

PROSPECTUS

6,435,548,000 Ordinary Shares



Represented by 16,088,870 American Depositary Shares

This prospectus relates to the resale, by the selling shareholders identified in this prospectus, of up to an aggregate of 6,435,548,000 ordinary shares of Quoin Pharmaceuticals Ltd., represented by 16,088,870 American Depositary Shares, or “ADSs,” which are issuable upon the exercise of warrants. Each ADS represents four hundred (400) ordinary shares of Quoin Pharmaceuticals Ltd.

We will not receive any proceeds from the sale of the ordinary shares represented by ADSs by the selling shareholders. All net proceeds from the sale of the ordinary shares represented by ADSs covered by this prospectus will go to the selling shareholders. However, we may receive the proceeds from any exercise of warrants if the selling shareholders do not exercise the warrants on a cashless basis. See “Use of Proceeds.”

The selling shareholders may sell all or a portion of the ordinary shares represented by ADSs from time to time in market transactions through any market on which our ADSs are then traded, in negotiated transactions or otherwise, and at prices and on terms that will be determined by the then prevailing market price or at negotiated prices directly or through a broker or brokers, who may act as agent or as principal or by a combination of such methods of sale. See “Plan of Distribution”.

Our ADSs are listed on the Nasdaq Capital Market under the symbol “QNRX.” On April 20, 2022, the last reported sale price of our ADSs on the Nasdaq Capital Market was \$1.20 per ADS.

The securities offered in this prospectus involve a high degree of risk. Before deciding whether to invest in our securities, you should consider carefully the risks and uncertainties under the heading “Risk Factors” beginning on page 9 of this prospectus.

Neither the U.S. Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

The date of this prospectus is April 22, 2022.

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form F-1 that we filed with the Securities and Exchange Commission, or “SEC,” utilizing a “shelf” registration process. Under this shelf registration process, the selling shareholders may from time to time sell ordinary shares represented by ADSs described in this prospectus in one or more offerings.

We have not authorized anyone to give any information or to make any representation other than those contained in this prospectus. You must not rely upon any information or representation not contained in this prospectus (as supplemented or amended) as having been authorized by us. The selling shareholders are offering to sell, and seeking offers to buy, ordinary shares represented by ADSs only in jurisdictions where it is lawful to do so. This prospectus does not constitute an offer to sell or the solicitation of an offer to buy any ordinary shares represented by ADSs other than the registered ordinary shares to which it relates, nor does this prospectus constitute an offer to sell or the solicitation of an offer to buy ordinary shares represented by ADSs in any jurisdiction to any person to whom it is unlawful to make such offer or solicitation in such jurisdiction.

You should not assume that the information contained in this prospectus (as supplemented or amended) is accurate on any date subsequent to the date set forth on the front of the document, even though this prospectus (as supplemented or amended) is delivered, or securities are sold, on a later date.

Unless otherwise indicated or the context otherwise requires, all references in this prospectus to the terms “Quoin Ltd.,” the “Company,” “us,” “we”, “our” and the “Registrant” refer to Quoin Pharmaceuticals Ltd., an Israeli company, and its consolidated subsidiaries.

For investors outside the United States: We have not done anything that would permit the offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the securities described herein and the distribution of this prospectus outside the United States.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus that we consider important. This summary does not contain all of the information you should consider before investing in our securities. You should read this summary together with the entire prospectus, including the risks related to our business, our industry, investing in our securities that we describe under “Risk Factors” and our consolidated financial statements and the related notes before making an investment in our securities.

Company Overview

We are an emerging specialty pharmaceutical company dedicated to developing products that help treat rare and orphan diseases for which there are currently no approved treatments. We believe the rare and orphan disease space represents an attractive commercial opportunity for a number of reasons.

Our initial focus is on the development of products, using our proprietary owned and in-licensed technology, that could help address rare skin diseases for which there are currently no approved treatments or cures. Our first lead product is QRX003, a once daily, topical lotion comprised of a broad-spectrum serine protease inhibitor, formulated with the proprietary Invisicare® technology, to treat Netherton Syndrome. In addition, we intend to pursue the clinical development of QRX003 in other rare dermatological diseases including Peeling Skin Syndrome, SAM Syndrome, and Palmoplantar Keratoderma. We are also developing QRX004 as a potential treatment for Dystrophic Epidermolysis Bullosa. In addition, we are also developing QRX006 as a potential therapy for an, as of yet, undisclosed rare skin disease. A provisional patent application for QRX006 was filed with the USPTO in May 2021.

Corporate Information

Our legal and commercial name is Quoin Pharmaceuticals Ltd. We were incorporated under the laws of the State of Israel in 1986 and operate under the Companies Law. We have been a public company traded on the Tel Aviv Stock Exchange (“TASE”) from 1990 until September, 2017 (when our shares were delisted from TASE), and our ADSs have been listed on the Nasdaq Capital Market since July 29, 2016. We were incorporated under the name Montiger Ltd. Between 1986 and 2021 we underwent several name changes, including the name change to Collect Biotechnology Ltd. (“Collect”) in July 2016 and most recently in October 2021 in connection with the business combination with Quoin Pharmaceuticals, Inc., a Delaware corporation (“Quoin Inc.”).

On October 28, 2021, Collect completed the business combination with Quoin Inc. in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of March 24, 2021 (the “Merger Agreement”), by and among Collect, Quoin Inc. and CellMSC, Inc., a Delaware corporation and wholly-owned subsidiary of Collect (“Merger Sub”), pursuant to which Merger Sub merged with and into Quoin Inc., with Quoin Inc. surviving as a wholly-owned subsidiary of Collect (the “Merger”). Immediately after completion of the Merger, Collect changed its name to “Quoin Pharmaceuticals, Ltd.” The ADSs listed on the Nasdaq Capital Market traded through the close of business on October 27, 2021 under the ticker symbol “APOP,” and commenced trading on the Nasdaq Capital Market, under the ticker symbol “QRNX” on October 29, 2021.

Our registered office is located in Azrieli Center, Round Tower, 30th Floor, 132 Menachem Begin Blvd, Tel Aviv, 6701101, Israel, and our telephone number is +972 58-448-8821. Our agent for service of process in the United States is Corporation Services Company, 251 Little Falls Drive, Wilmington, Delaware 19808.

The Quoin logo and other trademarks or service marks of Quoin Ltd. appearing in this prospectus are the property of Quoin Ltd. This prospectus contains references to our trademarks and to trademarks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ™ symbols, but such references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other companies’ trade names or trademarks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

Issuance of Warrants

On October 28, 2021, Collect and Quoin Inc. completed the private placement transaction with Altium Growth Fund, LP, referred to as “Altium” for an aggregate purchase price of approximately \$17.0 million (comprised of (x) the set off of approximately \$5 million of senior secured notes issued in connection with the bridge loan (“Bridge Financing”) that Altium made to Quoin Inc. at the time of the execution of the Merger Agreement, and (y) approximately \$12 million in cash from Altium whereby, among other things,

Quoin Inc. issued to Altium common stock of Quoin Inc. immediately prior to the Merger (the “Pre-Merger Financing”), pursuant to the Securities Purchase Agreement entered into as March 24, 2021, by and among Collect, Quoin Inc. and Altium, as amended by (i) the Amendment Agreement dated September 17, 2021 by and among Collect, Quoin Inc. and Altium and (ii) the Second Amendment Agreement, dated as of March 13, 2022, by and among Quoin Ltd., Quoin Inc. and Altium (collectively, the “Purchase Agreement”). In addition, on March 24, 2021, Collect and Altium also entered into the Registration Rights Agreement, as amended by (i) the Amendment Agreement dated September 17, 2021 by and among Collect, Quoin Inc. and Altium and (ii) the Second Amendment Agreement, dated as of March 13, 2022, by and among Quoin Ltd., Quoin Inc. and Altium (collectively, the “Registration Rights Agreement”), pursuant to which Quoin Ltd. agreed to file the registration statement, of which this prospectus forms a part, with the SEC to cover the resale of ordinary shares represented by ADSs issuable upon the exercise of Investor Warrants (as defined below).

At the closing of the Pre-Merger Financing, Quoin Inc. issued and sold to Altium common stock of Quoin Inc., and issued warrants to purchase 1,238,429 ADSs (the “Investor Exchange Warrants”) in exchange for warrants issued in connection with the Bridge Financing. In addition, under the Purchase Agreement, Quoin Ltd. issued to Altium as of March 13, 2022 (the one hundred thirty sixth (136th) day following the consummation of the Merger): (i) Series A Warrant to purchase 4,276,252 ADSs (the “Series A Warrant”) (ii) Series B Warrant to purchase 4,276,252 ADSs (the “Series B Warrant”) and (iii) Series C Warrant to purchase 2,389,670 ADSs (“Series C Warrant” and, together with the Series A Warrant and Series B Warrant, the “Initial Investor Warrants”), each at an exercise price of \$3.98 per ADS. The Investor Warrants became exercisable immediately upon issuance and, in the case of the Series A Warrant, will expire five years from March 13, 2022 and, in the case of the Series B Warrant and Series C Warrant, will expire two years from the Registration Date (as defined therein). Under the Purchase Agreement, upon the exercise of the Series C Warrant in full, Quoin Ltd. is obligated to issue to Altium: (i) an additional Series A Warrant to purchase 2,389,670 ADSs and (ii) an additional Series B Warrant to purchase 2,389,670 ADSs (“Additional Investor Warrants” and together with Initial Investor Warrants, the “Investor Warrants”).

Commencing in October 2020, Quoin Inc. issued promissory notes (the “2020 Notes”) to five noteholders, including our directors, Messrs. Langer and Culverwell (collectively, “2020 Noteholders”). The 2020 Notes were issued at a 25% original issue discount with an aggregate face value of \$1,213,313 with an interest at a rate of 20% per annum. The 2020 Notes were mandatorily convertible into ADSs based on the valuation negotiated in the Pre-Merger Financing.

The 2020 Noteholders also received warrants exercisable at any time after the issuance date for a number of shares of Quoin Inc.’s common stock equal to 100% of the “as if converted” shares as if the 2020 Notes principal and interest were convertible at the lowest price any securities are sold, convertible, or exercisable into in the Pre-Merger Financing or the next round of financing (whichever is lower).

At the closing of the Merger, ADSs were issued to the 2020 Noteholders upon the conversion of the principal of the 2020 Notes. In addition, effective as of March 13, 2022, Quoin Ltd. exchanged Quoin Inc. warrants held by the 2020 Noteholders for warrants on substantially the same terms as the Investor Exchange Warrants, exercisable for 367,356 ADSs, in the aggregate, at the exercise price of \$3.98 per ADS (the “Noteholder Warrants”). The Noteholder Warrants became exercisable immediately upon issuance and will expire five years from March 13, 2022.

The Investor Warrants and the Noteholder Warrants are collectively referred to herein as the “Warrants”.

Implications of Being a Foreign Private Issuer

We are considered a “foreign private issuer” subject to reporting requirements under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), as a non-U.S. company with foreign private issuer status. As a “foreign private issuer,” we are subject to different requirements of U.S. securities laws than U.S. domestic issuers. The rules governing the information that we must disclose differ from those governing U.S. corporations pursuant to the Exchange Act. This means that, as long as we qualify as a foreign private issuer under the Exchange Act, we will be exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

- the rules under the Exchange Act prescribing the furnishing and content of proxy statements to shareholders and requirements that the proxy statements conform to Schedule 14A of the proxy rules promulgated under the Exchange Act;
- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;

- the sections of the Exchange Act requiring insiders (i.e., officers, directors and holders of more than 10% of our issued and outstanding equity securities) to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and
- the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K, upon the occurrence of specified significant events.

We may choose to take advantage of some but not all of these reduced reporting requirements of which we have taken advantage of in this prospectus. Accordingly, the information contained herein may be different from the information you may receive from other companies that are U.S. domestic filers, or other U.S. domestic public companies in which you have made an investment.

Summary of Risk Factors

An investment in our securities is subject to a number of risks, including risks related to our business and industry, as well as risks related to our ADSs. You should carefully consider all of the information in this prospectus before making an investment in our securities. The following list summarizes some, but not all, of these risks. Please read the information in the section entitled “Risk Factors” for a more thorough description of these and other risks.

Risks Related to Our Financial Position and Capital Requirements

- We have a limited operating history that you can use to evaluate us, and the likelihood of our success must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered by a small developing company.
- We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.
- We have never generated any revenue from product sales or any other sources since inception, and may never be profitable.
- We expect that we will need to raise additional capital, which may not be available on acceptable terms, or at all.

Risks Related to the Discovery and Development of Product Candidates

- Preclinical and clinical studies of our product candidates may not be successful. If we are unable to generate successful results from preclinical and clinical studies of our product candidates, or experience significant delays in doing so, our business may be materially harmed.
- We may not be successful in our efforts to identify or develop potential product candidates.
- If future clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- Any of our product candidates may cause undesirable side effects or have other properties impacting safety that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.
- Even if we complete the necessary preclinical studies and clinical trials, we cannot predict whether or when we will obtain regulatory approval to commercialize a product candidate and we cannot, therefore, predict the timing of any revenue from a future product.
- Even if we obtain regulatory approval for a product candidate, we will still face extensive regulatory requirements and our products may face future development and regulatory challenges.
- We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.

- We may pursue Rare Pediatric Disease designation for QRX003 for the treatment of NS or other of our product candidates. There is no assurance that we will obtain such designation. Moreover, a Rare Pediatric Disease designation by the FDA does not guarantee that the NDA for the product will qualify for a priority review voucher upon approval, and it does not lead to a faster development or regulatory review process, or increase the likelihood that any of our product candidates will receive marketing approval.
- We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.
- We expect competition in the marketplace for our product candidates, should any of them receive regulatory approval.
- We face significant competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.
- The commercial success of our product candidates will depend upon the acceptance of these product candidates by the medical community, including physicians, patients and healthcare payors.
- If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenues.
- If we obtain approval to commercialize any approved products outside of the United States and Europe, a variety of risks associated with international operations could materially adversely affect our business.
- Coverage and adequate reimbursement may not be available for our product candidates, if approved, which could make it difficult for us to sell products profitably.

Risks Related to Our Reliance on Third Parties

- We rely on third parties to conduct some aspects of our compound formulation, research and preclinical studies, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such formulation, research or testing.
- We rely on third-party manufacturers to produce the supply of our preclinical product, clinical product candidates and commercial supplies of any approved product candidates.
- We rely on limited sources of supply for the drug substance of product candidates and any disruption in the chain of supply may cause a delay in developing and commercializing these product candidates.
- Manufacturing issues may arise that could increase product and regulatory approval costs or delay commercialization.
- We intend to rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

Risks Related to Our Intellectual Property

- If we are unable to obtain or protect intellectual property rights related to our future products and product candidates, we may not be able to compete effectively in our markets.
- Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.
- If we fail to obtain licenses or comply with our obligations in these agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

- We may be involved in lawsuits to protect or enforce our patents or the patents of our licensees, which could be expensive, time consuming and unsuccessful.
- We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

Other Risks Related to Our Business Operations and Industry

- Our future success depends on our ability to attract and retain key executives and to attract, retain and motivate qualified personnel.
- We may need to expand our organization and may experience difficulties in managing our growth, which could disrupt our operations.
- Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.
- Future relationships with customers and third-party payors as well as certain of our business operations may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.
- Recent and future healthcare legislation may further impact our business operations.
- We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs.
- Cyber security risks and the failure to maintain the confidentiality, integrity, and availability of our computer hardware, software, and Internet applications and related tools and functions could result in damage to our reputation and/or subject us to costs, fines or lawsuits.
- The coronavirus pandemic has caused interruptions or delays of our business plan and may have a significant adverse effect on our business.
- Business interruptions could delay us in the process of developing our future products.

Risks Related to Us Being an Israeli Company

- Shareholders may have difficulties enforcing a U.S. judgment, including judgments based upon the civil liability provisions of the U.S. federal securities laws, against us or our executive officers and directors, or asserting U.S. securities laws claims in Israel.
- Your rights and responsibilities as our shareholder will be governed by Israeli law, which may differ in some respects from the rights and responsibilities of shareholders of U.S. corporations.
- Provisions of Israeli law may delay, prevent or otherwise impede a merger with, or an acquisition of, our company, which could prevent a change of control, even when the terms of such a transaction are favorable to us and our shareholders.

Risks Related to Ownership of Our ADSs and Ordinary Shares

- We may not be able to raise additional funds unless we increase our authorized share capital.
- We do not know whether a market for our securities will be sustained or what the trading price of our securities will be and as a result it may be difficult for you to sell our securities held by you.

- The requirements of being a publicly traded company may strain our resources and divert management’s attention.
- Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business, results of operation or financial condition. In addition, current and potential shareholders could lose confidence in our financial reporting, which could have a material adverse effect on the price of the ADSs.
- We are a “foreign private issuer” and have disclosure obligations that are different from those of U.S. domestic reporting companies.
- As a “foreign private issuer,” we are permitted, and intend, to follow certain home country corporate governance practices instead of otherwise applicable SEC and Nasdaq requirements, which may result in less protection than is accorded to investors under rules applicable to domestic U.S. issuers.
- We may be unable to comply with the applicable continued listing requirements of Nasdaq.
- If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they adversely change their recommendations or publish negative reports regarding our business or our traded securities, our securities price and trading volume could be negatively impacted.
- The market price for our ADSs is likely to be highly volatile.
- We may be at risk of securities class action litigation.
- Substantial future sales or perceived potential sales of our ordinary shares or ADSs in the public market could cause the price of our ADSs decline.
- Your percentage ownership in us may be diluted by future issuances of share capital, which could reduce your influence over matters on which shareholders vote.
- We have not paid, and do not intend to pay, dividends on our ordinary shares and, therefore, unless our traded securities appreciate in value, our investors may not benefit from holding our securities.
- If we pay dividends or other distributions, an ADS holder may not receive the same distributions or dividends as those we make to the holders of our ordinary shares, and, in some limited circumstances, you may not receive dividends or other distributions on our ordinary shares and you may not receive any value for them, if it is illegal or impractical to make them available to you.
- Holders of ADSs must act through the depositary to exercise their rights.
- You may be subject to limitations on transfer of your ADSs.

Risks Related to this Offering

- The sale of a substantial amount of our ordinary shares or ADSs, including resale of the ADSs issuable upon the exercise of the Warrants held by the selling shareholder in the public market could adversely affect the prevailing market price of our ADSs.

The Offering

Ordinary shares outstanding	3,354,653,999 ordinary shares (as of April 12, 2022)
Ordinary shares offered by the selling shareholders	Up to 6,435,548,000 ordinary shares represented by up to 16,088,870 ADSs issuable upon the exercise of the Warrants.
Ordinary shares to be outstanding immediately after the full exercise of the Warrants	Approximately 9,790,201,999 ordinary shares
Terms of the offering	Each selling shareholder will determine when and how such selling shareholder will sell the ordinary shares represented by ADSs offered in this prospectus, as described in “Plan of Distribution.”
Use of proceeds	We will not receive any of the proceeds from the sale of ordinary shares represented by ADSs in this offering. The selling shareholders will receive all of the net proceeds from this offering (excluding commissions and discounts, if any). However, we may receive the proceeds from any exercise of the Warrants if any selling shareholder does not exercise the Warrants on a cashless basis. See “Use of Proceeds.”
Depositary	The Bank of New York Mellon
Transfer Agent and Registrar	Computershare Trust Company, N.A.
Risk factors	See “Risk Factors” beginning on page 9 for a discussion of factors you should carefully consider before deciding to invest in our securities.
Nasdaq Capital Market symbol for ADSs	QNRX

Unless otherwise indicated, the number of ordinary shares outstanding after the full exercise of the Warrants is based on 3,354,653,999 ordinary shares outstanding as of April 12, 2022, and excludes the following:

- 1,606,133,600 ordinary shares represented by 4,015,334 ADSs issuable upon the exercise of stock options outstanding at a weighted-average exercise price of \$1.66 per ADS;
- 495,371,600 ordinary shares represented by 1,238,429 ADSs issuable upon the exercise of outstanding Investor Exchange Warrants issued to Altium in connection with Bridge Financing at an exercise price of \$3.98 per ADS; and
- 44,102,000 ordinary shares represented by 110,255 ADSs issuable upon the exercise of outstanding warrants issued by Collect at an exercise price of \$11.00 per ADS.

Unless otherwise indicated, all information in this prospectus assumes no exercise of the outstanding options or warrants described above.

RISK FACTORS

Investing in our securities involves a high degree of risk. Before making an investment in our securities, you should carefully consider the risk factors discussed below as well as other information we include in this prospectus. If any of the following risks occur, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that case, the market price of our securities could decline and you could lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also materially harm our business, operating results and financial condition and could result in a complete loss of your investment.

Risks Related to Our Financial Position and Capital Requirements

We have a limited operating history that you can use to evaluate us, and the likelihood of our success must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered by a small developing company.

