.

EnBiotix stockholders should be aware that this summary is not comprehensive with respect to U.S. federal income tax considerations. For example, this discussion does not deal with all federal income tax considerations that may be relevant to particular EnBiotix stockholders in light of their particular circumstances, or to EnBiotix stockholders who are subject to special tax rules, including without limitation EnBiotix stockholders:

- who do not hold their EnBiotix capital stock as a capital asset for federal income tax purposes;
- who are financial institutions, mutual funds, tax-exempt organizations, insurance companies, dealers in securities, persons that mark-to-market their securities, or persons that hold EnBiotix’s stock as part of an integrated investment (including a constructive sale, “straddle”, “pledge against currency risk” or a “conversion” transaction consisting of share of EnBiotix capital stock and one or more other positions;
- who are not citizens or residents of the United States, are corporations (or other entities taxable as corporations for U.S. federal income tax purposes) created or organized outside of the United States, or are otherwise treated as foreign persons for U.S. tax law purposes;
- who are subject to the alternative minimum tax provisions of the Code;
- who are partnerships, limited liability companies that are not treated as corporations for U.S. federal income tax purposes, S corporations, or other pass-through entities or an estate or trust;
- who acquired their EnBiotix stock in connection with the exercise of compensatory stock options or otherwise in connection with services;
- who acquired their EnBiotix stock as qualified small business stock under Code Section 1202 or as “Section 1244
stock”;

- who acquired their EnBiotix capital stock in a transaction subject to the gain rollover provisions of Code Section 1045;

- who are U.S. expatriates;

- whose functional currency is not the U.S. dollar; or

- who exercise dissenters' rights.

In addition, this summary does not address the tax consequences of the Transaction under state, local or foreign, estate or gift tax laws, the tax consequences of transaction effectuated before or after, or concurrently with, the Transaction (whether or not any such transactions are consummated in connection with the Transaction), including without limitation any transaction in which shares of EnBiotix capital stock are acquired or the tax consequences to holders of options (including with respect to the cash out or cancellation of vested options at Closing), warrants or similar rights to acquire EnBiotix capital stock, or to creditors of EnBiotix or any of its subsidiaries. If a partnership (including any entity treated as such for purposes of U.S. federal income tax law) holds EnBiotix stock, the tax treatment of a partner of such partnership will generally depend upon the status of the partner and the activities of the partnership. Such partner should consult its tax advisors as to the tax consequences of the Transaction.

Neither EnBiotix, nor the Company has requested a ruling from the IRS in connection with the Transaction. Accordingly, the discussion below neither binds the IRS nor precludes it from adopting a contrary position. Furthermore, no opinion of counsel has been or will be rendered with respect to the tax consequences of the Combination.


2. The Transaction

The exchange of EnBiotix stock for Capital Increase Shares will constitute a fully taxable transaction for U.S. federal income tax purposes. As a result, each EnBiotix Stockholder will generally recognize gain or loss as a result of the exchange in an amount equal to the difference between the amount of the aggregate consideration received by such stockholder plus the stockholder’s adjusted tax basis in the EnBiotix capital stock surrendered by such stockholder in the Transaction. Subject to the exceptions noted below, such gain or loss will be capital gain or loss and will be long-term capital gain or loss if the stockholder’s holding period is more than one year. EnBiotix Stockholders who acquired different shares of EnBiotix capital stock at different times or different prices must determine their tax basis and holding period separately with respect to each identifiable block of such stock. The deductibility of capital losses is subject to limitation. The maximum U.S. federal income tax rate applicable to long-term capital gain of non-corporate taxpayers is currently 20%. The net investment income tax of 3.8% may apply to the net investment income of EnBiotix Stockholders who are individuals and whose income exceeds certain thresholds. For corporations, capital gain is taxed at the same rates as ordinary income.

Holders of EnBiotix options who receive 100% of their Capital Increase Shares as consideration of the conversion vesting and conversion of such options will recognize gain equal to (i) the number of shares of EnBiotix common stock subject to the Option, multiplied by (ii)(A) the fair market value of the number of Capital Increase Shares received by such recipient minus (B) the per share exercise price of such option. This amount will be subject to any applicable payroll, income tax or other withholding taxes. In each case, such gain will be ordinary income. The maximum U.S. federal income tax rate applicable to ordinary income of non-corporate taxpayers is currently 37%. For corporations, the U.S. federal income tax rate applicable to ordinary income is currently 21%.

3. Disclosure of Reportable Transactions

A taxpayer who participates in a “reportable transaction” is required to attach a disclosure statement to their federal income tax return disclosing such taxpayer’s participation in the transaction. Subject to various exceptions, a reportable transaction can include a transaction that results in a loss exceeding certain thresholds. Failure to comply with these and other reporting requirements could result in the imposition of significant penalties. EnBiotix Stockholders are urged to
consult their tax advisors regarding the applicability of any disclosure requirements to them.

4. Federal Backup Withholding

Certain payments due to non-corporate EnBiotix stockholders under the merger agreement may be subject to “backup withholding” at a rate of 28% for U.S. federal income tax purposes unless certain requirements are satisfied. In order to avoid backup withholding with respect to cash received pursuant to the Transaction, an EnBiotix stockholder must complete Form W-9 included in a letter of transmittal to be provided at the closing of the Transaction, or otherwise establish an exemption from backup withholding. Corporations are generally exempt from backup withholding. Holders of EnBiotix stock who fail to provide their correct taxpayer identification numbers and the appropriate certifications or to establish an exemption may be subject to backup withholding on payments received at a tax withholding rate of 24% and may be subject to penalties imposed by the IRS. Amounts withheld, if any, are not an additional tax and may be refunded or credited against the holder’s U.S. federal income tax liability, provided that the holder timely furnishes the required information to the IRS.

THE U.S. FEDERAL INCOME TAX SUMMARY SET FORTH ABOVE IS INCLUDED FOR GENERAL INFORMATION PURPOSES ONLY AND DOES NOT PURPORT TO BE A COMPLETE ANALYSIS OR SUMMARY OF ALL POTENTIAL TAX CONSEQUENCES RELEVANT TO HOLDERS OF ENBIOTIX STOCK. EACH HOLDER OF ENBIOTIX STOCK SHOULD CONSULT HIS, HER OR ITS OWN TAX ADVISORS TO DETERMINE THE U.S. FEDERAL INCOME TAX CONSEQUENCES APPLICABLE TO SUCH HOLDER AS A RESULT OF THE TRANSACTION AND ANY NON-INCOME TAX OR ANY STATE, LOCAL OR FOREIGN TAX CONSEQUENCES RELEVANT TO SUCH HOLDER AS A RESULT OF THE TRANSACTION. WITHOUT LIMITING THE FOREGOING, THE SUMMARY SET FORTH ABOVE DOES NOT PURPORT TO DESCRIBE, AND SHOULD NOT BE PRESUMED TO DESCRIBE, THE TAX CONSEQUENCES OF THE TRANSACTION TO CONTINUING OPTION HOLDERS OR WARRANT HOLDERS OF ENBIOTIX.
5. RESPONSIBILITY FOR PROSPECTUS

Spexis AG with its registered office at Hegenheimermattweg 125, 4123 Allschwil, Switzerland, assumes responsibility for the completeness and accuracy of this Prospectus and declares that to the best of its knowledge the information in this Prospectus is correct and no material factor has been omitted.
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