Our wholly owned subsidiary, Quoin Inc., commenced operations in 2018. As such, we have a limited operating history and our operations are subject to all of the risks inherent in the establishment of a new business enterprise, including a lack of operating history. Since inception, our operations have been primarily limited to acquiring and licensing intellectual property rights, undertaking research and conducting preclinical studies for our initial programs and negotiating and executing the Merger and financings. We have not yet obtained regulatory approval for any product candidates. Consequently, any predictions about our future success or viability, or any evaluation of our business and prospects, may not be accurate. The likelihood of our success must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered by a small developing company starting a new business enterprise and the highly competitive environment in which we will operate. Since we have a limited operating history, we cannot assure you that our business will be profitable or that we will ever generate sufficient revenues to meet our expenses and support our anticipated activities. In addition, there is no guarantee that any of our product candidates will ever receive approval from the U.S. Food and Drug Administration, or the “FDA.” We cannot be certain that our business strategy will be successful or that we will be solvent at any particular time. Our likelihood of success must be considered in light of the problems, expenses, difficulties, complications and delays frequently encountered in connection with the early stages of the development of any company. If we fail to address any of these risks or difficulties adequately, our business will likely suffer. Because of the numerous risks and uncertainties associated with developing and commercializing our products, we are unable to predict the extent of any future losses or when we will become profitable, if ever. We may never become profitable and you may never receive a return on an investment in our securities. An investor in our securities must carefully consider the substantial challenges, risks and uncertainties inherent in the attempted development and commercialization of products in the medical and pharmaceutical industries. We may never successfully commercialize our products and our business may fail.

We have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

To date, we have not commercialized any products and have not generated any revenue. We have devoted most of our financial resources to research and development, including our preclinical development activities. To date, we have funded our operations primarily through our founders’ funding expenditures and the sale of equity and convertible securities. We expect to continue to incur substantial and increased expenses, losses and negative cash flows as we expand our development activities and advance our preclinical programs. If our product candidates are not successfully developed or commercialized, including because of a lack of capital, or if we do not generate enough revenue following marketing approval, we will not achieve profitability and our business may fail. Even if we successfully obtain regulatory approval to market a product candidate, our revenues will also depend upon the size of any markets in which our product candidates receive market approval and our ability to achieve sufficient market acceptance and adequate market share for our products.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future. The net losses we incur may fluctuate significantly from quarter to quarter. We anticipate that our expenses will increase substantially if and as we:

- initiate clinical development of our product candidates, including our first lead product—QRX003—a once daily, topical lotion comprised of a broad-spectrum serine protease inhibitor, formulated with the proprietary Invisicare® technology, to treat Netherton Syndrome (“NS”);
- further enhance our internal control systems;

- initiate the development of additional product candidates for other rare disease indications;
- acquire or in-license other products and technologies and advance those product candidates into clinical trials;
- seek marketing approvals for our product candidates that successfully complete clinical trials;
- ultimately establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval;
- maintain, expand and protect our intellectual property portfolio;
- hire additional clinical, regulatory, research, executive and administrative personnel; and
- create additional infrastructure to support our operations and our product development and planned future commercialization efforts.

We have never generated any revenue from product sales or any other sources since inception, and may never be profitable.

Our ability to generate revenue and achieve profitability depends on our ability, alone or with strategic alliance partners, to successfully complete the development of, obtain the necessary regulatory approvals for and commercialize our product candidates. We do not anticipate generating revenues from sales of our products for the foreseeable future, if ever. Our ability to generate future revenues from product sales depends heavily on our success in:

- completing our research and preclinical development of product candidates;
- initiating and completing clinical trials for product candidates with favorable results;
- seeking, obtaining, and maintaining marketing approvals for product candidates that successfully complete clinical trials;
- establishing and maintaining supply and manufacturing relationships with third parties;
- launching and commercializing product candidates for which we may obtain marketing approval, with an alliance partner or, if launched independently, successfully establishing a sales force, marketing and distribution infrastructure;
- maintaining, protecting and expanding our intellectual property portfolio; and
- attracting, hiring and retaining qualified personnel.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to predict the timing or amount of increased expenses and when we will be able to achieve or maintain profitability, if ever. In addition, our expenses could increase beyond expectations if we are required by the FDA or other foreign regulatory agencies to perform studies and trials in addition to those that we currently anticipate.

Even if one or more of the product candidates that we independently develop is approved for commercial sale, we may incur significant costs associated with commercializing any approved product. Even if we are able to generate revenues from the sale of any approved products, we may not become profitable and may need to obtain additional funding to continue operations.

We expect that we will need to raise additional capital, which may not be available on acceptable terms, or at all.

Developing pharmaceutical products, including conducting preclinical studies and clinical trials, is expensive. We expect our research and development expenses to substantially increase in connection with our ongoing activities, particularly as we advance our product candidates towards or through clinical trials. We may need to raise additional capital to support our operations and such funding may not be available to us on acceptable terms, or at all. We cannot provide assurances that our plans will not change or that changed circumstances will not result in the depletion of our capital resources more rapidly than we currently anticipate. For example, our preclinical or clinical trials may encounter technical difficulties or be subject to delays or other issues. Any of these events may

increase our development costs more than we expect. In order to support our long-term plans, we may need to raise additional capital or otherwise obtain funding through additional strategic alliances if we choose to initiate preclinical or clinical trials for new product candidates other than programs currently partnered. In any event, we will require additional capital to obtain regulatory approval for, and to commercialize, future product candidates.

Any additional fundraising efforts may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize future product candidates. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. If we are unable to raise additional capital when required or on acceptable terms, we may be required to:

- significantly delay, scale back or discontinue the development or commercialization of any future product candidates;
- seek strategic alliances for research and development programs at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available; or
- relinquish or license on unfavorable terms, our rights to technologies or any future product candidates that we otherwise would seek to develop or commercialize ourselves.

If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we will be prevented from pursuing development and commercialization efforts, which will have a material adverse effect on our business, operating results and prospects.

Risks Related to the Discovery and Development of Product Candidates

Preclinical and clinical studies of our product candidates may not be successful. If we are unable to generate successful results from preclinical and clinical studies of our product candidates, or experience significant delays in doing so, our business may be materially harmed.

We have no products approved for commercial marketing and most of our product candidates are in preclinical development or about to enter into clinical testing in the first half of 2022 as is the case with our lead asset for Netherton Syndrome. In March 2022, we submitted an Investigational New Drug (IND) application to the FDA, as well as a Scientific Advice Briefing Document with the European Medicines Agency (the “EMA”), for QRX003, our investigational product for Netherton Syndrome, a rare and genetic disease. There is no assurance that the FDA or the EMA will permit our clinical trials to proceed. For example, while we have submitted in our IND a justification for the sufficiency of our nonclinical toxicology package to support initiation of our clinical study of QRX003, there is no assurance that the FDA will agree with our assessment. Moreover, the clinical development process can take several years, and there is no assurance that our clinical trials will be successful or that we will obtain marketing approvals for any of our product candidates from either the FDA or the EMA. Our ability to achieve and sustain profitability depends on obtaining regulatory approvals for and, if approved, successfully commercializing our product candidates, either alone or with third parties. Before obtaining regulatory approval for the commercial distribution of our product candidates, we or an existing or future collaborator must conduct extensive preclinical tests and clinical trials to demonstrate the safety and efficacy of our product candidates.

The success of our product candidates will depend on several factors, including the following:

- successfully implementing preclinical studies which may be predictive of clinical outcomes;
- successful enrollment in clinical trials and completion of those trials with favorable results;
- receipt of marketing approvals from applicable regulatory authorities;
- obtaining and maintaining patent and trade secret protection for current and future product candidates;
- establishing and maintaining manufacturing relationships with third parties or establishing our own manufacturing capability; and

- successfully commercializing our products, if approved, including successfully establishing a sales force, marketing and distribution infrastructure, whether alone or in collaboration with others.

If we do not achieve one or more of these factors in a timely manner or at all, we could experience significant delays or an inability to successfully complete the development or commercialization of our product candidates, which would materially harm our business.

We may not be successful in our efforts to identify or develop potential product candidates.

The success of our business depends primarily upon our ability to identify, develop and commercialize our product candidates. Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- our research methodology may be unsuccessful in identifying potential product candidates; or
- potential product candidates may be shown to have harmful side effects or may have other characteristics that may make the products unsuitable for administration in patients in clinical trials, unlikely to receive marketing approval or unmarketable.

If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations. Research programs to identify new product candidates require substantial technical, financial and human resources. We may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful.

If future clinical trials of our product candidates fail to demonstrate safety and efficacy to the satisfaction of regulatory authorities or do not otherwise produce positive results, we may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining marketing approval from regulatory authorities for the sale of product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates in humans. Clinical trials are expensive, difficult to design and implement, can take many years to complete and are uncertain as to the outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies and early clinical trials may not be predictive of the success of later clinical trials, and preliminary results or planned interim analyses of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval for their products.

Events which may result in a delay or unsuccessful completion of clinical development include:

- delays in reaching an agreement with the FDA or other regulatory authorities on final trial design;
- delays in obtaining from the FDA, or comparable foreign regulatory authority, authorization to administer an investigational new drug product to humans through the submission or acceptance of an IND or similar foreign application;
- imposition of a clinical hold of our clinical trial operations or trial sites by the FDA or other regulatory authorities;
- delays in reaching agreement on acceptable terms with prospective contract research organizations (“CROs”) and clinical trial sites;
- our inability to adhere to clinical trial requirements directly or with third parties such as CROs;
- clinical trial site or CRO non-compliance with good clinical practices (“GCPs”), good laboratory practices, or other regulatory requirements;
- inability or failure of clinical trial sites to adhere to the clinical trial protocol;

- delays in obtaining required IRB approval at each clinical trial site, or an IRB reversing such approval resulting in the suspension or termination of a trial at that ;
- delays in recruiting and retaining suitable patients to participate in a trial particularly for a rare disease such as NS;
- delays in the testing, validation, manufacturing and delivery of the product candidates to the clinical sites;
- delays in having patients complete participation in a trial or return for post-treatment follow-up;
- delays caused by patients dropping out of a trial due to protocol procedures or requirements, product side effects or disease progression;
- clinical sites dropping out of a trial to the detriment of enrollment;
- time required to add new clinical sites; or
- delays by our contract manufacturers to produce and deliver sufficient supply of clinical trial materials.

Accordingly, we cannot be sure that we will submit INDs on the expected timelines and we cannot be certain the FDA or foreign regulatory agencies such as the EMA, will allow us to progress into clinical trials based on the submission of any IND.

If we are required to conduct additional clinical trials or other testing of any product candidates beyond those that are currently contemplated, are unable to successfully complete clinical trials of any such product candidates or other testing, or if the results of these trials or tests are not positive, are only modestly positive or if there are safety concerns, we may:

- be delayed in obtaining marketing approval for our future product candidates;
- not obtain marketing approval at all;
- obtain approval for indications or patient populations that are not as broad as originally intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be subject to additional post-marketing testing requirements; or
- have the product removed from the market after obtaining marketing approval.

Our product development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether any clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring products to market before we do, which would impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. Any inability to successfully complete preclinical and clinical development could result in additional costs to us or impair our ability to generate revenues from product sales.

Any of our product candidates may cause undesirable side effects or have other properties impacting safety that could delay or prevent their regulatory approval or limit the scope of any approved label or market acceptance.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other regulatory authorities. While we have not yet initiated clinical trials for any of our product candidates, it is possible that there will be side effects associated with their use. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Such side effects could also affect patient recruitment, the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may materially and adversely affect our business, financial condition, results of operations and prospects.

Further, clinical trials by their nature test product candidates in only small samples of the potential patient populations. With a limited number of patients and limited duration of exposure in such trials, rare and potentially severe side effects of our product candidates may not be uncovered until a significantly larger number of patients are exposed to the product candidate.

If any of our product candidates receive marketing approval, and causes serious, unexpected, or undesired side effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw, suspend, or limit their approval of the product or impose restrictions on its distribution in the form of a modified risk evaluation and mitigation strategy;
- regulatory authorities may require the addition of labeling statements, such as black box warnings or contraindications;
- we may be required to change the way the product is administered or conduct additional clinical trials or post-marketing surveillance;
- we could be sued and held liable for harm caused to patients; or
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing our future products and impair our ability to generate revenues from the commercialization of these products.

Even if we complete the necessary preclinical studies and clinical trials, we cannot predict whether or when we will obtain regulatory approval to commercialize a product candidate and we cannot, therefore, predict the timing of any revenue from a future product.

We cannot commercialize a product until the appropriate regulatory authorities, such as the FDA, have reviewed and approved the product candidate. The regulatory authorities may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval for many reasons including:

- regulatory authorities disagreeing with the design or implementation of our clinical trials;
- such authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- such authorities may not accept clinical data from trials which are conducted at clinical facilities or in countries where the standard of care is potentially different from that of the United States;
- unfavorable or unclear results from our clinical trials or results that may not meet the level of statistical significance required by the FDA or comparable foreign regulatory agencies for approval;
- serious and unexpected drug-related side effects experienced by participants in our clinical trials or by individuals using drugs similar to our product candidates;
- the population studied in the clinical trial may not be sufficiently broad or representative to assure safety in the full population for which we seek approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- such authorities may not agree that the data collected from clinical trials of our product candidates are acceptable or sufficient to support the submission of a New Drug Application ("NDA") or other submission or to obtain regulatory approval in the United States or elsewhere, and such authorities may impose requirements for additional preclinical studies or clinical trials;
- such authorities may disagree regarding the formulation, labeling and/or the specifications of our product candidates;

- such authorities may find deficiencies in the manufacturing processes, testing systems or facilities of our third-party manufacturers with which we contract for clinical and commercial supplies; or
- regulations of such authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Additional delays may result if an FDA advisory committee recommends restrictions on approval or recommends non-approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials and the review process.

Even if we obtain regulatory approval for a product candidate, we will still face extensive regulatory requirements and our products may face future development and regulatory challenges.

Even if we obtain regulatory approval in the United States, the FDA may still impose significant restrictions on the indicated uses or marketing of our product candidates, or impose ongoing requirements for potentially costly post-approval studies or post-market surveillance. The FDA may also require risk evaluation and mitigation strategies as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Additionally, the manufacturing processes, packaging, distribution, adverse event reporting, labeling, advertising, promotion, and recordkeeping for the product will be subject to extensive and ongoing FDA regulatory requirements, in addition to other potentially applicable federal and state laws. These requirements include monitoring and reporting of adverse events (“AEs”) and other post-marketing information and reports, registration, as well as continued compliance with current good manufacturing practice (“cGMP”) regulations. The holder of an approved NDA must also submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. If we or a regulatory agency discovers previously unknown problems with a product such as AEs of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions relative to that product or the manufacturing facility, including requiring recall or withdrawal of the product from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of any of our product candidates, a regulatory agency may:

- issue a warning or untitled letter asserting that we are in violation of the law;
- seek an injunction or impose civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending NDA or supplements to an NDA submitted by us;
- seize product or require a product recall; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize our future products, if approved, and generate revenues.

We may not be able to obtain or maintain orphan drug designation or exclusivity for our product candidates.

Regulatory authorities in some jurisdictions, including the United States, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals in the United States, or

if the disease or condition affects more than 200,000 individuals in the United States and there is no reasonable expectation that the cost of developing the drug for the type of disease or condition will be recovered from sales of the product in the United States.

Orphan drug designation entitles a party to financial incentives, such as tax advantages and user fee waivers. Additionally, if a product that has orphan designation subsequently receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan drug exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for seven years, except in certain circumstances, such as a showing of clinical superiority (i.e., another product is safer, more effective or makes a major contribution to patient care) over the product with orphan exclusivity or where the manufacturer is unable to assure sufficient product quantity. Competitors, however, may receive approval of different products for the same indication for which the orphan product has exclusivity, or obtain approval for the same product but for a different indication than that for which the orphan product has exclusivity.

We intend to apply for orphan drug designation in the United States for QRX003 for the treatment of NS. However, obtaining an orphan drug designation can be difficult, and we may not be successful in doing so. Even if we obtain orphan drug designation for a product candidate in specific indications, we may not be the first to obtain regulatory approval of the product candidate for the orphan-designated indication. In addition, exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for orphan designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Orphan drug designation does not ensure that we will receive marketing exclusivity in a particular market, and we cannot assure you that any future application for orphan drug designation in any other geography or with respect to any other future product candidate will be granted. Orphan drug designation neither shortens the development time or regulatory review time of a drug, nor gives the drug any advantage in the regulatory review or approval process.

We may pursue Rare Pediatric Disease designation for QRX003 for the treatment of NS or other of our product candidates. There is no assurance that we will obtain such designation. Moreover, a Rare Pediatric Disease designation by the FDA does not guarantee that the NDA for the product will qualify for a priority review voucher upon approval, and it does not lead to a faster development or regulatory review process, or increase the likelihood that any of our product candidates will receive marketing approval.

Under the Rare Pediatric Disease Priority Review Voucher program, upon the approval of a qualifying NDA for the treatment of a rare pediatric disease, the sponsor of such an application may be awarded a transferable rare pediatric disease priority review voucher that can be used to obtain priority review for a subsequent NDA or BLA. We intend to pursue Rare Pediatric Disease designation for QRX003 for the treatment of NS, but there is no assurance that we will receive such designation. On December 27, 2020, the Creating Hope Reauthorization Act extended the Rare Pediatric Disease Priority Review Voucher Program, and after September 30, 2024, the FDA may only award a voucher for an approved rare pediatric disease product application if the sponsor has rare pediatric disease designation for the drug, and that designation was granted by September 30, 2024. After September 30, 2026, the FDA may not award any rare pediatric disease priority review vouchers. However, there is no guarantee that any of our product candidates will be approved by that date, or at all, and, therefore, we may not be in a position to obtain a priority review voucher prior to expiration of the program, unless Congress further reauthorizes the program. Additionally, designation of a drug for a rare pediatric disease does not guarantee that an NDA will meet the other eligibility criteria for a rare pediatric disease priority review voucher at the time the application is approved. Finally, a Rare Pediatric Disease designation does not lead to faster development or regulatory review of the product, or increase the likelihood that it will receive marketing approval.

We may use our financial and human resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.

As a result of our limited financial and human resources, we will have to make strategic decisions as to which product candidates to pursue and may forego or delay pursuit of opportunities with other product candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on research and development programs and product candidates for specific indications may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product candidate through strategic alliance, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate, or we may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

We expect competition in the marketplace for our product candidates, should any of them receive regulatory approval.

If successfully developed and approved, our product candidates may face competition. We may not be able to compete successfully against organizations with competitive products, particularly large pharmaceutical companies. Many of our potential competitors have significantly greater financial, technical and human resources than us, and may be better equipped to develop, manufacture, market and distribute products. Many of these companies operate large, well-funded research, development and commercialization programs, have extensive experience in nonclinical and clinical studies, obtaining FDA and other regulatory approvals and manufacturing and marketing products, and have multiple products that have been approved or are in late-stage development. These advantages may enable them to receive approval from the FDA or any foreign regulatory agency before us.

Currently, there are no approved products to treat NS. However, to our knowledge, there are a number of potentially competing therapeutic products at various stages of development for the treatment of NS, including, but not limited to, candidates from LifeMax Laboratories, PellePharma, Sixera Pharmaceuticals Krystal Biotech, QID Pharmaceuticals, Azitra and Dermadis. Currently, to the best of our knowledge, there are no clinical trials in NS being conducted under an open IND.

We face significant competition from other biotechnology and pharmaceutical companies and our operating results will suffer if we fail to compete effectively.

The biotechnology and pharmaceutical industries are intensely competitive. We have competitors both in the United States and internationally, including major multinational pharmaceutical companies, biotechnology companies and universities and other research institutions. Our competitors may have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis, drug products that are more effective or less costly than any product candidate that we may develop.

All of our programs are either preclinical or about to begin clinical development and targeted toward indications for which there may be other product candidates in clinical development. We may face competition from other drugs currently approved or that may be approved in the future for the same therapeutic indications as our product candidates. Our ability to compete successfully will depend largely on our ability to leverage our experience in drug development to:

- develop therapeutics that are superior to other products in the market;
- attract qualified scientific, product development and commercial personnel;
- obtain patent and/or other proprietary protection for our product candidates;
- obtain required regulatory approvals; and
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new therapeutics.

The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize. We will not achieve our business plan if the acceptance of any of these products is inhibited by price competition or the reluctance of physicians to switch from existing drug products to our products, or if physicians switch to other new drug products or choose to reserve our future products for use in limited circumstances. The inability to compete with existing or subsequently introduced drug products would have a material adverse impact on our business, financial condition and prospects.

Established pharmaceutical companies may invest heavily to accelerate discovery and development of novel compounds or to in-license novel compounds that could make our product candidates less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or discovering, developing and commercializing product candidates before we do, which would have a material adverse impact on our business.

The commercial success of our product candidates will depend upon the acceptance of these product candidates by the medical community, including physicians, patients and healthcare payors.

The degree of market acceptance of any product candidates will depend on a number of factors, including:

- demonstration of clinical safety and efficacy compared to other products;
- the relative convenience, ease of administration and acceptance by physicians, patients and healthcare payors;
- the prevalence and severity of any AEs;
- limitations or warnings contained in the FDA-approved label for such products;
- availability of alternative treatments;
- pricing and cost-effectiveness;
- the effectiveness of our, or any of our collaborators', sales and marketing strategies;
- our ability to obtain hospital or payor formulary approval;
- our ability to obtain and maintain sufficient third-party coverage and adequate reimbursement; and
- the willingness of patients to pay out-of-pocket in the absence of third-party coverage.

If a product is approved but does not achieve an adequate level of acceptance by physicians, patients and healthcare payors, we may not generate sufficient revenues from such product and we may not become or remain profitable. Such increased competition may decrease any future potential revenue for future product candidates due to increasing pressure for lower pricing and higher discounts in the commercialization of our product.

If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, we may be unable to generate any revenues.

We currently do not have an organization for the sales, marketing and distribution of pharmaceutical products and the cost of establishing and maintaining such an organization may exceed the cost-effectiveness of doing so. In order to market any products that may be approved, we must build our sales, marketing, managerial and other non-technical capabilities or make arrangements with third parties to perform these services. With respect to future programs, we may rely completely on an alliance partner for sales and marketing. In addition, we may enter into strategic alliances with third parties to commercialize other product candidates, if approved, including in markets outside of the United States and Europe or for other large markets that are beyond our resources. Although we intend to establish a sales organization if we are able to obtain approval to market any product candidates in the United States, and Europe we will also consider the option to enter into strategic alliances for future product candidates in the United States and Europe if commercialization requirements exceed our available resources. This will reduce the revenue generated from the sales of these products.

Any future strategic alliance partners may not dedicate sufficient resources to the commercialization of our product candidates, if approved, or may otherwise fail in their commercialization due to factors beyond our control. If we are unable to establish effective alliances to enable the sale of our product candidates, if approved, to healthcare professionals and in geographical regions, including the United States and Europe, that will not be covered by our own marketing and sales force, or if our potential future strategic alliance partners do not successfully commercialize the product candidates that may be approved, our ability to generate revenues from product sales will be adversely affected.

If we are unable to establish adequate sales, marketing and distribution capabilities, whether independently or with third parties, we may not be able to generate sufficient product revenue and may not become profitable. We will be competing with many companies that currently have extensive and well-funded marketing and sales operations. Without an internal team or the support of a

third party to perform marketing and sales functions, we may be unable to compete successfully against these more established companies.

If we obtain approval to commercialize any approved products outside of the United States and Europe, a variety of risks associated with international operations could materially adversely affect our business.

If we obtain approval to commercialize any approved products outside of the United States and Europe, we expect that we will be subject to additional risks related to entering into international business relationships, including:

- different regulatory requirements for drug approvals in foreign countries;
- differing payor reimbursement regimes, governmental payors or patient self-pay systems and price controls;
- reduced protection for intellectual property rights;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires.

Coverage and adequate reimbursement may not be available for our product candidates, if approved, which could make it difficult for us to sell products profitably.

Market acceptance and sales of any product candidates that we develop will depend on coverage and reimbursement policies and may be affected by future healthcare reform measures. Government authorities and third-party payors, such as private health insurers, government payors and health maintenance organizations, decide which drugs they will pay for and establish reimbursement levels. We cannot be sure that coverage and adequate reimbursement will be available for any future product candidates. In the United States, the Centers for Medicare & Medicaid Services (“CMS”), an agency within the U.S. Department of Health and Human Services, decides whether and to what extent a new drug will be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for novel product candidates. Inadequate reimbursement amounts may reduce the demand for, or the price of, our future products. Further, one payor’s determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. If reimbursement is not available, or is available only at limited levels, we may not be able to successfully commercialize product candidates that we develop and that may be approved. Thus, even if we succeed in bringing a product to market, it may not be considered medically necessary or cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis.

There have been a number of legislative and regulatory proposals to change the healthcare system in the United States and in some foreign jurisdictions that could affect our ability to sell products profitably. These legislative and/or regulatory changes may negatively impact the reimbursement for drug products, following approval. The availability of numerous generic treatments may also substantially reduce the likelihood of reimbursement for our future products. We expect to experience pricing pressures in connection with the sale of any products that we develop, due to the trend toward managed healthcare, the increasing influence of health

maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, and prescription drugs in particular, has and is expected to continue to increase in the future. For instance, government and private payors who reimburse patients or healthcare providers are increasingly seeking greater upfront discounts, additional rebates and other concessions to reduce prices for pharmaceutical products. If we fail to successfully secure and maintain reimbursement coverage for our future products or are significantly delayed in doing so, we will have difficulty achieving market acceptance of our future products and our business will be harmed.

In addition, 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 EU provides options for its 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. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the U.S. and generally tend to be priced significantly lower.

Risks Related to Our Reliance on Third Parties

We rely on third parties to conduct some aspects of our compound formulation, research and preclinical studies, and those third parties may not perform satisfactorily, including failing to meet deadlines for the completion of such formulation, research or testing.

We do not expect to independently conduct all aspects of our drug development activities, compound formulation research or preclinical studies of product candidates. We currently rely and expect to continue to rely on third parties to conduct some or all aspects of our preclinical studies and formulation development.

Any of these third parties may terminate their engagements with us at any time. If we need to enter into alternative arrangements, it could delay our product development activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities.

If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our studies in accordance with regulatory requirements or our stated study plans and protocols, we will not be able to complete, or may be delayed in completing, the necessary preclinical studies to enable us to select viable product candidates for IND submissions and will not be able to, or may be delayed in our efforts to, successfully develop and commercialize such product candidates.

We rely on third-party manufacturers to produce the supply of our preclinical product, clinical product candidates and commercial supplies of any approved product candidates.

Reliance on third-party manufacturers entails risks, including risks that we would not be subject to if we manufactured the product candidates ourselves.

Third-party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside of the United States. If the FDA determines that our third-party manufacturers are not in compliance with FDA laws and regulations, including those governing cGMPs, the FDA may not approve an NDA until the deficiencies are corrected or we replace the manufacturer in our application with a manufacturer that is in compliance. Moreover, our failure, or the failure of our third-party manufacturers and suppliers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products. In addition, approved products and the facilities at which they are manufactured are required to maintain ongoing compliance with extensive FDA requirements and the requirements of other similar agencies, including ensuring that quality control and manufacturing procedures conform to cGMP requirements. As such, our third-party manufacturers are subject to continual review and periodic inspections to assess compliance with cGMPs. Furthermore, although we do not have day-to-day control over the operations of our third-party manufacturers, we are responsible for ensuring compliance with applicable laws and regulations, including cGMPs.

Other risks of reliance on third-party manufacturers include:

- the inability to meet any product specifications and quality requirements consistently;
- a delay or inability to procure or expand sufficient manufacturing capacity;
- manufacturing and product quality issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- the inability to negotiate manufacturing or supply agreements with third parties under commercially reasonable terms;
- termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- the reliance on a limited number of sources, and in some cases, single sources for raw materials, such that if we are unable to secure a sufficient supply of these product components, we will be unable to manufacture and sell future product candidates in a timely fashion, in sufficient quantities or under acceptable terms;
- the lack of qualified backup suppliers for any raw materials that are currently purchased from a single source supplier;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier;
- carrier disruptions or increased costs that are beyond our control; and
- the failure to deliver products under specified storage conditions and in a timely manner.

Any of these events could lead to clinical study delays or failure to obtain regulatory approval, or impact our ability to successfully commercialize future products, if approved. Some of these events could be the basis for FDA action, including injunction, recall, seizure or total or partial suspension of production.

We rely on limited sources of supply for the drug substance of product candidates and any disruption in the chain of supply may cause a delay in developing and commercializing these product candidates.

We have established manufacturing relationships with a limited number of suppliers to manufacture raw materials and the drug substance used to create our product candidates. The availability of such suppliers to manufacture raw materials and drug substance for our product candidates in sufficient quantities for evaluation in preclinical or clinical studies or, if our product candidates are approved, for commercial supply may be limited. Further, each supplier may require licenses to manufacture such components if such processes are not owned by the supplier or in the public domain. Our ability to obtain the necessary drug substance of product candidates could be adversely impacted by the Coronavirus pandemic. As part of any marketing approval, a manufacturer and its processes are required to be qualified by the FDA prior to commercialization. If supply from any vendor approved in the NDA is interrupted, there could be a significant disruption in commercial supply. An alternative vendor would need to be qualified through an NDA supplement which could result in further delay. The FDA or other regulatory agencies outside of the United States may also require additional studies if a new supplier is relied upon for commercial production. Switching vendors may involve substantial costs and is likely to result in a delay in our desired clinical and commercial timelines.

These factors could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our product candidates, cause us to incur higher costs and prevent us from commercializing our products successfully. Furthermore, if our suppliers fail to deliver the required commercial quantities of active pharmaceutical ingredients on a timely basis and at commercially reasonable prices, and we are unable to secure one or more replacement suppliers capable of production in a timely manner at a substantially equivalent cost, our clinical trials may be delayed or we could lose potential revenue.

Manufacturing issues may arise that could increase product and regulatory approval costs or delay commercialization.

Manufacturing of product candidates and conducting required stability testing, product, packaging, equipment and process-related issues may require refinement or resolution in order to proceed with any clinical trials and obtain regulatory approval for commercial marketing. We may identify significant impurities, which could result in increased scrutiny by the regulatory agencies, delays in clinical programs and regulatory approval, increases in our operating expenses, or failure to obtain or maintain approval for product candidates or any approved products.

We intend to rely on third parties to conduct, supervise and monitor our clinical trials, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials. While we will have agreements governing their activities, we have limited influence over their actual performance. We will control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our clinical trials are conducted in accordance with the applicable protocol, legal, regulatory and scientific standards and our reliance on the CROs will not relieve us of our regulatory responsibilities.

We and our CROs will be required to comply with the FDA's or other regulatory agency's GCPs, for conducting, recording and reporting the results of IND-enabling studies and clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. The FDA and non-U.S. regulatory agencies enforce these GCPs through periodic inspections of trial sponsors, CROs, principal investigators and clinical trial sites. If we or our CROs fail to comply with applicable GCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or applicable non-U.S. regulatory agency may require us to perform additional clinical trials before approving any marketing applications for the relevant jurisdiction. Upon inspection, the FDA or applicable non-U.S. regulatory agency may determine that our future clinical trials did not comply with GCPs. In addition, our future clinical trials will require a sufficiently large number of test subjects to evaluate the safety and effectiveness of a potential drug product. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of patients, we may be required to repeat such clinical trials, which would delay the regulatory approval process.

Our CROs will not be our employees, and we will not be able to control whether or not they devote sufficient time and resources to our future clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our competitive position. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements, or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for such products and any product candidates that we develop would be harmed, our costs could increase, and our ability to generate revenues could be delayed.

We intend to rely on other third parties to package, store and deliver drug products to the clinical trial sites for any clinical trials that we may conduct. Any performance failure on the part of these third parties could delay clinical development or marketing approval of our product candidates or commercialization of our products, if approved, producing additional losses and depriving us of potential product revenue.

Risks Related to Our Intellectual Property

If we are unable to obtain or protect intellectual property rights related to our future products and product candidates, we may not be able to compete effectively in our markets.

Our success depends in part on our ability to obtain and maintain patents and other forms of intellectual property rights, including in-licenses of intellectual property rights of others, for our product candidates, methods used to develop and manufacture our product candidates and methods for treating patients using our product candidates, as well as our ability to preserve our trade secrets, to prevent third parties from infringing upon our proprietary rights and to operate without infringing upon the proprietary rights of others. The strength of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and can be uncertain. The patent applications that we own or in-license may fail to result in patents with claims that cover the products in the United States or in other countries. There is no assurance that all of the potentially relevant prior art relating to our patents and patent

applications has been found; such prior art can invalidate a patent or prevent a patent from issuing based on a pending patent application. Even if patents do successfully issue, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed or invalidated. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims.

If the patent applications we hold or have in-licensed with respect to our programs or product candidates fail to issue or if their breadth or strength of protection is threatened, it could dissuade companies from collaborating with us to develop product candidates, and threaten our ability to commercialize, future products. We cannot offer any assurances about which, if any, patents will issue or whether any issued patents will be found invalid and unenforceable or will be threatened by third parties. A patent may be challenged through one or more of several administrative proceedings including post-grant challenges, re-examination or opposition before the USPTO or foreign patent offices. Any successful challenge of patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of any product candidates that we may develop.

Since patent applications in the United States and most other countries are confidential for a period of time after filing, and some remain so until issued, we cannot be certain that we were the first to file any patent application related to a product candidate. Furthermore, in certain situations, if we and one or more third parties have filed patent applications in the United States and claiming the same subject matter, an administrative proceeding, known as an interference, can be initiated to determine which applicant is entitled to the patent on that subject matter. Such an interference proceeding provoked by third parties or brought by us may be necessary to determine the priority of inventions with respect to our patents or patent applications, or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to require us to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license at all, or on commercially reasonable terms. Our defense of a patent or patent application in such a proceeding may not be successful and, even if successful, may result in substantial costs and distract our management and other employees.

In addition, patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after it is filed. Various extensions may be available however the life of a patent, and the protection it affords is limited. Once the patent life has expired for a product, we may be open to competition from generic medications. Further, if we encounter delays in regulatory approvals, the period of time during which we could market a product candidate under patent protection could be reduced.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, including processes for which patents are difficult to enforce and any other elements of our drug discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although each of our employees agrees to assign their inventions to us through an employee inventions agreement, and all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology are required to enter into confidentiality agreements, we cannot provide any assurances that all such agreements have been duly executed, that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all.

Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the non-patented intellectual property related to our technologies to third parties, and there is no guarantee that we will have any such enforceable trade secret protection, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

Third-party claims of intellectual property infringement may prevent or delay our development and commercialization efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are pursuing development

candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in patents that our product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of any of our product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block our ability to commercialize such product candidate unless we obtained a license under the applicable patents, or until such patents expire. Similarly, if any third-party patents were held by a court of competent jurisdiction to cover aspects of our formulations, processes for manufacture or methods of use, including combination therapy, the holders of any such patents may be able to block our ability to develop and commercialize the applicable product candidate unless we obtained a license or until such patent expires. In either case, such a license may not be available on commercially reasonable terms or at all.

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

If we fail to obtain licenses or comply with our obligations in these agreements under which we license intellectual property rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

We are a party to intellectual property license agreements that are important to our business and expect to enter into additional license agreements in the future. Our existing license agreements impose, and we expect that future license agreements will impose, various obligations on us.

We may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our future products, resulting in either an injunction prohibiting our sales, or, with respect to our sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensees, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensees. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours or of our licensees is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing.

Our defense in a lawsuit may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensees, misappropriation of our intellectual property rights, particularly in countries where the laws may not protect those rights as fully as in the United States.

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

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

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

Other Risks Related to Our Business Operations and Industry

Our future success depends on our ability to attract and retain key executives and to attract, retain and motivate qualified personnel.

We are highly dependent on principal members of our executive team, and any reduction or loss of their services may adversely impact the achievement of our objectives. While we have entered into employment agreements with each of our executive officers, any of them could leave our employment at any time. Recruiting and retaining other qualified employees for our business, including scientific and technical personnel, will also be critical to our success. There is currently a shortage of skilled executives in our industry, which is likely to continue. As a result, competition for skilled personnel is intense and the turnover rate can be high. We may not be able to attract and retain personnel on acceptable terms given the competition among numerous pharmaceutical companies for individuals with similar skill sets. In addition, failure to succeed in preclinical studies and clinical trials may make it more challenging to recruit and retain qualified personnel. The inability to recruit any executive or key employee or the loss of the services of any executive or key employee might impede the progress of our research, development and commercialization objectives.

We may need to expand our organization and may experience difficulties in managing our growth, which could disrupt our operations.

In the future we may expand our employee base to increase our managerial, scientific, operational, commercial, financial and other resources and we may hire more consultants and contractors. Future growth would impose significant additional responsibilities on our management, including the need to identify, recruit, maintain, motivate and integrate additional employees, consultants and contractors. Also, our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure or give rise to operational mistakes, loss of business opportunities, loss of employees or reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. Moreover, if our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional or nonintentional failures to comply with the regulations of the FDA and non-U.S. regulators, to provide accurate information to the FDA and non-U.S. regulators, to comply with healthcare fraud and abuse laws and regulations in the United States and abroad, to report financial information or data accurately or to 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 may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements.

Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and cause serious harm to our reputation. We have adopted a code of conduct, but it is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or

lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, fines, possible exclusion from Medicare, Medicaid and other government healthcare programs, additional reporting requirements and/or oversight, particularly if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance, disgorgement, imprisonment, and contractual damages. Even if we are ultimately successful in defending against any such action, we could be required to divert financial and managerial resources in doing so and adverse publicity could result, all of which could harm our business.

Future relationships with customers and third-party payors as well as certain of our business operations may be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws and health information privacy and security laws. If we are unable to comply, or have not fully complied, with such laws, we could face criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

If we obtain FDA approval for any of our product candidates and begin commercializing those products in the United States, our operations may be directly, or indirectly through our customers, further subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act. These laws may impact, among other things, our proposed sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by the federal government and by the U.S. states and foreign jurisdictions in which we conduct our business. The healthcare laws and regulations that may affect our ability to operate include:

- The 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, to induce, or in return for, either the referral of an individual, or the purchase or recommendation of an item or service for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. Remuneration has been interpreted broadly to include anything of value. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and those activities may be subject to scrutiny or penalty if they do not qualify for an exemption or safe harbor. A conviction for violation of the Anti-Kickback Statute requires mandatory exclusion from participation in federal healthcare programs. This statute has been applied to arrangements between pharmaceutical manufacturers and those in a position to purchase products or refer others, including prescribers, patients, purchasers and formulary managers. In addition, the Affordable Care Act amended the Social Security Act to provide that the U.S. government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act penalties for which are described below.
- Federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act (“FCA”), which imposes criminal or civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, claims for payment to the federal government, including Medicare or Medicaid, that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties per false claim or statement.
- The civil monetary penalties statute, which imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.
- The federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), which imposes civil and criminal penalties for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (“HITECH”), and its implementing regulations, which imposes certain requirements on certain types of individuals and entities, such as

healthcare providers, health plans and healthcare clearing houses, known as “covered entities,” as well as their “business associates,” independent contractors or agents of covered entities that receive or obtain individually identifiable health information in connection with providing a service on behalf of a covered entity, relating to the privacy, security and transmission of individually identifiable health information.

- The federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children’s Health Insurance Program, with specific exceptions, to report annually to CMS, information related to payments or other transfers of value made to physicians, physician assistants, certain types of advance practice nurses and teaching hospitals, and further requires applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information for all covered payments, transfers of value and ownership or investment interests may result in civil monetary penalties.; and
- Many state and foreign law equivalents of each of the above federal laws, such as: anti-kickback and false claims laws which may apply to items or services reimbursed by any third party payor, including commercial insurers; state laws that require pharmaceutical companies to comply with the pharmaceutical industry’s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government; state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; state and local laws that require the registration of pharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts.

In addition, the European Union (“EU”) has established its own data security and privacy legal framework, including but not limited to Directive 95/46/EC (the “Data Protection Directive”). The European General Data Protection Regulation (“GDPR”) contains new provisions specifically directed at the processing of health information, higher sanctions and extra-territoriality measures intended to bring non-EU companies under the regulation. We anticipate that over time we may expand our business operations to include additional operations in the EU, including potentially conducting preclinical and clinical trials. With such expansion, we would be subject to increased governmental regulation in the EU countries in which we might operate, including regulation due to the GDPR.

If our operations are found to be in violation of any of the laws described above or any other governmental regulations or laws that apply to us, we may be subject to penalties, including, without limitation, civil, criminal and administrative penalties, damages, fines, possible exclusion from Medicare, Medicaid and other government healthcare programs, additional reporting requirements and/or oversight, particularly if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance, disgorgement, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Recent and future healthcare legislation may further impact our business operations.

The United States and some foreign jurisdictions are considering or have enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the “ACA”) was enacted, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. The ACA included a number of provisions that may reduce the profitability of drug products, including revising the rebate methodology for covered outpatient drugs under the Medicaid Drug Rebate Program, extending Medicaid rebates to individuals enrolled in Medicaid managed care plans, and requiring drug manufacturers to pay an annual fee based on their market share of prior year total sales of branded programs to certain federal health care programs.

Since its passage, there have been judicial and Congressional challenges to certain aspects of the ACA, as well as recent efforts to repeal or replace certain aspects of the ACA. Former President Trump signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance

mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the ACA have been signed into law. On December 22, 2017, former President Trump signed into law H.R. 1, “An Act to provide for reconciliation pursuant to titles II and V of the concurrent resolution on the budget for fiscal year 2018,” informally titled the Tax Cuts and Jobs Act, which significantly revises the U.S. Internal Revenue Code of 1986, as amended (the “Code”). The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the “individual mandate.” Additionally, on December 23, 2019, former President Trump signed a spending bill that repealed the implementation of certain ACA-mandated fees, including the so-called “Cadillac” tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018 (the “BBA”), among other things, amended the ACA, effective January 1, 2019, to increase from 50 percent to 70 percent the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and to close the coverage gap in most Medicare drug plans, commonly referred to as the “donut hole.” On June 17, 2021, the United States Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the “individual mandate” was repealed by Congress. Thus, the ACA will remain in effect in its current form. It is possible that the ACA will be subject to judicial or Congressional challenges in the future. It is uncertain how any such challenges and the healthcare measures of the Biden administration will impact the ACA and our business.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 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 \$1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation’s automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of 2% per fiscal year, which started in April 2013, and, due to subsequent legislative amendments, will remain in effect through 2030 with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 due to the COVID 19 pandemic, unless additional Congressional action is taken. The Medicare reductions phase back in starting with a 1% reduction in effect from April 1, 2022 to June 30, 2022 before increasing to the full 2% reduction. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, also reduced Medicare payments to several categories of healthcare providers

Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Biden administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, to encourage importation from other countries and bulk purchasing.

We expect that healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors.

We cannot predict what healthcare reform initiatives may be adopted in the future. Further federal, state and foreign legislative and regulatory developments are likely, and we expect ongoing initiatives to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

We face potential product liability, and, if successful claims are brought against us, we may incur substantial liability and costs.

The use of our product candidates in future clinical trials and the sale of any products for which we obtain marketing approval exposes us to the risk of product liability claims. Product liability claims might be brought against us by consumers, healthcare providers, pharmaceutical companies or others selling or otherwise coming into contact with our products. For example, unanticipated adverse effects could result from the use of our future products or product candidates which may result in a potential product liability

claim. If we cannot successfully defend against product liability claims, we could incur substantial liability and costs. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- impairment of our business reputation;
- withdrawal of clinical trial participants;
- costs due to related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants;
- the inability to commercialize our product candidates; and
- decreased demand for our product candidates, if approved for commercial sale.

We plan to obtain product liability insurance relating to the use of our therapeutics in future clinical trials. However, such insurance coverage may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive and in the future we may not be able to obtain or maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. If and when we obtain marketing approval for product candidates, we intend to expand our insurance coverage to include the sale of commercial products; however, we may be unable to obtain product liability insurance on commercially reasonable terms or in adequate amounts. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated adverse effects. A successful product liability claim or series of claims brought against us could cause our share price to decline and, if judgments exceed our insurance coverage, could adversely affect our results of operations and business.

Cyber security risks and the failure to maintain the confidentiality, integrity, and availability of our computer hardware, software, and Internet applications and related tools and functions could result in damage to our reputation and/or subject us to costs, fines or lawsuits.

Our business depends on the continuous, effective, reliable, and secure operation of external computer hardware, software, networks, Internet servers, and related infrastructure. To the extent that hardware or software malfunctions of these external systems could cause our business to suffer. The integrity and protection of our employee and company data is critical to our business and employees have a high expectation that we will adequately protect their personal information. The regulatory environment governing information, security and privacy laws is increasingly demanding and continues to evolve. Maintaining compliance with applicable security and privacy regulations may increase our operating costs. Although the external computer and communications systems we utilize is protected through physical and software safeguards, it is still vulnerable to fire, storm, flood, power loss, earthquakes, telecommunications failures, physical or software break-ins, software viruses, and similar events. These events could lead to the unauthorized access, disclosure and use of non-public information. The techniques used by criminal elements to attack computer systems are sophisticated, change frequently and may originate from less regulated and remote areas of the world. As a result, because of our dependence on external providers, we may not be able to address these threats proactively or implement adequate preventative measures. If our computer systems are compromised, we could be subject to fines, damages, litigation and enforcement actions, and we could lose trade secrets, the occurrence of which could harm our business. In addition, any sustained disruption in internet access provided by other companies could harm our business.

The coronavirus pandemic has caused interruptions or delays of our business plan and may have a significant adverse effect on our business.

In December 2019, a strain of coronavirus, COVID-19, was reported to have surfaced in Wuhan, China, and on March 12, 2020, the World Health Organization declared COVID-19 to be a pandemic. In an effort to contain and mitigate the spread of COVID-19, many countries, including the United States, Canada and China, have imposed unprecedented restrictions on travel, quarantines, and other public health safety measures. The extent to which the pandemic may impact our business will depend on future developments, which are highly uncertain and cannot be predicted, but the development of clinical supply materials could be delayed and enrollment of patients in our pending clinical trials may be delayed or suspended, as hospitals and clinics in areas where we are conducting trials shift resources to cope with the COVID-19 pandemic and may limit access or close clinical facilities due to the COVID-19 pandemic.

Additionally, if trial participants are unable to travel to clinical study sites as a result of quarantines or other restrictions resulting from the COVID-19 pandemic, we may experience higher drop-out rates or delays in clinical studies once commenced.

Government-imposed quarantines and restrictions may also require us to temporarily terminate our clinical sites once commenced. We cannot predict the ultimate impact of the COVID-19 pandemic as consequences of such an event are highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical studies or as a whole; however, the COVID-19 pandemic may materially disrupt or delay our business operations, further divert the attention and efforts of the medical community to coping with COVID-19, disrupt the marketplace in which we operate, and/or have a material adverse effect on our operations.

Moreover, the various precautionary measures taken by many governmental authorities around the world in order to limit the spread of the coronavirus has had and may continue to have an adverse effect on the global markets and global economy generally, including on the availability and pricing of employees, resources, materials, manufacturing and delivery efforts and other aspects of the global economy. There have been business closures and a substantial reduction in economic activity in countries that have been significantly affected by COVID-19. Significant uncertainty remains as to the potential impact of the COVID-19 pandemic on the global economy as a whole. It is currently not possible to predict how long the pandemic will last or the time that it will take for economic activity to return to prior levels. The COVID-19 pandemic could materially disrupt our business and operations, interrupt our sources of supply, hamper our ability to raise additional funds or sell securities, continue to slow down the overall economy or curtail consumer spending.

Business interruptions could delay us in the process of developing our future products.

We are vulnerable to natural disasters such as earthquakes and wild fires, as well as other events that could disrupt our operations. We do not carry insurance for earthquakes or other natural disasters and we may not carry sufficient business interruption insurance to compensate us for losses that may occur. Any losses or damages we incur could have a material adverse effect on our business operations.

Risks Related to Us Being an Israeli Company

Shareholders may have difficulties enforcing a U.S. judgment, including judgments based upon the civil liability provisions of the U.S. federal securities laws, against us or our executive officers and directors, or asserting U.S. securities laws claims in Israel.

Service of process upon us in Israel or upon our non-U.S. resident directors and officers may be difficult to obtain within the United States and it may be difficult to enforce judgments obtained in the United States against our non-U.S. directors and executive officers. In addition, we have been informed by our legal counsel in Israel that it may be difficult to assert claims under U.S. securities laws in original actions instituted in Israel or obtain a judgment based on the civil liability provisions of U.S. federal securities laws. Israeli courts may refuse to hear a claim based on a violation of U.S. securities laws against us or our officers and directors because Israel may not be the most appropriate forum to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel addressing the matters described above. Israeli courts might not enforce judgments rendered outside Israel, which may make it difficult to collect on judgments rendered against us or our officers and directors in Israel.

Moreover, an Israeli court will not enforce a foreign judgment if it was given in a state whose laws do not provide for the enforcement of judgments of Israeli courts (subject to exceptional cases) or if its enforcement is likely to prejudice the sovereignty or security of the State of Israel or due to, among other reasons, absence of due process, or the existence of a judgment which is at variance with another judgment that was given in the same matter if a suit in the same matter between the same parties was pending before a court or tribunal in Israel.

Your rights and responsibilities as our shareholder will be governed by Israeli law, which may differ in some respects from the rights and responsibilities of shareholders of U.S. corporations.

Since we are incorporated under Israeli law, the rights and responsibilities of our shareholders are governed by our articles of association and Israeli law. These rights and responsibilities differ in some respects from the rights and responsibilities of shareholders of U.S.-based corporations. In particular, a shareholder of an Israeli company, such as us, has a duty to act in good faith and in a

customary manner in exercising its rights and performing its obligations towards us and other shareholders and to refrain from abusing its power in us, including, among other things, in voting at the general meeting of shareholders on certain matters, such as an amendment to our articles of association, an increase of our authorized share capital, a merger, and approval of related party transactions that require shareholder approval. A shareholder also has a general duty to refrain from taking advantage of other shareholders. In addition, a controlling shareholder (as defined below), or any shareholder who knows that it possesses the power to determine the outcome of a shareholders' vote, or who has the power to appoint or prevent the appointment of one of our office holders (as defined below), or who holds any other power in our regard, has a duty to act in fairness towards us. However, Israeli law does not define the substance of this duty of fairness. There is little Israeli case law addressing the provisions described above, and these provisions may be interpreted to impose additional obligations and liabilities on our shareholders that are not typically imposed on shareholders of U.S. corporations.

Provisions of Israeli law may delay, prevent or otherwise impede a merger with, or an acquisition of, our company, which could prevent a change of control, even when the terms of such a transaction are favorable to us and our shareholders.

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares above specified thresholds, requires special approvals for transactions involving directors, officers or significant shareholders, and regulates other matters that may be relevant to these types of transactions. For example, a merger may not be consummated unless at least 50 days have passed from the date that a merger proposal was filed by each merging company with the Israel Registrar of Companies, and at least 30 days from the date that the shareholders of both merging companies approved the merger. In addition, the holder of a majority of each class of securities of the target company must approve a merger. Moreover, a full tender offer can only be completed if the acquirer receives at least 95% of the issued share capital (provided that a majority of the offerees that do not have a personal interest in such tender offer shall have approved the tender offer, except that if the total votes to reject the tender offer represent less than 2% of the company's issued and outstanding share capital, in the aggregate, approval by a majority of the offerees that do not have a personal interest in such tender offer is not required to complete the tender offer), and the shareholders, including those who indicated their acceptance of the tender offer, may, at any time within six months following the completion of the tender offer, petition the court to alter the consideration for the acquisition (unless the acquirer stipulated in the tender offer that a shareholder that accepts the offer may not seek appraisal rights).

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to those of our shareholders whose country of residence does not have a tax treaty with Israel exempting such shareholders from Israeli tax. For example, Israeli tax law does not recognize tax-free share exchanges to the same extent as U.S. tax law. With respect to mergers, Israeli tax law allows for tax deferral in certain circumstances, but makes the deferral contingent on the fulfillment of numerous conditions, including a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are restricted. Moreover, with respect to certain share swap transactions, the tax deferral is limited in time, and when such time expires, the tax becomes payable even if no actual disposition of the shares has occurred. Additional tax considerations or exemptions from the foregoing may apply to certain non-Israeli tax resident shareholders; please refer to the section headed "Taxation" below.

These and other similar provisions could delay, prevent or impede an acquisition of us or our merger with another company, even if such an acquisition or merger would be beneficial to us or to our shareholders.

Risks Related to Ownership of Our ADSs and Ordinary Shares

We may not be able to raise additional funds unless we increase our authorized share capital.

As of April 12, 2022, we had 50,000,000,000 authorized ordinary shares, out of which 3,354,653,999 ordinary shares were issued and outstanding (which excludes 2,641,693 shares held in treasury), and 8,825,290,117 ordinary shares reserved for purposes of our Amended and Restated Equity Incentive Plan described below and for the exercise of our options and warrants. Any equity financing necessary in order to fund our operations may require us to increase our authorized share capital prior to initiating any such financing transaction. Increasing our share capital is subject to the approval of our shareholders. In the event we fail to obtain the approval of our shareholders to such increase in our authorized share capital, our ability to raise sufficient funds, if at all, might be adversely effected.

We do not know whether a market for our securities will be sustained or what the trading price of our securities will be and as a result it may be difficult for you to sell our securities held by you.

Although our ADSs trade on Nasdaq, an active trading market for the ADSs may not be sustained. It may be difficult for you to sell your ADSs without depressing the market price for the ADSs. As a result of these and other factors, you may not be able to sell your ADSs. Further, an inactive market may also impair our ability to raise capital by issuing securities and may impair our ability to enter into strategic partnerships or acquire companies or products by using our equity as consideration.

The requirements of being a publicly traded company may strain our resources and divert management's attention.

As a publicly traded company, we have incurred, and will continue to incur, significant legal, accounting and other expenses that we did not incur as a private company. In addition, the Sarbanes-Oxley Act and the Dodd-Frank Wall Street Reform and Consumer Protection Act (the "Dodd-Frank Act"), as well as rules subsequently implemented by the SEC and Nasdaq under such acts have imposed various requirements on public companies. Shareholder activism, the current political environment and the current high level of government regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. Our management will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain our current levels of such coverage.

Failure to maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business, results of operation or financial condition. In addition, current and potential shareholders could lose confidence in our financial reporting, which could have a material adverse effect on the price of the ADSs.

Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. We are required to document and test our internal control procedures in order to satisfy the requirements of Section 404 of the Sarbanes-Oxley Act, which requires annual management assessments of the effectiveness of our internal control over financial reporting. In addition, if we fail to maintain the adequacy of our internal controls, as such standards are modified, supplemented or amended from time to time, we may not be able to ensure that we can conclude on an ongoing basis that we have effective internal controls over financial reporting in accordance with Section 404. Disclosing deficiencies or weaknesses in our internal controls, failing to remediate these deficiencies or weaknesses in a timely fashion or failing to achieve and maintain an effective internal control environment may cause investors to lose confidence in our reported financial information, which could have a material adverse effect on the price of the ADSs. If we cannot provide reliable financial reports or prevent fraud, our operating results could be harmed.

We are a "foreign private issuer" and have disclosure obligations that are different from those of U.S. domestic reporting companies.

We are a foreign private issuer and are not subject to the same requirements that are imposed upon U.S. domestic issuers by the Securities and Exchange Commission (the "SEC"). Under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), we will be subject to reporting obligations that, in certain respects, are less detailed and less frequent than those of U.S. domestic reporting companies. For example, we will not be required to issue quarterly reports or proxy statements that comply with the requirements applicable to U.S. domestic reporting companies. Furthermore, although as an Israeli public company listed overseas we will be required to disclose the compensation of our five most highly compensated officers on an individual basis, this disclosure may not be as extensive as that required of U.S. domestic reporting companies. We will also have four months after the end of each fiscal year to file our annual reports with the SEC and will not be required to file current reports as frequently or promptly as U.S. domestic reporting companies. Furthermore, our officers, directors and principal shareholders will be exempt from the requirements to report transactions and short-swing profit recovery required by Section 16 of the Exchange Act. Also, as a "foreign private issuer," we are not subject to the requirements of Regulation FD (Fair Disclosure) promulgated under the Exchange Act. These exemptions and leniencies will reduce the frequency and scope of information and protections available to you in comparison to those applicable to a shareholder of a U.S. domestic reporting companies.

As a “foreign private issuer,” we are permitted, and intend, to follow certain home country corporate governance practices instead of otherwise applicable SEC and Nasdaq requirements, which may result in less protection than is accorded to investors under rules applicable to domestic U.S. issuers.

As a “foreign private issuer,” we are permitted to follow certain home country corporate governance practices instead of those otherwise required under the listing rules of Nasdaq for domestic U.S. issuers. For instance, we follow home country practice in Israel with regard to, among other things, director nomination procedures, compensation committee matters and approval of interested party transactions. In addition, we will follow our home country law instead of the listing rules of Nasdaq that require that we obtain shareholder approval for certain dilutive events, such as an issuance that will result in a change of control of us, certain transactions other than a public offering involving issuances of a 20% or greater interest in the company, and certain acquisitions of the stock or assets of another company. There are however, certain, home country practices that, in accordance with Israeli law, we have opted not to follow – in particular those rules relating to the appointment of “External Directors” (see “Management—Board Practices—External Directors”). We may in the future elect to follow home country corporate governance practices in Israel with regard to other matters. Following our home country corporate governance practices as opposed to the requirements that would otherwise apply to a U.S. company listed on Nasdaq may provide less protection to you than what is accorded to investors under the listing rules of Nasdaq applicable to domestic U.S. issuers.

We may be unable to comply with the applicable continued listing requirements of Nasdaq.

ADSs representing our ordinary shares are currently listed on Nasdaq. In order to maintain this listing, we must satisfy minimum financial and other continued listing requirements and standards, including a minimum closing bid price requirement for our ADSs of \$1.00 per ADS. There can be no assurance that we will be able to comply with the applicable listing standards. For example, if we were to fail to meet the minimum bid price requirement for 30 consecutive business days, we could become subject to delisting. Although Nasdaq may provide us with a compliance period in which to regain compliance with the minimum bid price requirement, we cannot assure you that we would be able to regain compliance within the period provided by Nasdaq. In order to regain compliance with such requirement, the closing bid price of our ADSs would need to meet or exceed \$1.00 per share for at least 10 consecutive business days during the compliance period. If we were not able to regain compliance within the allotted compliance period for this requirement or any other applicable listing standard, including any extensions that may be granted by Nasdaq, our ADSs would be subject to delisting. In the event that our ADSs are delisted from Nasdaq and are not eligible for quotation or listing on another market or exchange, trading of our ADSs could be conducted only in the over-the-counter market established for unlisted securities such as OTC Markets. In such event, it could become more difficult to dispose of, or obtain accurate price quotations for our ADSs, which could cause the price of our ADSs to decline further.

If securities or industry analysts do not publish or cease publishing research or reports about us, our business or our market, or if they adversely change their recommendations or publish negative reports regarding our business or our traded securities, our securities price and trading volume could be negatively impacted.

The trading market for our securities will be influenced by the research and reports that industry or securities analysts may publish about us, our business, our market or our competitors. We do not have any control over these analysts, and we cannot provide any assurance that analysts will cover us or provide favorable coverage. If any of the analysts who may cover us adversely change their recommendation regarding the ADSs, or provide more favorable relative recommendations about our competitors, the price of the ADSs would likely decline. If any analyst who may cover us were to cease coverage of our company or fail to regularly publish reports on us, we could lose visibility in the financial markets, which in turn could negatively impact the price of the ADSs or their trading volume.

The market price for our ADSs may be volatile.

The market price for our ADSs is likely to be highly volatile and subject to wide fluctuations in response to numerous factors including the following:

- our failure to obtain the approvals necessary to commence clinical trials;
- results of clinical and preclinical studies;
- announcements of regulatory approval or the failure to obtain it, or changes or delays in the regulatory review process;

- announcements of new products or product enhancements by us or others;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws, regulations or decisions applicable to our product candidates or patents;
- any adverse changes to our relationship with manufacturers or suppliers;
- announcements concerning our competitors or healthcare industries in general;
- achievement of expected product sales and profitability or our failure to meet expectations;
- our commencement of or results of, or involvement in, litigation, including, but not limited to, any product liability actions or intellectual property infringement actions;
- any major changes in our board of directors, management or other key personnel;
- announcements by us of significant strategic partnerships, out-licensing, in-licensing, joint ventures, acquisitions or capital commitments;
- expiration or terminations of licenses, research contracts or other collaboration agreements;
- public concern as to the safety of our products that we, our licensees or others develop;
- success of research and development projects;
- developments concerning intellectual property rights or regulatory approvals;
- variations in our and our competitors' results of operations;
- changes in earnings estimates or recommendations by securities analysts, if our ordinary shares or the ADSs are covered by analysts;
- future issuances of ordinary shares, ADSs or other securities;
- general market conditions and other factors, including factors unrelated to our operating performance, such as natural disasters and political and economic instability, including wars, terrorism, political unrest, results of certain elections and votes, emergence of a pandemic, or other widespread health emergencies (or concerns over the possibility of such an emergency, including for example, the COVID-19 pandemic), boycotts, adoption or expansion of government trade restrictions, and other business restrictions; and
- the other factors described in this "Risk Factors" section.

These factors and any corresponding price fluctuations may materially and adversely affect the market price of the ADSs, which would result in substantial losses by our investors. In addition, the securities market has from time to time experienced significant price and volume fluctuations that are not related to the operating performance of any particular company. These market fluctuations may also have a material adverse effect on the market price of the ADSs.

We may be at risk of securities class action litigation.

We may be at risk of securities class action litigation. This risk is especially relevant for us due to our dependence on positive clinical trial outcomes and regulatory approvals of our product candidates. In the past, medical, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with such events such as clinical trials and

product approvals. If we face such litigation, it could result in substantial costs, divert management's attention and resources, and have a material adverse effect on our business, operating results and prospects.

Substantial future sales or perceived potential sales of our ordinary shares or ADSs in the public market could cause the price of our ADSs decline.

Substantial sales of our ADSs on Nasdaq may cause the market price of our ADSs to decline. Sales by us or our security holders of substantial amounts of our ADSs or the perception that these sales may occur in the future, could cause a reduction in the market price of our shares ADSs. The issuance of any additional ordinary shares or any additional ADSs, or any securities that are exercisable for or convertible into our ordinary shares or ADSs, may have an adverse effect on the market price of our ADSs and will have a dilutive effect on our existing shareholders and holders of ADSs.

Your percentage ownership in us may be diluted by future issuances of share capital, which could reduce your influence over matters on which shareholders vote.

We expect that significant additional capital will be needed in the future to continue our planned operations. To the extent we raise additional capital by issuing equity securities, our shareholders may experience substantial dilution. Pursuant to our equity incentive plan, our management may grant options to our employees, directors and consultants. We may sell ordinary shares represented by ADSs, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time, any of which may result in material dilution to our existing shareholders. New investors could also be issued securities with rights superior to those of our existing shareholders.

We have not paid, and do not intend to pay, dividends on our ordinary shares and, therefore, unless our traded securities appreciate in value, our investors may not benefit from holding our securities.

We have not paid any cash dividends on our ordinary shares, and we do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future. Moreover, the Companies Law imposes certain restrictions on our ability to declare and pay dividends. As a result, investors in our ADSs or ordinary shares will not be able to benefit from owning these securities unless their market price becomes greater than the price paid by such investors and they are able to sell such securities. We cannot assure you that you will ever be able to resell our securities at a price in excess of the price paid.

If we pay dividends or other distributions, an ADS holder may not receive the same distributions or dividends as those we make to the holders of our ordinary shares, and, in some limited circumstances, you may not receive dividends or other distributions on our ordinary shares and you may not receive any value for them, if it is illegal or impractical to make them available to you.

The depositary for the ADSs has agreed to pay to you the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities underlying the ADSs, after deducting its fees and expenses. You will receive these distributions, if any, in proportion to the number of ordinary shares your ADSs represent. However, the depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any holders of ADSs. For example, it would be unlawful to make a distribution to a holder of ADSs if it consists of securities that require registration under the Securities Act, but that are not properly registered or distributed under an applicable exemption from registration. In these cases, the depositary may determine not to distribute such property and hold it as "deposited securities" or may seek to effect a substitute dividend or distribution, including net cash proceeds from the sale of the dividends that the depositary deems an equitable and practicable substitute. We have no obligation to register under U.S. securities laws any ADSs, ordinary shares, rights or other securities received through such distributions. We also have no obligation to take any other action to permit the distribution of ADSs, ordinary shares, rights or anything else to holders of ADSs. In addition, the depositary may withhold from such dividends or distributions its fees and an amount on account of taxes or other governmental charges to the extent the depositary believes it is required to make such withholding. This means that you may not receive the same distributions or dividends as those we make to the holders of our ordinary shares, and, in some limited circumstances, you may not receive any value for such distributions or dividends if it is illegal or impractical for us to make them available to you. These restrictions may cause a material decline in the value of the ADSs.

Holders of ADSs must act through the depositary to exercise their rights.

Holders of the ADSs do not have the same rights as our shareholders and may only exercise the voting rights with respect to the underlying ordinary shares in accordance with the provisions of the deposit agreement for the ADSs. Under Israeli law and our articles of association, the minimum notice period required to convene a shareholders meeting is not less than 35 or 14 calendar days,

depending on the proposals on the agenda for the shareholders meeting. When a shareholder meeting is convened, holders of the ADSs may not receive sufficient notice of a shareholders meeting to permit them to withdraw their ordinary shares to allow them to cast their vote with respect to any specific matter. In addition, the depository and its agents may not be able to send voting instructions to holders of the ADSs or carry out their voting instructions in a timely manner. We will make all reasonable efforts to cause the depository to extend voting rights to holders of the ADSs in a timely manner, but we cannot assure holders that they will receive the voting materials in time to ensure that they can instruct the depository to vote their ADSs. Furthermore, the depository and its agents will not be responsible for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, holders of the ADSs may not be able to exercise their right to vote and they may lack recourse if their ADSs are not voted as they requested. In addition, in the capacity as a holder of ADSs, they will not be able to call a shareholders meeting.

You may be subject to limitations on transfer of your ADSs.

Your ADSs are transferable on the books of the depository. However, the depository may close its transfer books at any time or from time to time when it deems expedient in connection with the performance of its duties. In addition, the depository may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depository are closed, or at any time if we or the depository deems it advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason in accordance with the terms of the deposit agreement.

Risks Related to this Offering

The sale of a substantial amount of our ordinary shares or ADSs, including resale of the ADSs issuable upon the exercise of the Warrants held by the selling shareholder in the public market could adversely affect the prevailing market price of our ADSs.

We are registering for resale 6,435,548,000 ordinary shares represented by 16,088,870 ADSs issuable upon the exercise of the Warrants held by the selling shareholders. Sales of substantial amounts of our ordinary shares or ADSs in the public market, or the perception that such sales might occur, could adversely affect the market price of our ADSs. We cannot predict if and when the selling shareholder may sell such ADSs in the public markets. Furthermore, in the future, we may issue additional ordinary shares or ADSs or other equity or debt securities convertible into ordinary shares or ADSs. Any such issuance could result in substantial dilution to our existing shareholders and could cause our stock price to decline.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

Certain information included in this prospectus may be deemed to be “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995 and other securities laws. Forward-looking statements are often characterized by the use of forward-looking terminology such as “may,” “will,” “expect,” “anticipate,” “estimate,” “continue,” “believe,” “should,” “intend,” “project” or other similar words, but are not the only way these statements are identified.

These forward-looking statements may include, but are not limited to, statements relating to our objectives, plans and strategies, statements that contain projections of results of operations or of financial condition, expected capital needs and expenses, statements relating to the research, development, completion and use of our products, and all statements (other than statements of historical facts) that address activities, events or developments that we intend, expect, project, believe or anticipate will or may occur in the future.

Forward-looking statements are not guarantees of future performance and are subject to risks and uncertainties. We have based these forward-looking statements on assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate.

Important factors that could cause actual results, developments and business decisions to differ materially from those anticipated in these forward-looking statements include, among other things:

- our history of losses and needs for additional capital to fund our operations and our inability to obtain additional capital on acceptable terms, or at all;
- our limited operating history and the difficulties encountered by a small developing company;
- our lack of revenue generated from product sales since inception, and potential inability to be profitable;
- uncertainties of cash flows and inability to meet working capital needs;
- our ability to obtain regulatory approvals;
- our ability to obtain favorable pre-clinical and clinical trial results;
- our ability to identify and develop potential product candidates;
- additional costs or delays associated with unsuccessful clinical trials;
- the inability to predict the timing of revenue from a future product;
- the extensive regulatory requirements and future developmental and regulatory challenges we will still face even if we obtain approval for a product candidate;
- our ability to obtain or maintain orphan drug designation or exclusivity for our product candidates;
- our ability to obtain Rare Pediatric Disease designation for our product candidates;
- the potential oversight of programs or product candidates that may be more profitable or more successful;
- our technology may not be validated and our methods may not be accepted by the scientific community;
- the ability to conduct clinical trials, because of difficulties enrolling patients or other reasons;
- the requirements of being publicly traded may strain our resources;
- potential adverse effects resulting from failure to maintain effective internal controls;

- our obligations and governance practices as a “foreign private issuer” being different from those of U.S. domestic reporting companies may result in less protection for investors;
- our ability to comply with the applicable continued listing requirements of Nasdaq;
- the potential negative impact on our securities price and trading volume if securities or industry analysts do not publish reports about us or if they adversely change their recommendations about our business;
- the potential volatility of the market price for our ADSs;
- the potential dilution of our shareholders’ potential ownership due to future issuances of share capital;
- the requirement for holders of ADSs to act through the depository to exercise their rights;
- the potential limitations on ADS holders with respect to the transfer of their ADSs
- the risks of securities class action litigation; and
- other factors referred to in section “Risk Factors” in this prospectus.

All forward-looking statements contained herein speak only as of the date of this prospectus and are expressly qualified in their entirety by the cautionary statements included in this prospectus. We do not undertake to update or revise forward-looking statements to reflect events or circumstances that arise after the date on which such statements are made or to reflect the occurrence of unanticipated events, except as required by law. In evaluating forward-looking statements, you should consider these risks and uncertainties and not place undue reliance on our forward-looking statements.

USE OF PROCEEDS

We will not receive any proceeds from the sale of the ordinary shares represented by ADSs by the selling shareholders. All net proceeds from the sale of the ordinary shares represented by ADSs covered by this prospectus will go to the selling shareholders. We expect that the selling shareholders will sell their respective ordinary shares represented by ADSs as described under “Plan of Distribution.”

We may receive proceeds from the exercise of the Warrants and the issuance of ADSs upon such exercise to the extent that these Warrants are exercised for cash. The Warrants, however, are also exercisable on a cashless basis under certain circumstances. For example, Series B Warrants include cashless exercise terms that make the exercise of Series B Warrants for cash highly unlikely. Each of the Series A Warrants and Noteholder Warrants have a five-year term, and we do not anticipate they will be exercised in the near future. For the purposes of this prospectus, we have assumed the full exercise for cash of Series C Warrant, in which case the gross proceeds of such exercise will be approximately \$9.5 million. We intend to use the net proceeds of such warrant exercise, if any, for research and development, general and administrative expenses, and for working capital purposes.

DIVIDEND POLICY

We have never declared or paid any dividends on our ordinary shares. We do not anticipate paying any dividends in the foreseeable future. We currently intend to retain future earnings, if any, to finance operations and expand our business. Our board of directors has sole discretion whether to pay dividends. If our board of directors decides to pay dividends, the form, frequency and amount will depend upon our future operations and earnings, capital requirements and surplus, general financial condition, contractual restrictions and other factors that our directors may deem relevant. The Companies Law imposes restrictions on our ability to declare and pay dividends. See “Description of Share Capital” for additional information. Payment of dividends may be subject to Israeli withholding taxes. See “Certain Material Israeli Tax Considerations” for additional information.

CAPITALIZATION

The following table sets forth our cash and capitalization as of December 31, 2021 on:

- an actual basis; and
- an as adjusted basis, assuming the full exercise of the Series C Warrant only due to the mandatory exercise terms of such warrants, to reflect the receipt by us of gross proceeds of approximately \$9.5 million in exercise price in connection with the exercise of the Series C Warrant, and the corresponding issuance of 955,868,000 ordinary shares represented by 2,389,670 ADSs, without giving effect to any expenses payable by us in connection with the registration of the ordinary shares hereunder.
- The Series B Warrants have been excluded from the table below on the basis that cashless exercise is likely to be elected, and the Series A Warrants and Noteholder Warrants have been excluded on the basis that they each have a five-year term and we do not anticipate they will be exercised in the near future.

You should read this table in conjunction with our consolidated financial statements included elsewhere in this prospectus and the sections of this prospectus titled “Use of Proceeds” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

	At December 31, 2021	
	Actual (audited)	As Adjusted (unaudited)
Cash	\$ 7,482,773	\$ 16,993,660
Shareholders’ equity:		
Ordinary shares, no par value, 12,500,000,000 ordinary shares authorized and 3,354,650,799 ordinary shares issued and outstanding (represented by 8,386,627 ADSs) at December 31, 2021	—	—
Treasury Stock, 2,641,693 ordinary shares	(2,932,000)	(2,932,000)
Additional paid in capital	31,659,017	41,169,904
Accumulated deficit	(28,069,985)	(28,069,985)
Total shareholders’ equity	657,032	10,167,919
Total capitalization	\$ 657,032	10,167,919

The above table is based on 3,354,650,799 ordinary shares outstanding as of December 31, 2021 and excludes the following:

- 1,606,133,600 ordinary shares represented by 4,015,334 ADSs issuable upon the exercise of stock options outstanding at a weighted-average exercise price of \$1.66 per ADS;
- 495,371,600 ordinary shares represented by 1,238,429 ADSs issuable upon the exercise of outstanding Investor Exchange Warrants issued to Altium in connection with Bridge Financing at an exercise price of \$3.98 per ADS; and
- 44,105,200 ordinary shares represented by 110,263 ADSs issuable upon the exercise of outstanding warrants issued by Collect, at a weighted-average exercise price of \$11.00 per ADS, of which 3,200 ordinary shares represented by 8 ADSs were issued in March 2022 pursuant to a warrant exercise; and
- 6,435,548,000 ordinary shares represented by 16,088,870 ADSs issuable upon the exercise of the Warrants at an exercise price of \$3.98 per ADS.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion together with the consolidated financial statements and related notes included elsewhere in this prospectus. This discussion contains forward-looking statements regarding our expectations regarding our future performance, liquidity and capital resources, as well as other non-historical statements. These forward-looking statements are subject to numerous risks and uncertainties, including, but not limited to, the risks and uncertainties described in "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements." Our actual results may differ materially from those contained in or implied by any forward-looking statements.

Operating Results

Overview

We are an emerging pharmaceutical company dedicated to the development and commercialization of therapeutic products that treat rare and orphan diseases for which there are currently no approved treatments. Quoin's first lead product, QRX003, is a once daily topical lotion which is under development as a potential treatment for Netherton Syndrome, a rare hereditary skin disease. In addition to Netherton Syndrome, we intend to pursue the clinical development of QRX003 in other rare dermatological diseases including Peeling Skin Syndrome, SAM Syndrome and Palmoplantar Keratoderma.

Our objective is to develop and commercialize proprietary therapeutic drug products. To this effect, we intend to develop and seek marketing approvals from the FDA and other worldwide regulatory bodies for rare and orphan diseases. To achieve these objectives, we plan to:

- seek the necessary regulatory approvals to complete the clinical development of QRX003 and, if successful, file for marketing approval in the United States and other territories;
- prepare to commercialize QRX003 by establishing our own sales infrastructure in the U.S. and Europe and entering into distribution partnerships in other territories such as Canada, Australia, the Middle East and Asia; and
- Pursue business development activities by seeking partnering, licensing, merger and acquisition opportunities or other transactions to further expand our pipeline and drug-development capabilities and which take advantage of our financial resources for the benefit of increasing stockholder value.

The ultimate impact of the COVID-19 pandemic is still uncertain and subject to change. To the extent possible, we are conducting business as usual, with necessary or advisable modifications to employee travel and with all of our employees and consultants working remotely. We will continue to actively monitor the continually evolving situation related to COVID-19 and may take further actions that alter our operations, including those that may be required by federal, state or local authorities, or that we determine are in the best interests of our employees and other third parties with whom we do business.

We do not expect to generate revenue from product sales unless and until we successfully complete development and obtain marketing approval for one or more of our product candidates, which we expect will take a number of years and is subject to significant uncertainty. Accordingly, we will need to raise additional capital prior to the commercialization of QRX003 or any other product candidate. Until such time, if ever, as we can generate substantial revenue from product sales, we expect to finance our operating activities through a combination of equity offerings, debt financings, government or other third-party funding, commercialization, marketing and distribution arrangements and other collaborations, strategic alliances and licensing arrangements. However, we may be unable to raise additional funds or enter into such other arrangements when needed on favorable terms or at all. Our failure to raise capital or enter into such other arrangements as and when needed would have a negative impact on our financial condition and our ability to develop our product candidates.

Key Recent Events

On October 28, 2021, Collect completed the business combination with Quoin Inc. in accordance with the terms of the Merger Agreement, by and among Collect, Quoin Inc. and Merger Sub, which was a wholly-owned subsidiary of Collect, pursuant to which Merger Sub merged with and into Quoin Inc., with Quoin Inc. surviving as a wholly-owned subsidiary of Collect (the "Merger"). Immediately after completion of the Merger, Collect changed its name to "Quoin Pharmaceuticals Ltd." We have accounted for the

transaction as a reverse recapitalization with Quoin Inc. as the accounting acquirer. Because Quoin Inc. is the accounting acquirer, its historical financial statements became our historical financial statements and such assets and liabilities continued to be recorded at their historical carrying values. The impact of the recapitalization has been retroactively applied to all periods presented.

In addition, on October 28, 2021, Celect sold the entire share capital of its subsidiary, Celect Biotherapeutics Ltd., which essentially included all of Celect's then existing net assets, to EnCellX Inc. ("EnCellX"), a newly formed U.S. privately held company based in San Diego, CA (the "Share Transfer"), pursuant to an Amended and Restated Share Transfer Agreement. We have no interests in EnCellX subsequent to the closing of the Merger.

On October 28, 2021, we also completed the private placement transaction with an investor (the "Investor") for an aggregate purchase price of approximately \$17.0 million (comprised of the set off of approximately \$5 million of notes issued in connection with the bridge loan that the Investor previously made to Quoin Inc. (the "Bridge Financing") and approximately \$12 million in cash from the Investor (the "Primary Financing").

Components of Our Results of Operations

Operating Expenses

Our current operating expenses consist of two components – research and development expenses, and general and administrative expenses.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development expenses include personnel costs associated with research and development activities, including third-party contractors to perform research, conduct clinical trials and manufacture drug supplies and materials. We utilize outside consultants and third parties to conduct the majority of our research and development, under the supervision of our management team.

Future research and development expenses may include:

- employee-related expenses, such as salaries, bonuses and benefits, consultant-related expenses, share-based compensation, overhead related expenses and travel related expenses for our research and development personnel;
- expenses incurred under agreements with CROs, as well as consultants that support the implementation of the clinical studies described above;
- manufacturing and packaging costs in connection with conducting clinical trials and for stability and other studies required to support the NDA filing as well as manufacturing drug product for commercial launch;
- formulation, research and development expenses related to QRX003; and other products we may choose to develop; and
- costs for sponsored research.

Research and development activities will continue to be central to our business plan. Products in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect our research and development expenses to be significant over the next several years as personnel and compensation costs increase and we conduct late-stage clinical studies and prepare to seek regulatory approval for QRX003 and any other future product.

The duration, costs and timing of clinical trials of QRX003 and any other future product will depend on a variety of factors that include, but are not limited to:

- the number of trials required for approval;
- the per patient trial costs;

- the number of patients that participate in the trials;
- the number of sites included in the trials;
- the countries in which the trial is conducted;
- the length of time required to enroll eligible patients;
- the number of doses that patients receive;
- the drop-out or discontinuation rates of patients;
- the potential additional safety monitoring or other studies requested by regulatory agencies;
- the duration of patient follow-up;
- the timing and receipt of regulatory approvals; and
- the efficacy and safety profile of our product candidates.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for the founders and executive officers, professional fees and other corporate expenses, including significant costs incurred in 2021 in connection with the Merger and associated regulatory filings.

We anticipate that our general and administrative expenses will increase in the future to support our continued research and development activities. These increases will likely include increased costs related to the hiring of personnel, including compensation and employee-related expenses, and fees to outside consultants, lawyers and accountants. Additionally, we anticipate increased costs associated with being a public company, including compliance with The Nasdaq Capital Market and SEC requirements, insurance and investor relations costs.

Other Expenses

Other expenses consist primarily of non-cash costs associated with the financing arrangements entered into during 2020 and 2021, including fair value adjustments to notes payable and warrants and interest expense associated with debt instruments. The majority of such costs will cease upon conversion of the debt instruments and exchange of the warrants, most of which occurred at the Merger date.

Comparison of Period-to-Period Results of Operations

The following table presents consolidated statement of operations data for the years ended December 31, 2021, 2020 and 2019:

	2021	2020	2019
Operating Expenses			
General and administrative	\$ 4,499,923	\$ 1,425,855	\$ 1,514,752
Research and development	1,562,927	244,155	45,650
Total operating expenses	6,062,850	1,670,010	1,560,402
Other Expenses			
Fair value adjustments to debt	1,250,000	378,333	—
Warrant liability expense	12,784,329	—	—
Financing expense	275,000	—	—
Interest expense	1,090,409	47,021	—
Total other expenses	15,399,738	425,354	—
Net loss	\$ (21,462,588)	\$ (2,095,364)	\$ (1,560,402)

Year ended December 31, 2021 compared to the year ended December 31, 2020

The following table sets forth our results of operations for the year ended December 31, 2021, compared to the year ended December 31, 2020:

	2021	2020	Change
Operating Expenses			
General and administrative	\$ 4,499,923	\$ 1,425,855	\$ 3,074,068
Research and development	1,562,927	244,155	1,318,772
Total operating expenses	6,062,850	1,670,010	4,392,840
Other Expenses			
Fair value adjustments to debt	1,250,000	378,333	871,667
Warrant liability expense	12,784,329	—	12,784,329
Financing expense	275,000	—	275,000
Interest expense	1,090,409	47,021	1,043,388
Total other expenses	15,399,738	425,354	15,611,663
Net loss	\$ (21,462,588)	\$ (2,095,364)	\$ (20,004,503)

General and Administrative Expenses

General and administrative expenses were approximately \$4.5 million and \$1.4 million, in the years ended December 31, 2021 and 2020, respectively, representing an increase of \$3.1 million, or 216%. Approximately \$1.5 million of the increase related to professional fees associated with the Merger and costs of becoming a public company. In addition, there were increases in wages associated with the hiring of our CFO and bonuses paid to executives associated with completion of the Merger.

Research and Development Expenses

Our research and development expenses during the years ended December 31, 2021 and 2020 were approximately \$1.6 million and \$244,000, respectively, representing an increase of \$1.3 million, or approximately 640%. The increase was primary due to increased expenditures on our development programs following the completion of financings in late 2020 and 2021. Also, included in the 2021 expenses were approximately \$555,000 of compensation costs related to managing the development programs. We expect to significantly increase our research and development efforts by conducting the remaining studies necessary for the development and approval of QRX003, see “Components of Our Results of Operations – Research and Development Expenses” above.

We amortize licensed or acquired intellectual property over its expected useful life, included in research and development expenses set out above. The license from Skinvisible was obtained in October 2019, see “—Research and Development, Patents and Licenses.” Amortization of intangible assets was \$104,000 in each of the years ended December 31, 2021 and 2020.

Other Expenses:

Interest Expense

In the fourth quarter of 2020, we issued convertible promissory notes in an initial bridge financing with an aggregate face value of \$1,213,333 (the “2020 Notes”) with a 20% coupon interest. In 2021, we issued additional convertible promissory notes in a subsequent Bridge Financing (the “Bridge Notes”) with an aggregate face value of \$5,000,000 with a 15% coupon interest.

Interest expense was \$1,090,000 and \$47,000 in the years ended December 31, 2021, 2020 respectively. Interest on the Bridge Notes was paid in October 2021 upon closing of the Primary Financing, and interest on the 2020 Notes remained unpaid and included as a liability on our consolidated balance sheet as of December 31, 2021. We recorded \$697,000 in the year ended December 31, 2021 in connection with the estimated settlement of amounts due under the 2020 Notes. See “—Liquidity and Capital Resources.”

Fair value adjustment to convertible notes payable

We elected to value the 2020 Notes and the Bridge Notes at fair value, which was remeasured at each reporting period. In the year ended December 31, 2021 we incurred a fair value adjustment of \$1,250,000 related to the Bridge Notes and in the year ended

December 31, 2020 we incurred a fair value adjustment of \$378,000 related to the 2020 Notes. The Bridge Notes and 2020 Notes were converted into equity in October 2021 on the closing of the Primary Financing.

Warrant liability expense

We record our warrants at fair value, which was remeasured at each reporting period. In year ended December 31, 2021, we incurred a fair value adjustment of \$0.4 million related to the warrants associated with the 2020 Notes and \$12.4 million related to warrants associated with the Bridge Notes. The Bridge Note warrants which were exchanged for the Investor Exchange Warrants (as defined below) with a fixed exercise price of \$3.98 per share and reclassified as an equity instrument in October 2021 upon closing of the Primary Financing. We did not have any such expense in the year ended December 31, 2020.

Net Loss

We recorded a net loss of \$21.5 million in for the year ended December 31, 2021, as compared to a net loss of \$2.1 million for the year ended December 31, 2020, representing an increase of approximately \$20.0 million. The increase was primarily due to financing related charges aggregating \$15.4 million, including warrant expense of \$12.8 million, in the year ended December 31, 2021 compared to \$425,000 in the year ended December 20, 2020, as well increases in research and development expense and general and administrative expense as the Company used more resources to develop and implement its business plan.

Equity-Based Compensation Expense

Quoin Inc. did not have a share incentive plan from inception up to the year ended December 31, 2021. Upon closing of the Merger in October 2021, options held by former Collect option holders under Collect Ltd. Employee Shares Incentive Plan (the "2014 Plan") fully vested and expire between January and October 2022. The incremental value of the stock options at the closing of the Merger was not significant and no expense incurred in the year ended December 31, 2021. The 2014 Plan was amended and restated and initial grants were made to Company officers and directors, approved at the Company Annual General Meeting held on April 12, 2022.

Income Taxes

For the years ended December 31, 2021 and 2020, no income tax expense or benefit was recognized. Our deferred tax assets are comprised primarily of net operating loss carryforwards. We maintain a full valuation allowance on our deferred tax assets since we have not yet achieved sustained profitable operations. As a result, we have not recorded any income tax benefit since our inception. *Year ended December 31, 2020 compared to the year ended December 31, 2019*

The following table sets forth our results of operations for the year ended December 31, 2020, compared to the year ended December 31, 2019:

	2020	2019	Change
Operating Expenses			
General and administrative	\$ 1,425,855	\$ 1,514,752	\$ (88,897)
Research and development	244,155	45,650	198,505
Total operating expenses	1,670,010	1,560,402	109,608
Other Expenses			
Fair value adjustment to bridge note payable	378,333	—	378,333
Financing expense	—	—	—
Interest expense	47,021	—	47,021
Total other expenses	425,354	—	425,354
Net loss	\$ (2,095,364)	\$ (1,560,402)	\$ (534,962)

General and Administrative Expenses

General and administrative expenses were \$1.4 million and \$1.5 million, in the years ended December 31, 2020 and December 31, 2019, respectively, representing a decrease of \$89,000. The decrease was primarily due to reduced travel and conference related expenditures as a result of the COVID-19 pandemic.

Research and Development Expenses

Our research and development expenses during the years ended December 31, 2020 and 2019 were approximately \$244,000 and \$46,000, respectively representing an increase of \$199,000 or approximately 535%. The increase was primary due to increased expenditures on our development programs, and increased amortization of intangible assets described below.

We amortize licensed or acquired intellectual property over its expected useful life, included in research and development expenses set out above. The license from Skinvisible was obtained in October 2019, see “—Research and Development, Patents and Licenses.” Amortization of intangible assets was \$104,000 in the year ended December 31, 2020, and \$21,000 in the year ended December 31, 2019, representing an increase of \$83,000 or almost 400% in the year ended December 31, 2020. The reason for such increase was a full year of expense in 2020 as compared to three months in 2019.

Other expenses:

Interest Expense

In the fourth quarter of 2020, we issued the 2020 Notes convertible promissory notes in an initial bridge financing with an aggregate face value of \$1,213,333 with a 20% coupon interest. Interest expense was \$47,000 in the year ended December 31, 2020. We did not have any interest expense in the year ended December 31, 2019. See “—Liquidity and Capital Resources.”

Fair value adjustment to convertible notes payable

We elected to value the 2020 Notes and the Bridge Notes at fair value, which was remeasured at each reporting period. In the year ended December 31, 2020 we incurred a fair value adjustment of \$378,000 related to the 2020 Notes. We did not have any such expense in the year ended December 31, 2019.

Income Taxes

For the years ended December 31, 2020 and 2019, no income tax expense or benefit was recognized. Our deferred tax assets are comprised primarily of net operating loss carryforwards. We maintain a full valuation allowance on our deferred tax assets since we have not yet achieved sustained profitable operations. As a result, we have not recorded any income tax benefit since our inception.

Net Loss

We recorded a net loss of \$2.1 million in for the year ended December 31, 2020, as compared to a net loss of \$1.6 million for the year ended December 31, 2019, representing an increase of \$0.53 million or approximately 34%. The increase in net loss was primarily due to increases in interest expense, the fair value adjustment to the 2020 Notes and a modest increase in operating expenses.

Critical Accounting Policies and Use of Estimates

The preparation of our consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, including those related to accrued expenses, valuation allowance on deferred tax assets and valuation of intangible assets. We base our estimates on historical experience and on various other assumptions that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Results may differ from these estimates due to actual outcomes being different from those on which we based our assumptions. These estimates and judgments are regularly reviewed by management on an ongoing basis at the end of each quarter prior to the public release of our financial results.

Critical accounting policies are those that, in management’s view, are most important to the portrayal of a company’s financial condition and results of operations and most demanding on their calls on judgment, often as a result of the need to make estimates about the effect of matters that are inherently uncertain and may change in subsequent periods. We believe our most critical accounting policies and estimates relate to:

Use of estimates:

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts in the consolidated financial statements and accompanying notes. Actual results could materially differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. In addition, other factors may affect estimates, including: expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. Estimates are used in the following areas, among others: settlement of debt or other obligations, fair value of debt instruments and warrants, research and development expense recognition, intangible asset estimated useful lives and impairment assessments, allowances of deferred tax assets, contingency recognition, and cash flow assumptions regarding going concern considerations.

Long-lived assets:

Long-lived assets are comprised of acquired technology and licensed rights to use technology, which are considered platform technology with alternative future uses beyond the current products in development. Such intangible assets are being amortized on a straight-line basis over their expected useful life of 10 years.

The Company assesses the impairment for long-lived assets whenever events or circumstances indicate the carrying value may not be recoverable. Factors we consider that could trigger an impairment review include the following:

- Significant changes in the manner of our use of the acquired assets or the strategy for our overall business,
- Significant underperformance relative to expected historical or projected development milestones,
- Significant negative regulatory or economic trends, and
- Significant technological changes which could render the platform technology obsolete.

The Company recognizes impairment when the sum of the expected undiscounted future cash flows is less than the carrying amount of the asset. Impairment losses, if any, are measured as the excess of the carrying amount of the asset over its estimated fair value. During the years ended December 31, 2021, 2020 and 2019, there were no impairment indicators which required an impairment loss measurement.

Research and development:

Research and development costs are expensed as incurred. Research and development expenses include personnel costs associated with research and development activities, including third-party contractors to perform research, conduct clinical trials and manufacture drug supplies and materials. The Company accrues for costs incurred by external service providers, including contract research organizations and clinical investigators, based on its estimates of service performed and costs incurred. These estimates include the level of services performed by third parties, patient enrollment in clinical trials when applicable, administrative costs incurred by third parties, and other indicators of the services completed. Based on the timing of amounts invoiced by service providers, the Company may also record payments made to those providers as prepaid expenses that will be recognized as expense in future periods as the related services are rendered.

Fair value of financial instruments:

The Company considers its cash, accounts payable, accrued expenses and the convertible and bridge notes payable to meet the definition of financial instruments. The convertible and bridge notes payable are recorded at fair value and the warrants are recorded at fair value. The carrying amounts of the remaining financial instruments approximated their fair values due to the short maturities.

The Company measures fair value as required by ASC Topic 820, Fair Value Measurements and Disclosures ("ASC Topic 820"). ASC Topic 820 defines fair value, establishes a framework and gives guidance regarding the methods used for measuring fair value, and expands disclosures about fair value measurements. ASC Topic 820 clarifies that fair value is an exit price, representing the

amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants. The significant assumptions that were used in fair value calculations are summarized as follows:

The fair value of the convertible notes payable issued in 2020 was determined to be \$1,213,333, resulting in a charge to operations of \$378,333 during 2020. The fair value adjustment from December 31, 2020 to their conversion to ADS's at the Merger date was not material. The initial fair value of the Bridge Notes issued in 2021 was determined to be approximately \$5,000,000, resulting in a charge to operations of \$1,250,000 during 2021. The fair value adjustment from the Bridge Notes issuances to their conversion to ADS's upon the Merger date was not significant. The Bridge Notes and 2020 Notes were converted into ADS's at the Merger date.

The Company utilized a Monte Carlo simulation model for periods prior to Merger and Primary Financing, and a Black Scholes model to determine the fair value of 2020 Notes warrants at December 31, 2021. The significant estimates used in the determining the fair value of such warrants were as follows:

	12/31/2021 (1)	12/31/2020
Stock price	\$ 1.82	\$ 3.98
Initial exercise price	\$ 3.98	\$ 3.98
Contractual Term	5.0	5.0
Volatility	89.2 %	98 %
Discount rate	1.26 %	0.81 %

- (1) The warrants issued during 2020 were not exchanged for fixed term warrants until 2022, therefore the existing warrants were still considered outstanding at December 31, 2021 and classified as a liability instrument.

The Company utilized a Monte Carlo simulation model to determine the fair value of the Bridge Financing warrants. The significant estimates used in such calculation of the fair value of such warrants were as follows:

	Transaction Date March - May 2021	Merger Date 10/28/2021
Stock price	\$ 3.98 (post exchange ratio)	\$ 11.64 (post exchange ratio)
Initial exercise price	\$ 3.98 (post exchange ratio)	\$ 3.98 (post exchange ratio)
Contractual Term	5.0	5.0
Volatility	92 %	103 %
Discount rate	0.98 %	1.14 %

New accounting pronouncements:

The Company has evaluated all recent accounting pronouncements and believes that none of them will have a material effect on the Company's financial position, results of operations or cash flows except as discussed below.

Debt with Conversion and Other Options and Derivatives and Hedging

The FASB recently issued ASU 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging – Contracts in Entity's Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity's Own Equity*, to reduce complexity in applying GAAP to certain financial instruments with characteristics of liabilities and equity. The guidance in ASU 2020-06 simplifies the accounting for convertible debt instruments and convertible preferred stock by removing the existing guidance that requires entities to account for beneficial conversion features and cash conversion features in equity, separately from the host convertible debt or preferred stock. The guidance in ASC 470-20 applies to convertible instruments for which the embedded conversion features are not required to be bifurcated from the host contract and accounted for as derivatives. In addition, the amendments revise the scope exception from derivative accounting in ASC 815-40 for freestanding financial instruments and embedded features that are both indexed to the issuer's own stock and classified in shareholders' equity, by removing certain criteria required for equity classification. These amendments are expected to result in more freestanding financial instruments qualifying for equity classification (and, therefore, not accounted for as derivatives), as well as fewer embedded features requiring separate accounting from the host contract. The amendments in ASU 2020-06 further revise the guidance in ASC 260, Earnings Per Share, to require entities to calculate diluted earnings per share (EPS) for convertible instruments by using the if-converted method. In addition, entities must presume share settlement for purposes of calculating diluted EPS when an instrument may be settled in cash or

shares. The amendments in ASU 2020-06 are effective for public entities, excluding smaller reporting companies as defined, for fiscal years beginning after December 15, 2021. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2023. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. The Company is currently evaluating the impact this standard will have on its financial statements.

Earnings Per Share

In May 2021, the FASB issued ASU 2021-04, Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40). The new ASU addresses issuer's accounting for certain modifications or exchanges of freestanding equity-classified written call options. This amendment is effective for all entities, for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted. The Company does not believe the impact of the adoption of this pronouncement is significant to the consolidated financial statements.

Recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the Securities and Exchange Commission did not or are not believed by management to have a material impact on the Company's present or future consolidated financial statement presentation or disclosures.

Liquidity and Capital Resources

We expect to continue to incur significant and increasing operating losses at least for the foreseeable future. We do not expect to generate product revenue unless and until we successfully complete development of and obtain regulatory approval for QRX003, or any other future products. Our net losses may fluctuate significantly from quarter-to-quarter and year-to-year, depending on the timing of planned clinical trials and our expenditures on other research and development activities. We anticipate that our expenses will increase substantially in 2022 as we advance the clinical development of QRX003 and begin to operate as a publicly traded company.

Future Funding Requirements

The Company expects to receive additional funding through the mandatory exercise provision of the Series C Warrant issued to the Investor as of March 2022 which would result in proceeds of approximately \$9.5 million. In the event the requirements of the mandatory exercise provision of such warrant are not met, the Company has a commitment from the Investor to provide funding equal to the \$9.5 million expected upon exercise of the Series C Warrant, at prevailing market rates. As such, the Company believes that it has sufficient resources to affect its business plan for at least one year from the issuance of its consolidated financial statements. The Company is also in the process of negotiating a line of credit with a bank which has not yet been closed as of April 13, 2022 and is likely to be conditional on additional equity funding which could be satisfied by the aforementioned Investor funding, as well as the achievement of clinical development milestones.

We will need to obtain further funding through public or private offerings of our capital stock, debt financing, collaboration and licensing arrangements or other sources, the requirements for which will depend on many factors, including:

- the scope, timing, rate of progress and costs of our drug development efforts, preclinical development activities, the timing of laboratory testing and clinical trials for our product candidates;
- the number and scope of clinical programs we decide to pursue;
- the cost, timing and outcome of preparing for and undergoing regulatory review of our product candidates;
- the scope and costs of development and commercial manufacturing activities;
- the cost and timing associated with commercializing our product candidates, if they receive marketing approval;
- the extent to which we acquire or in-license other product candidates and technologies;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- our ability to establish and maintain collaborations on favorable terms, if at all;
- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates and, ultimately, the sale of our products, following FDA approval;
- our implementation of operational, financial and management systems; and
- the costs associated with being a public company.

Adequate additional funding may not be available to us on acceptable terms, or at all. If we are unable to raise capital in sufficient amounts or on terms acceptable to us, we may have to significantly delay, scale back or discontinue the development or commercialization of QRX003, any future product, or potentially discontinue operations.

To the extent that we raise additional capital through the sale of our equity or convertible debt securities, and pursuant to the exercise of warrants issued to our investors in connection with the 2020 Notes, the Bridge Financing and the Primary Financing, the ownership interest of our equity holders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our equity holders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends.

If we raise additional funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may be required to relinquish valuable rights to our technologies, future revenue streams, research programs or proposed products, or to grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to develop and market any future product that we would otherwise prefer to develop and market ourselves.

Summary Statement of Cash Flows

As of December 31, 2021, we had approximately \$7.5 million in cash.

The table below presents our cash flows for the years ended December 31, 2021, 2020 and 2019 (\$000):

	<u>2019</u>	<u>2020</u>	<u>2021</u>
Net cash used in operating activities	\$ (1,299)	\$ (1,339)	\$ (5,720)
Net cash used in investing activities	—	(125)	(625)
Net cash provided by financing activities	<u>1,299</u>	<u>1,787</u>	<u>13,504</u>
Net increase in cash and cash equivalents	<u>\$ —</u>	<u>\$ 324</u>	<u>\$ 7,159</u>

Operating Activities

Net cash used in operating activities was \$5.7 million, \$1.3 million and \$1.3 million for the years ended December 31, 2021, 2020 and 2019, respectively. The increase in 2021 was primarily due to the increase in research and development and general and administrative expenses, including significant expenses incurred in connection with the Merger and associated regulatory filings and increased compensation costs.

Investing Activities

Net cash used by investing activities was \$625,000 and \$125,000 in the years ended December 31, 2021 and 2020, respectively, each representing payments under the Skinvisible license agreement (see “—Research and Development, Patents and Licenses”). We did not have any cash flows from investing activities for the year ended December 31, 2019.

Financing Activities

Net cash from financing activities was \$13.5 million, \$1.8 million and \$1.3 million during the years ended December 31, 2021, 2020 and 2019, respectively. Prior to the initial 2020 Note financing commencing October 2020, all expenditures of the Company were paid for by Company officers. For 2020, financing activities primarily represented net proceeds received from the 2020 Notes and net increase of amounts due to Company officers. For 2021, such amounts primarily represented net proceeds received from the Bridge Financing and Primary Financing. Since the closing of the Primary Financing in October 2021, the Company has been repaying amounts due to officers at the aggregate rate of \$50,000 per month.

2020 Notes

On October 2, 2020, Quoin Inc. commenced an offering of promissory notes (the “2020 Notes” or “Convertible Notes Payable”) and warrants. The 2020 Notes were issued at a 25% original issue discount and bear interest at a rate of 20% per annum. The 2020 Notes are due one year from their respective dates of issuance. In October through December 2020, Quoin Inc. received an aggregate of approximately \$910,000 pursuant to this offering, resulting in the issuance of 2020 Notes with an aggregate face value of \$1,213,313 and an original issue discount of \$303,333. Approximately 23% of such financing was received from our directors, Messrs. Langer and Culverwell. No additional funding from the 2020 Notes was received in the year ended December 31, 2021.

Based upon the terms agreed to in March 2021 in the Primary Financing, the 2020 Notes were mandatorily convertible into 64,784 ADS’s in the Primary Financing, subject to adjustment.

The Company elected to account for the Convertible Notes Payable using the fair value model due to the short maturity. The fair value of the Convertible Notes Payable was estimated to be approximately \$1.2 million at the date of issuance, resulting in a \$378,000 expense recognized in the fourth quarter of 2020. There was no material change in the fair value from issuance until the conversion to equity on the Merger date.

The noteholders also were entitled to receive warrants exercisable at any time after the issuance date for a number of shares of Quoin Inc.’s common stock that equates to 100% of the “as if converted” shares as if the 2020 Notes principal and interest were convertible at the lowest price any securities are sold, convertible, or exercisable into in the Primary Financing or the next round of financing (whichever is lower). The exercise price was based on a valuation equal to the next financing round and since the number of shares issuable upon the exercise of the warrants and exercise price were not knowable at the time they were not recognized as of December 31, 2020.

After entering into the Merger Agreement in March 2021, the terms of the warrants became measurable and were exercisable for 367,356 ADS’s at an initial exercise price of \$3.98 per share. The Company determined that these warrants met the criteria to be recorded as a liability instrument. Each holder agreed to exchange its warrant for the warrant (an “Exchange Warrant”) with substantially the same terms as an Investor Exchange Warrant and with a number of shares issuable upon the exercise of an Exchange Warrant as upon the exercise of the original warrant and the same exercise price as under the original warrant and a contractual term of 5 years. The Exchange Warrants have been determined to warrant equity classification and, as such only the fair value change through the exchange date will be included in warrant liability expense in the accompanying statement of operations.

At the closing of the Merger, 64,784 ADS’s were issued upon the conversion of the principle of the Convertible Notes Payable. In addition, effective as of March 13, 2022, the Company exchanged noteholders’ warrants for Exchange Warrants exercisable for 367,356 ADS’s, in the aggregate, at the exercise price of \$3.98 per ADS.

In December 2021, the Company concluded that the calculation of ADS’s due to the 2020 Noteholders did not account for accrued interest due when the ADS’s were issued. The Company reached cash settlements with, and plans to issue additional ADS’s to, the 2020 Noteholders to account for this. The estimated amount required to settle these obligations was determined to be approximately \$744,000 at December 31, 2021 and is included in accrued liabilities in the consolidated balance sheet; and \$697,000 is included in interest expense in the consolidated statement of operations for the year ended December 31, 2021.

Interest expense, at the stated interest rate, recognized in the year ended December 31, 2021, 2020 and 2019 was approximately \$202,000, \$47,000, and \$0, respectively.

Bridge Financing

In connection with the Merger Agreement and the Securities Purchase Agreement (described below), Quoin Inc. entered into a “Bridge Purchase Agreement” on March 24, 2021 with the Investor, pursuant to which the Investor agreed to purchase, and Quoin Inc. agreed to issue notes (the “Bridge Notes”) in the aggregate principal amount of up to \$5.0 million in exchange for an aggregate purchase price of up to \$3.8 million together with warrants. The Bridge Notes were purchased in three closings: (i) the first purchase of \$2.0 million on March 25, 2021 (Quoin Inc. received proceeds of \$1.5 million less fees of \$90,000); (ii) the second purchase of \$1.7 million in April 2021 (Quoin Inc. received proceeds of \$1.25 million); and (iii) a third purchase of \$1.3 million in May 2021 (Quoin Inc. received proceeds of \$1.0 million less fees of \$185,000). The Bridge Notes were secured by a lien on Quoin Inc.’s current and future assets, were senior to all other outstanding and future indebtedness of Quoin Inc. and included covenants limiting future indebtedness, among others.

The Bridge Notes were issued with a 25% original issue discount, at an interest rate of 15% per annum and had a maturity date of the earliest to occur of: (i) December 25, 2021, (ii) the date on which Quoin Inc.'s equity is registered under the Exchange Act or is exchanged for equity so registered or (iii) immediately prior to the closing of the Merger.

The Bridge Notes were offset against the purchase price under the Securities Purchase Agreement related to the Primary Financing and converted into 1,257,721 ADS's (including shares held in escrow for the benefit of the Investor) upon the closing of the Primary Financing. The accrued interest amounting to \$393,611 was paid in cash. Interest expense, at the stated interest rate, recognized in the year ended December 31, 2021 was \$393,611.

Upon the funding of each Bridge Note tranches described above, the Investor received warrants (the "Bridge Warrants") to purchase a number of shares of Quoin Inc.'s common stock equal to the aggregate principal amount of the Bridge Notes. Upon the closing of the Primary Financing, the Bridge Warrants were exchanged for Investor Exchange Warrants as described below.

Primary Financing

On October 28, 2021, the Company completed the private placement transaction with the Investor for an aggregate purchase price of approximately \$17.0 million (comprised of (x) the set off of approximately \$5 million of Bridge Notes, and (y) approximately \$12 million in cash from the Investor) (the "Primary Financing"), and the Investor paid the Company approximately \$11,504,000, which was net of \$393,611 in accrued interest on the Bridge Notes. The Company incurred an additional approximate \$1.4 million in costs associated with the Primary Financing, which resulted in the net proceeds of approximately \$10.1 million. The Company issued 4,276,252 ADS's to the Investor, consisting of 833,773 delivered to the Investor on or after the Merger closing and 3,442,479 initially held in an escrow account for the benefit of the Investor as per the terms of the Securities Purchase Agreement. All such escrow shares were released to the Investor prior to December 31, 2021.

In addition, pursuant to the terms of the Securities Purchase Agreement related to the Primary Financing, Quoin Ltd. issued to the Investor warrants to purchase 1,238,429 ADS's (the "Investor Exchange Warrants") at an exercise price of \$3.98 per ADS, in exchange for Bridge Warrants. The Investor Exchange Warrants and ordinary shares underlying the Investor Exchange Warrants were registered with the SEC on the Registration Statement on Form F-4. An amendment to the Investor Exchange Warrants was entered into in September 2021, which replaced reset provisions with a fixed number of shares and exercise price.

Quoin Ltd. also issued to the Investor, effective as of March 13, 2022, the 136th trading day following the consummation of the Merger (i) Series A Warrant to purchase 4,276,252 ADS's (the "Series A Warrant") (ii) Series B Warrant to purchase 4,276,252 ADS's (the "Series B Warrant") and (iii) Series C Warrant to purchase 2,389,670 ADS's ("Series C Warrant" and, together with the Series A Warrant and Series B Warrant, the "Investor Warrants"). The exercise price for the Investor Warrants is \$3.98 per ADS, with Series A Warrant having a five-year maturity and Series B Warrant and Series C Warrant having a two-year maturity. The Company has the right to require the mandatory exercise of the Series C Warrant, subject to an effective registration statement being in place for the resale of the shares underlying such warrants and the satisfaction of equity market conditions as defined in the Series C Warrant. As of April 13, 2022, not all of the market related conditions were met. Upon the exercise of the Series C Warrant in full, the Investor will be granted an additional Series A Warrant to purchase 2,389,670 ADS's and an additional Series B Warrant to purchase 2,389,670 ADS's at an exercise price of \$3.98 per ADS.

Research and Development, Patents and Licenses

We devote substantial research and development resources to developing new products.

Skinvisible

On October 17, 2019, Quoin Inc. entered into an exclusive license agreement with Skinvisible Inc. ("Skinvisible"), pursuant to which Skinvisible granted a license to use certain patented technology for the development of products for commercial sale in the orphan rare skin disease field, and for the use of a proprietary polymer deliver system technology. This technology is currently being used in the development of QRX003. In exchange for the license, Quoin Inc. agreed to pay Skinvisible \$1,000,000, as well as development and sales milestone payments and a single digit royalty on all net sales, as defined.

The development milestones required payments upon achieving development milestones for the first Rare Skin Disease drug product developed using the licensed technology and the first two Ketamine products, as defined. Payments were originally due upon successful completions of certain clinical milestones (\$7.5 million) and obtaining US and EU regulatory approval (\$15 million). The

sales milestones required for every licensed product commercialized by Quoin Inc. are \$10 million upon achievement of \$100 million in sales being achieved in the annual period; \$25 million upon achievement of \$250 million in sales and \$50 million upon the achievement of \$400 million in sales in an annual period. On January 27, 2021, Quoin Inc. and Skinvisible entered into an amendment which modified the clinical milestone payment requirements such that \$750,000 would be payable to Skinvisible upon achievement of specified clinical milestones, and \$21.75 million upon regulatory approval in the U.S. and EU respectively. No development milestones, sales milestones or royalty payments were due through in 2019, 2020 or 2021.

The agreement has a termination clause that is triggered if no product has commenced clinical testing 12 months after the date of the agreement or the latest subsequent amendment. On April 19, 2021, Quoin Inc. and Skinvisible entered into another amendment which established the development deadline as December 31, 2022. Should the Company not commence clinical testing as defined by the development deadline, the license agreement will terminate immediately except in certain circumstances as specified in the agreement.

The license fee was originally due in two equal installments of \$500,000 payable no later than December 31, 2019 and June 30, 2020, which were not paid. The agreement was subsequently amended for payment due on July 31, 2020. On July 31, 2020, the agreement was amended to further extend the payment until September 30, 2020. On September 30, 2020, the agreement was again amended, requiring payment of the license fee only when outside financing is received, as defined in the agreement. On June 21, 2021, the parties entered into an additional amendment which modified the payment terms and required a payment of \$107,500 on June 26, 2021, a payment of \$250,000 within 10 days of the Primary Financing, and the remaining \$250,000 upon the earlier of approval of an Investigatory New Drug application by the FDA or December 31, 2021. This amendment also eliminated the \$750,000 clinical milestone payments described above and reduced the milestone payment upon regulatory approval of the product containing the Skinvisible technology in either the U.S. or E.U., whichever happens first to a total of \$5,000,000.

At December 31, 2021 and December 31, 2020, the license acquisition liability due was \$250,000 and \$875,000 respectively. The remaining license acquisition liability has not been paid in accordance with the terms but has not impaired the Company's rights to the technology as the Company is in the process of renegotiating this payment with Skinvisible.

The major research and development vendors utilized by the Company include the following:

Quoin Inc. entered into three consulting agreements with Axella Research LLC ("Axella") to provide regulatory and pre-clinical/clinical services with respect to QRX003 and QRX004. The combined fees of the three agreements are approximately \$270,000, payable as milestones under the three agreements are met. Quoin Inc. has also engaged Axella for additional services pursuant to separate work orders. Further, Quoin Inc. has two options to pay the milestones due 1) one half in equity (at a pre-negotiated valuation) and one-half in cash or 2) entirely in cash, in which case a discount of approximately 20% would be applicable. We recognized research and development expenses for services provided and milestones met of approximately \$247,000, \$50,000 and \$25,000 for the years ended December 31, 2021, 2020 and 2019, respectively, and have accrued expenses of \$193,537, \$105,052 and \$24,940 at December 31, 2021, 2020 and 2019, respectively.

In November 2020, Quoin Inc. entered into a Master Service Agreement for an initial term of three years with Therapeutics Inc. for managing preclinical and clinical development for new products in the field of dermatology. The agreement required the execution of individual work orders. Quoin Inc. may terminate any work order for any reason with 90 days written notice subject to costs incurred through termination and a defined termination fee, unless there is a material breach by Therapeutics Inc. The first work order was entered into in late 2020 for a clinical study at an expected estimated cost of approximately \$3.5 million and expected timing through the first quarter of 2023. For the year ended December 31, 2021, we incurred approximately \$340,000 of research and development costs related to this agreement.

In November 2021, we entered into a commitment with Queensland University of Technology for research related services associated with Netherton Syndrome of approximately \$250,000 for an expected period of eighteen months, of which an initial \$25,000 expense was incurred in 2021.

We are a development stage company, and it is not possible for us to predict with any degree of accuracy the outcome of our research, development or commercialization efforts. As such, it is not possible for us to predict with any degree of accuracy any significant trends, uncertainties, demands, commitments or events that are reasonably likely to have a material effect on our liquidity or capital resources or that would cause financial information to not necessarily be indicative of future operating results or financial condition. However, to the extent possible, certain trends, uncertainties, demands, and commitments are described above in this section.

BUSINESS

Company Overview

We are an emerging specialty pharmaceutical company dedicated to developing products that help treat rare and orphan diseases for which there are currently no approved treatments. We believe the rare and orphan disease space represents an attractive commercial opportunity for a number of reasons.

Our initial focus is on the development of products, using our proprietary owned and in-licensed technology, that could help address rare skin diseases for which there are currently no approved treatments or cures. Our first lead product is QRX003, a once daily, topical lotion comprised of a broad-spectrum serine protease inhibitor, formulated with the proprietary Invisicare® technology, to treat Netherton Syndrome. In addition, we intend to pursue the clinical development of QRX003 in other rare dermatological diseases including Peeling Skin Syndrome, SAM Syndrome, and Palmoplantar Keratoderma. We are also developing QRX004 as a potential treatment for Dystrophic Epidermolysis Bullosa. In addition, we are also developing QRX006 as a potential therapy for an, as of yet, undisclosed rare skin disease. A provisional patent application for QRX006 was filed with the USPTO in May 2021.

Netherton Syndrome

NS is a rare autosomal recessive genetic disease caused by a mutation in the SPINK5 gene and has an incidence of approximately 1/200,000 births. The SPINK5 gene encodes a protein, called lympho-epithelial kazal type related inhibitor (“LEKTI”) that serves as a brake system on the activity of certain proteases (enzymes that digest proteins) in the skin called Kallikreins. The absence of the LEKTI protein as a result of the genetic defect that causes NS leads to unregulated protease activity in the skin by the Kallikreins, resulting in too few layers of the outer skin (stratum corneum), thereby leading to a highly defective and compromised skin barrier.

Newborns with NS have reddened skin (erythroderma) and sometimes a thick parchment-like covering of skin (collodion membrane). The skin is red and scaly all over. Hair shafts are fragile and break easily due to trichorrhexis or “bamboo hair,” resulting in short sparse hair. In older children and adults the scaling may have a distinctive circular pattern (ichthyosis linearis circumflexa). Another characteristic of NS is a predisposition to allergies, asthma, and eczema.

Babies with NS may be born prematurely. Trouble gaining weight in infancy and childhood is common and can be severe. Infants may also have recurrent skin infections and septicemia. They may develop hypernatremia (elevated sodium levels in the blood) due to excessive loss of fluid from the skin surface. Because hairs may not be affected at birth, and then may be sparse in all babies in the first months of life, the characteristic hair defect that is diagnostic of NS may not be detected initially.

Infants with NS may be misdiagnosed as having congenital ichthyosiform erythroderma (“CIE”), atopic dermatitis or psoriasis. Atopic dermatitis (red, itchy patches of skin) may be present and a cradle cap-like scale and redness may appear on the face, scalp and eyebrows.

Unmet Medical Needs in NS

The target indication for QRX003 is the treatment of NS. There are currently no approved therapies to treat NS. In the absence of an approved therapeutic product, only certain symptoms of NS can be treated, generally by the regular use of emollients and moisturizing creams and lotions. Other topical agents must be used with caution because the skin in NS patients may allow ingredients from some topically applied medications to be absorbed into the bloodstream, which may pose a danger to the patient. Use of topical keratolytic agents, such as urea or lactic acid derivatives, may be limited by skin irritation and is generally reserved for older children or adults. Base line treatment may also include oral antihistamines, which can help to control the itchy, eczematous component, and topical or systemic antibiotics as needed. Oral and topical steroids are beneficial in reducing inflammation and the eczematous component of the disease. However, the well-documented side effects of long-term steroid use need to be considered. There is a critical need for a new and effective treatment for NS

Rationale for Developing QRX003 as a Potential Treatment for NS

QRX003 is a once-daily topical lotion being developed for the treatment of NS. The active ingredient in QRX003 is a competitive broad-spectrum serine protease inhibitor whose mechanism of action is to target the Kallikreins responsible for the process of skin shedding. As a result of the genetic mutation of the SPINK5 gene, that causes NS, these Kallikreins go unregulated and become hyperactive resulting in the uncontrolled desquamation that leads to the highly defective skin barrier in NS patients. When

applied daily to the skin, QRX003 is designed to act to regulate the activity of these Kallikreins, leading to a more normalized skin shedding process and the formation of a stronger and more effective skin barrier.

Regulatory Status of QRX003 for the Treatment of NS

On November 29, 2019 we submitted a pre-IND (“PIND”) meeting request to the FDA regarding the proposed development of QRX003 as a potential treatment for NS. On December 20, 2019, we received a letter from the FDA stating that written responses to the questions we posed in the PIND submission would be given in-lieu of an in-person meeting. We subsequently submitted a background package to the FDA on December 26, 2019 that provided information on the product and the proposed clinical plan along with a series of questions we wished to obtain agency feedback on. We received those written responses from the FDA on January 30, 2020. The feedback provided by the FDA has provided us with a clear path forward for the development of QRX003 as a potential treatment for NS.

With regard to the proposed clinical program, the agency confirmed that in the case of a rare disease, findings from a single Phase 3 trial along with supportive data could be used to establish efficacy. With regard to IND-enabling nonclinical studies, while the agency stated that the typical battery toxicology studies would apply to this product candidate, the agency expressed a willingness to consider the sufficiency of already-conducted studies in the public literature in the absence of GLP toxicity studies in animals. In response to our query, the agency stated that the QRX003 may be a candidate for one or more expedited programs.

We submitted an IND in March 2022 to the FDA to initiate a clinical study of QRX003 in adult NS patients. In March 2022, we submitted a briefing document to the EMA seeking guidance regarding the clinical and regulatory development of QRX003 for the EU. We also intend to apply for Orphan Drug status as well as Pediatric Disease designation for QRX003 at a later date. To date, no NS patients have been tested with QRX003.

Safety of QRX003 in the Treatment of NS

The safety of QRX003 in NS patients has not been assessed as of yet.

Commercial Strategy

QRX003 has the potential to become the first approved treatment for NS to reach the market both in the U.S. and Europe and may therefore likely be used in a large proportion of patients. We currently anticipate that QRX003, if approved, would be applied once daily to the diseased skin over the patient’s entire body. Because NS is a chronic disease and does not spontaneously resolve, we believe there is an opportunity for the product, should it be approved, for long-term chronic use.

We intend to self-commercialize QRX003, and other rare disease products the company may develop, if approved, in both the U.S. and Europe. Because of the very low number of patients and the fact that diagnosis and treatment are generally provided by a relatively small number of board-certified dermatologists in major urban areas, this concentration of care will enable us to market QRX003 with a small, dedicated salesforce to target patients and caregivers. Outside of the U.S and in Europe, we have currently established marketing partnerships for QRX003 that cover approximately 60 different countries including Australia, New Zealand, the Middle East, Central and Eastern Europe, Turkey and some countries in Latin America.

Once the commercial infrastructure has been established for QRX003 for Netherton Syndrome, the subsequent approval and addition of new rare disease indications or products will not result in a significant increase in the size of that infrastructure. In particular, it is highly likely that physicians who treat patients with Netherton Syndrome would also treat patients with Peeling Skin Syndrome, SAM Syndrome, Palmoplantar Keratoderma and Epidermolysis Bullosa, enabling our sales personnel to discuss several products, once approved, with each treating physician.

A key element of our commercial strategy will be to add new products to our portfolio beyond those which we develop ourselves. This will be achieved through in-licensing, acquisition or the establishment of research partnerships with universities or other institutions. While it is intended that that these products will treat rare and orphan diseases, we may widen our scope of interest beyond rare skin diseases as we believe this will not add significant incremental burden to an already established commercial infrastructure.

Pricing

We have not conducted a formal pricing analysis of QRX003 in NS. We anticipate that pricing at launch may be influenced by the product label negotiated with the FDA, pharmacoeconomic data developed to support pricing and the potential for greater sales under negotiated government contracts.

Competition

Currently, there are no approved products to treat NS. However, to our knowledge, there are a number of therapeutic products at various stages of development for the treatment of NS, including candidates from LifeMax Laboratories, PellePharma, Krystal Biotech, Sixera Pharmaceuticals, QID Pharmaceuticals, Azitra and Dermadis. Currently, to the best of our knowledge there are no active studies on NS patients being conducted under an open IND.

Manufacturing

Our manufacturing strategy is to contract with third parties to manufacture our clinical and commercial API and drug product supplies. The formulation and processes used to manufacture our products are proprietary, and are covered by multiple issued U.S. patents and counterparts in other regions of the world, and we have agreements with various third-party manufacturers and suppliers, such as Ferndale Contract Manufacturing and TopChem Pharmaceuticals Limited, that are intended to restrict these manufacturers from using or revealing any unpublished proprietary information.

Exclusive Licensing Agreement with Skinvisible Pharmaceuticals, Inc.

In October 2019, we entered into an Exclusive Licensing Agreement the (as amended from time to time, the “License Agreement”) with Skinvisible Pharmaceuticals, Inc. (“Skinvisible”), under which Skinvisible granted us an exclusive royalty-bearing license relating to the production and manufacture of prescription drug products related to certain patents held by Skinvisible, including those related to QRX003. Once the License Fee (as defined below) is fully paid, the grant of the rights under the License Agreement fully come into effect. Until then our rights will be limited to R&D, clinical trial and regulatory submission uses only. We are required to pay Skinvisible a one-time non-refundable, non-creditable license fee of \$1 million dollars (the “License Fee”). In addition, we agreed to pay Skinvisible a single digit royalty percentage of our net sales revenues for any licenses product relating the patent rights licensed to us under the License Agreement. We also agreed to pay Skinvisible 25% of any revenues we receive as royalties in the event that we sublicense any licensed products to a third party. The License Agreement also requires that we make a \$5 million payment to Skinvisible upon receiving approval in the US for the first drug product developed using intellectual property licensed thereunder.

Employees

As of December 31, 2021, we had four employees.

Regulatory

General

Government authorities in the United States and other countries extensively regulate, among other things, the pre-clinical and clinical testing, manufacturing, labeling, storage, record-keeping, advertising, promotion, export, marketing and distribution of pharmaceutical products. In the United States, pharmaceutical products are subject to rigorous review under the Federal Food, Drug, and Cosmetic Act, and other federal statutes and regulations.

FDA Approval Process

To obtain approval of our product candidates from the FDA, we must, among other requirements, demonstrate in preclinical studies and well-controlled clinical trials that the product is safe and effective for its intended use and that the manufacturing facilities, processes and controls are adequate to preserve the drug’s identity, strength, quality and purity. The drug approval process generally includes:

- preclinical laboratory tests, *in vitro* and *in vivo* preclinical studies and formulation and stability studies;

- the submission to the FDA of an application for human clinical testing, which is known as an investigational new drug application (“IND”);
- adequate and well-controlled human clinical trials to demonstrate the safety and effectiveness of the drug;
- the submission to the FDA of a new drug application (“NDA”) for a drug; and
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current GMP, (“cGMP”), requirements to assure that the facilities, methods and controls are adequate to preserve the drug’s identity, strength, quality and purity;
- the approval by the FDA of an NDA.

Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. Preclinical trials must also be conducted in accordance with FDA and comparable foreign authorities’ legal requirements, regulations or guidelines, including Good Laboratory Practice (“GLP”). Violations of these regulations can, in some cases, lead to invalidation of the studies, requiring them to be replicated. Before human clinical testing can begin, a sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND, a request for authorization from the FDA to administer an investigational new drug product to humans.

A 30 day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30 day period, the clinical trial proposed in the IND may begin. Clinical trials involve the administration of the investigational drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with good clinical practices (“GCP”), an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND. Clinical trials must be conducted under the supervision of one or more qualified investigators pursuant to protocols detailing, among other things, the objectives of the trial, dosing procedures, subject selection and exclusion criteria and the safety and effectiveness criteria to be evaluated. For each institution where a clinical trial will be conducted, an institutional review board (“IRB”) must review and approve the clinical trial protocol and informed consent form required to be provided to each trial subject or his or her legal representative prior to a clinical trial commencing, and conduct on-going monitoring of the study until completed or termination to assure that appropriate steps are taken to protect the human subjects participating in the research.

The FDA may order the temporary or permanent discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA regulations or presents an unacceptable risk to the clinical trial patients. Imposition of a clinical hold may be full or partial. The IRB will also monitor the clinical trial until completed. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB’s requirements, or may impose other conditions. Additionally, some 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 authorization for whether a trial may move forward at designated checkpoints based on access to certain data from the trial.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

Phase 1: In Phase 1 studies, the product candidate is initially introduced into healthy human volunteers and tested for safety, dosage and tolerability, absorption, distribution, metabolism and excretion and, effect on the body.

Phase 2: Phase 2 studies are conducted in a limited patient population. These studies continue to evaluate safety while gathering preliminary data on effectiveness in patients with the targeted disease or condition.

Phase 3: Phase 3 trials further evaluate efficacy and safety in an expanded patient population, generally at geographically dispersed clinical study sites. These clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide, if appropriate, an adequate basis for product labeling. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the safety and efficacy of the drug. In rare instances, a single Phase 3 trial may be sufficient when either (1) the trial is a large, multicenter trial demonstrating internal consistency and a

statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible or (2) the single trial is supported by other confirmatory evidence. Approval on the basis of a single trial may be subject to a requirement for additional post-approval studies.

Post-approval studies, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval. These studies are used to gather additional information about a product's safety and/or efficacy in patients affected by the therapeutic indication.

After completion of the required clinical testing, an NDA is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing and distribution of the product may begin in the United States. The NDA must include the results of all preclinical, clinical, and other testing and a compilation of data relating to the product's pharmacology, chemistry, manufacture, and controls. The submission of most NDAs is subject to the payment of a substantial application user fee. Under an approved NDA, the applicant is also subject to an annual program fee. These fees typically increase annually. An NDA for a drug that has been designated as an orphan drug is not subject to an application fee, unless the NDA includes an indication for other than a rare disease or condition.

Pursuant to the current Prescription Drug User Fee Act ("PDUFA"), goals, FDA's goal for acting on the submission of an NDA for a new molecular entity is ten months from the date the FDA files the NDA. The FDA conducts a preliminary review of an NDA within 60 days after submission to determine whether it is sufficiently complete to permit substantive review, before determining whether to file the NDA. This two-month preliminary review effectively extends the typical NDA review period to twelve months. In rare cases, the FDA may request additional information rather than file an NDA. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

The FDA may also refer applications for novel pharmaceutical products, as well as pharmaceutical products that present difficult questions of safety or efficacy, to be reviewed by an advisory committee, typically a panel that includes clinicians, statisticians and other experts. for review, evaluation, and a recommendation as to whether the NDA should be approved. The FDA is not bound by the recommendation of an advisory committee, but generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the pharmaceutical product is manufactured. The FDA will not approve the product unless compliance with cGMP is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the respective claimed indication.

Following the FDA's evaluation of an NDA, it will issue an approval letter or a complete response letter ("CRL"). An approval letter authorizes the sponsor to begin commercial marketing of the drug for specific indications. A CRL means that the review cycle of the application is complete and the application will not be approved in its present form. A CRL describes the specific deficiencies in the NDA identified by the FDA and may recommend actions that the applicant might take, including providing additional clinical data, such as an additional Phase 3 trial or other significant and time consuming requirements related to clinical trials, nonclinical studies or manufacturing, to resolve the deficiencies. If a CRL is issued, the sponsor must resubmit the NDA addressing all of the deficiencies identified in the letter, or withdraw the application. Even if the sponsor submits the recommended data and information, the FDA may decide that the NDA does not satisfy the criteria for approval.

As condition to a product's regulatory approval, the FDA may require a sponsor to conduct Phase 4 studies designed to further assess the drug's safety and effectiveness after NDA approval, or may require other testing and surveillance programs to monitor the safety of the approved product. The FDA may also place other conditions on approval including the requirement for a risk evaluation and mitigation strategy ("REMS") to assure the safe use of the drug. A REMS could include medication guides, communication plans to healthcare professionals or other elements to assure safe use, such as provider certification or training, restricted distribution methods, and patient registries.

There are a variety of regulations governing clinical trials and requirements for obtaining marketing approval for pharmaceutical products outside the United States. Whether or not FDA approval has been obtained, approval of a product by the comparable regulatory authorities of foreign countries and regions must be obtained prior to the commencement of marketing the product in those countries. The approval process varies from one regulatory authority to another and the time may be longer or shorter than that required for FDA approval. In the EU, Canada and Australia, regulatory requirements and approval processes are similar, in principle, to those in the United States.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including drugs and biologic products, are required to register and disclose certain clinical trial information on the website www.clinicaltrials.gov. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of a clinical trial are then 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 clinical trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of clinical development programs as well as clinical trial design.

Pediatric Information

Under the Pediatric Research Equity Act (“PREA”), NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug product 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 full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any product with orphan product designation except a product with a new active ingredient that is a molecularly targeted cancer product intended for the treatment of an adult cancer and directed at a molecular target determined by FDA to be substantially relevant to the growth or progression of a pediatric cancer.

The Best Pharmaceuticals for Children Act (“BPCA”) provides a six-month extension of any patent or non-patent exclusivity for a drug if certain conditions are met. Conditions for exclusivity include the FDA’s determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, FDA making a written request for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Expedited Programs

FDA is required to facilitate the development, and expedite the review, of drug products that are intended for the treatment of a serious or life-threatening disease or condition for which there is no effective treatment and which demonstrate the potential to address unmet medical needs for the condition. Fast track designation may be granted for products that are intended to treat a serious or life-threatening disease or condition for which there is no effective treatment and preclinical or clinical data demonstrate the potential to address unmet medical needs for the condition. Fast track designation applies to both the product and the specific indication for which it is being studied. Any product submitted to FDA for marketing, including under a fast track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review.

Priority review may be granted for products that are intended to treat a serious or life-threatening condition and, if approved, would provide a significant improvement in safety and effectiveness compared to available therapies. FDA will attempt to direct additional resources to the evaluation of an application designated for priority review in an effort to facilitate the review.

FDA is also required to expedite the development and review of applications for approval of products that are intended to treat a serious or life-threatening disease or condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. Under the breakthrough therapy program, the sponsor of a new product candidate may request that FDA designate the product candidate for a specific indication as a breakthrough therapy concurrent with, or after, the submission of the IND for the product candidate. FDA must determine if the product candidate qualifies for breakthrough therapy designation within 60 days of receipt of the sponsor’s request. The FDA may take certain actions with respect to breakthrough therapies, including holding meetings with the sponsor throughout the development process, providing timely advice to the product sponsor regarding development and approval, involving more senior staff in the review process, assigning a cross disciplinary project lead for the review team and taking other steps to design the clinical studies in an efficient manner.

Orphan Drug Designation

Pursuant to the Orphan Drug Act, FDA may grant special status, or orphan designation, to a drug intended to treat a rare disease or condition, which is defined as a disease or condition that affects fewer than 200,000 individuals in the United States, or there is no reasonable expectation that the sales of the product will offset the cost of developing and making the drug available in the United States. A request for orphan drug designation must be submitted before the NDA is submitted. Following the grant of orphan designation, FDA will publicly disclose the identity of the therapeutic drug candidate and its potential orphan use. Orphan designation does not shorten the duration of the regulatory review and approval process.

If a drug candidate with orphan designation subsequently receives the first FDA approval for the disease or condition for which it has orphan designation, the drug is entitled to a seven-year period of market exclusivity subject to certain exceptions (e.g., clinical superiority of a subsequent product). This means that FDA may not approve another drug application authorizing another manufacturer to market the same drug for the same indication for seven years. This does not preclude competitors from receiving approval of the same product that has orphan exclusivity for a different indication or a different product for the same indication for which the orphan product has exclusivity. The orphan designation of a drug also provides the sponsor with certain financial incentives including tax credits and waiver of PDUFA fees.

Rare Pediatric Disease Priority Review Voucher Program

Under the Rare Pediatric Disease Priority Review Voucher program, the FDA may award a priority review voucher to the sponsor of an approved marketing application for a product that treats or prevents a rare pediatric disease. The voucher entitles the sponsor to priority review of one subsequent marketing application.

A voucher may be awarded only for an approved rare pediatric disease product application. A rare pediatric disease product application is an NDA for a product that treats or prevents a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years; in general, the disease must affect fewer than 200,000 such individuals in the U.S.; the NDA must be deemed eligible for priority review; the NDA must not seek approval for a different adult indication (i.e., for a different disease/condition); the product must not contain an active ingredient that has been previously approved by FDA; and the NDA must rely on clinical data derived from studies examining a pediatric population such that the approved product can be adequately labeled for the pediatric population. Before NDA approval, FDA may designate a product in development as a product for a rare pediatric disease, but such designation is not required to receive a voucher.

To receive a rare pediatric disease priority review voucher, a sponsor must notify the FDA, upon submission of the NDA, of its intent to request a voucher. If the FDA determines that the NDA is a rare pediatric disease product application and grants priority review, and if the NDA is approved, the FDA will award the sponsor of the NDA a voucher upon approval of the NDA. The FDA may revoke a rare pediatric disease priority review voucher if the product for which it was awarded is not marketed in the U.S. within 365 days of the product's approval.

The voucher, which is transferable to another sponsor, may be submitted with a subsequent NDA or biologics license application ("BLA") and entitles the holder to priority review of the accompanying NDA or BLA. The sponsor submitting the priority review voucher must notify FDA of its intent to submit the voucher with the NDA or BLA at least 90 days prior to submission of the NDA or BLA and must pay a priority review user fee in addition to any other required user fee. FDA must take action on an NDA or BLA under priority review within six months of receipt of the NDA or BLA.

The Rare Pediatric Disease Priority Review Voucher program was reauthorized in the Creating Hope Reauthorization Act in December 2020, allowing a product that is designated as a product for a rare pediatric disease prior to October 1, 2024 to be eligible to receive a rare pediatric disease priority review voucher upon approval of a qualifying NDA or BLA prior to October 1, 2026.

Post-Marketing Obligations

All approved drug products are subject to continuing regulation by the FDA, including record-keeping requirements, reporting of adverse experiences with the product, sampling and distribution requirements, notifying the FDA and gaining approval for certain manufacturing or labeling changes, complying with certain electronic records and signature requirements, submitting periodic reports to the FDA, maintaining and providing updated safety and efficacy information to the FDA, and complying with FDA promotion and advertising requirements. Failure to comply with the statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, seizure of product, injunctive action, criminal prosecution, or civil penalties.

The FDA may require post-marketing studies or clinical trials to develop additional information regarding the safety of a product. These studies or trials may involve continued testing of a product and development of data, including clinical data, about the product's effects in various populations and any side-effects associated with long-term use. The FDA may require post-marketing studies or trials to investigate known serious risks or signals of serious risks or identify unexpected serious risks and may require periodic status reports if new safety information develops. Failure to conduct these studies in a timely manner may result in substantial civil fines.

Drug manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and to list their products with the FDA. The FDA periodically inspects manufacturing facilities in the United States and abroad in

order to assure compliance with the applicable cGMP regulations and other requirements. Facilities also are subject to inspections by other federal, foreign, state or local agencies. In complying with the cGMP regulations, manufacturers must continue to assure that the product meets applicable specifications, regulations and other post-marketing requirements. Any third-party manufacturers must also maintain compliance with all applicable regulations and requirements. Failure to comply with these requirements subjects the manufacturer to possible legal or regulatory action, such as suspension of manufacturing or recall or seizure of product.

Also, newly discovered or developed safety or efficacy data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, additional pre-clinical or clinical studies, or even in some instances, revocation or withdrawal of the approval. Violations of regulatory requirements at any stage, including after approval, may result in various adverse consequences, including the FDA's withdrawal of an approved product from the market, other voluntary or FDA-initiated action that could delay or restrict further marketing, and the imposition of civil fines and criminal penalties against the NDA holder. In addition, later discovery of previously unknown problems may result in restrictions on the product or NDA holder, including withdrawal of the product from the market. Furthermore, new government requirements may be established that could delay or prevent regulatory approval of our products under development, or affect the conditions under which approved products are marketed.

Data Privacy

Numerous federal and state laws, including state security breach notification laws, state health information privacy laws and federal and state consumer protection laws, govern the collection, use and disclosure of personal information. Other countries also have, or are developing, laws governing the collection, use and transmission of personal information. In addition, most healthcare providers who prescribe our product and from whom we obtain patient health information are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). We are not a HIPAA-covered entity and therefore, these privacy and security requirements do not apply to us. However, we could be subject to criminal penalties if we knowingly obtain individually identifiable health information from a covered entity in a manner that is not authorized or permitted by HIPAA or for aiding and abetting the violation of HIPAA. We are unable to predict whether our actions could be subject to prosecution in the event of an impermissible disclosure of health information to us. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing amount of focus on privacy and data protection issues with the potential to affect our business, including recently enacted laws in a majority of states requiring security breach notification. These laws could create liability for us or increase our cost of doing business.

Commercial Product Pricing

In the United States and some foreign jurisdictions, many of the markets in which we may do business in the future, the prices of pharmaceutical products are subject to direct price controls (by law) and to drug reimbursement programs with varying price control mechanisms.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or Medicare Modernization Act, changed the way Medicare covers and pays for pharmaceutical products. The legislation expanded Medicare coverage for drug purchases by the elderly and introduced a new reimbursement methodology based on average sales prices for physician administered drugs. In addition, this legislation provided authority for limiting the number of drugs that will be covered in any therapeutic class in certain cases. Cost reduction initiatives and other provisions of this and other more recent legislation could decrease the coverage and reimbursement that is provided for any approved products. While the Medicare Modernization Act applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from the Medicare Modernization Act or other more recent legislation may result in a similar reduction in payments from private payors.

Healthcare Reform

Healthcare reforms that have been adopted, and that may be adopted in the future, could result in further reductions in coverage and levels of reimbursement for pharmaceutical products, increases in rebates payable under U.S. government rebate programs and additional downward pressure on pharmaceutical product prices. On September 9, 2021, the Biden administration published a wide-ranging list of policy proposals, most of which would need to be carried out by Congress, to reduce drug prices and drug payment. The Department of Health and Human Services, or HHS, plan includes, among other reform measures, proposals to lower prescription drug prices, including by allowing Medicare to negotiate prices and disincentivizing price increases, and to support market changes that strengthen supply chains, promote biosimilars and generic drugs, and increase price transparency. Many similar proposals, including the plans to give Medicare Part D authority to negotiate drug prices, require drug manufacturers to pay rebates on drugs whose prices increase greater than the rate of inflation, and cap out-of-pocket costs, have already been included in policy statements and legislation

currently being considered by Congress. It is unclear to what extent these and other statutory, regulatory, and administrative initiatives will be enacted and implemented.

European Regulatory Authorities

In the European Union, governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of such products to consumers. The approach taken varies from member state to member state. Some jurisdictions operate positive and/or negative list systems under which products may be marketed only once a reimbursement price has been agreed. Other member states allow companies to fix their own prices for medicines, but monitor and control company profits. The downward pressure on healthcare costs in general, particularly prescription drugs, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products, as exemplified by the role of the National Institute for Health and Clinical Excellence in the United Kingdom, which evaluates the data supporting new medicines and passes reimbursement recommendations to the government. In addition, in some countries cross-border imports from low-priced markets (parallel imports) exert commercial pressure on pricing within a country.

Environmental and Safety Laws

We are subject to a variety of federal, state and local regulations relating to the use, handling, storage and disposal of hazardous materials, including chemicals and radioactive and biological materials. Our operations produce such hazardous waste products. Although we believe that our safety procedures for handling and disposing of these materials comply with the standards prescribed by federal, state and local regulations, the risk of accidental contamination or injury from these materials cannot be eliminated. We generally contract with third parties for the disposal of such substances. We are also subject to various laws and regulations governing laboratory practices and the experimental use of animals.

We are also subject to regulation by the Occupational Safety and Health Administration (“OSHA”), and the Environmental Protection Agency (the “EPA”), and to regulation under the Toxic Substances Control Act, the Resource Conservation and Recovery Act and other regulatory statutes, and may in the future be subject to other federal, state or local regulations. OSHA and/or the EPA may promulgate regulations that may affect our research and development programs.

Organizational Structure

We have one wholly-owned subsidiary, Quoin Pharmaceuticals, Inc., a Delaware corporation.

Property, Plants and Equipment

Our principal location is at 42127 Pleasant Forest Ct, Ashburn, VA 20148. We may add new facilities as we add employees, and we believe that suitable additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Legal Proceedings

From time to time, we may become involved in legal proceedings or be subject to claims arising in the ordinary course of our business. We are currently not a party to any material legal or administrative proceedings and except as set forth below, are not aware of any pending or threatened material legal or administrative proceedings against us.

On February 12, 2020, we received a letter from counsel to Kishore Shah and Aruna Shah seeking payment of certain amounts based on a Securities Purchase Agreement with Polytherapeutics, Inc. dated March 24, 2018 (the “Polytherapeutics Agreement”). The amount requested was originally payable, under the terms of the Polytherapeutics Agreement, over a period of 36 months for consulting services to be provided by Kishore Shah (the “Consultant”). The Consultant has not provided any services and has not complied with other technical requirements under the Research Agreement with the Consultant, and therefore is considered to be in breach of contract. The Company and the Consultant have had communications with respect to the duration, commencement date and payment of the consulting services, but a revised agreement has not been reached. No lawsuits have been filed as of the date of this prospectus. Should a formal claim or lawsuit be filed, the Company believes it has meritorious defenses.

MANAGEMENT

Directors and Senior Management

We are managed by a board of directors, which is currently comprised of seven members, and our senior management. Each of our members of senior management is appointed by our board of directors. The table below sets forth the name, age and position of each of our directors and senior management.

Name	Age	Position(s)
Dr. Michael Myers(1)	60	Chairman of the Board of Directors and Chief Executive Officer
Denise Carter	53	Director and Chief Operating Officer
Gordon Dunn	57	Chief Financial Officer
Joseph Cooper(2)(3)(5)	64	Director
James Culverwell(2)(3)	65	Director
Dr. Dennis H. Langer(2)(4)	70	Director
Natalie Leong(2)(3)(5)	37	Director
Michael Sember(2)(4)	72	Director

- (1) The shareholder approval of Dr. Myers serving as our Chairman of the Board of Directors while serving as our Chief Executive Officer was obtained at our 2022 annual general meeting of shareholders held on April 12, 2022 (the “2022 AGM”).
- (2) Indicates an independent director under Nasdaq rules.
- (3) Member of our Audit Committee.
- (4) Member of our Compensation Committee.
- (5) Member of Nominating and Governance Committee.

Set forth below is a biographical summary of each of the above-named directors and senior management.

Dr. Michael Myers, Chief Executive Officer and Director. Dr. Myers is the co-founder of Quoin Inc. and has served as director and Chief Executive Officer of Quoin Inc. since its inception. Dr. Myers has served as director and Chief Executive Officer of Quoin Ltd. since October 28, 2021. Dr. Myers has 35 years of industry experience in the drug delivery and specialty pharmaceutical sectors. He has served CEO of Innocoll, Inc. and was responsible for taking that company public in 2014. During his tenure as CEO of Innocoll, Dr. Myers raised over \$160 million in public and private funding and was the inventor of the company’s lead commercial product. He has also served as President of the drug delivery division of West Pharmaceutical Services, President of pharmaceutical operations for Fuisz Technologies (Biovail) and has held executive positions in Flamel Technologies and Elan Corporation. He is listed as an inventor on numerous patents and has led the development and commercialization of a number of highly successful pharmaceutical products. Dr. Myers earned his Ph.D. in Chemistry from the University College Cork, Ireland. Dr. Myers serves on the Board of Directors of Sonoran Bioscience in addition to the Board of Advisers for a number of Penn State start-up companies.

Denise Carter, Chief Operating Officer and Director. Ms. Carter is the co-founder of Quoin Inc. and has served as director and Chief Operating Officer of Quoin Inc. since its inception. Ms. Carter has served as director and Chief Operating Officer of Quoin Ltd. since October 28, 2021. Ms. Denise Carter has over 30 years of experience in the drug delivery and specialty pharmaceutical industries. Prior to Quoin, Ms. Carter was executive vice president of business development and corporate affairs at Innocoll, Inc., vice president of business development of the drug delivery division of West Pharmaceuticals, and she has held executive positions at Eurand and Fuisz Technologies (Biovail.) Ms. Carter earned her MBA from Wharton School of Business, University of Pennsylvania and a B.S. in Chemistry from the College of William and Mary.

Gordon Dunn, Chief Financial Officer. Mr. Dunn has served as Chief Financial Officer of Quoin Ltd. since November 1, 2021. Mr. Dunn has over 30 years of finance experience. He served as Chief Financial Officer of Qured, a UK-based healthcare provider, from March 2020 to October 2021, and as Chief Financial Officer of U-Research, an online company information platform, from July 2017 to March 2020. Mr. Dunn also served as Chief Financial Officer of Anton Corporation, a film and media finance company, from September 2016 to July 2017, and as Chief Financial Officer of Innocoll AG from 2012-2016. Prior to these roles, he had deep experience in investment banking and private equity, serving as Portfolio Manager of NewSmith Asset Management, a private equity fund from 2004 to 2014, and as Director of Investment Banking and Co-Head of Private Equity at Merrill Lynch, in addition to other roles, from 1994 to 2003. Mr. Dunn was an associate at Morrison & Foerster LLP from 1991 to 1993. Mr. Dunn earned his JD from New York University School of Law and a BA from Stanford University.

Joseph Cooper, Director. Mr. Cooper has served as director of Quoin Inc. since May 2021. Mr. Cooper has served as director of Quoin Ltd. since October 28, 2021. Mr. Cooper brings more than 30 years of experience in operational, corporate development and general management roles within the pharmaceutical industry. He currently serves Chief of Strategy and Corporate Development for Resonea, Inc. Previously he has held a series of general management, operational and strategic roles within pharmaceutical companies including serving 15 years as Executive Vice President of Corporate Development with Medicis Pharmaceutical and previously with Schein Pharmaceuticals and GD Searle. He is a founding board member of First Place AZ, a nonprofit dedicated to developing new housing options for adults with autism and related disorders and has served as a past board member and chair of the Research and Medical Affairs Committee for the Southwest Autism Research & Resource Center. Mr. Cooper holds an MBA from the WP Carey School of Business at Arizona State University and a BA from Northeastern Illinois University. He serves on the board of Sonoran Biosciences, and has previously served on the board of Bioenvision and as a board observer for several specialty pharmaceutical companies.

James Culverwell, Director. Mr. Culverwell has served as director of Quoin Inc. since April 2021. Mr. Culverwell has served as director of Quoin Ltd. since October 28, 2021. Mr. Culverwell was for 25 years a leading healthcare investment analyst, formerly SVP and Global Coordinator Healthcare at Merrill Lynch. He is currently chairman of HOX Therapeutics, a company involved in prostate cancer research, and is a director of TC Biopharm, a NASDAQ listed company developing treatments for cancer based on gamma delta T-cells. He also serves on the board of directors of Safeguard Biosystems, a high throughput molecular diagnostics company. He has been a non-executive director in early stage life science companies, both private and public, including Innocoll, Atlantic Healthcare, ToHealth, Bioco, and Amryt Pharmaceuticals. He received an MSc with honors from the University of Aberdeen.

Dennis H. Langer, M.D., J.D., Director. Dr. Langer has served as director of Quoin Inc. since 2019. Dr. Langer has served as director of Quoin Ltd. since October 28, 2021. Dr. Langer is a Director of Myriad Genetics, Inc., and Brooklyn ImmunoTherapeutics, Inc., and several private health care companies. He has served as a Director of several public and private biotechnology, specialty pharmaceutical and diagnostic companies, including Sirna Therapeutics, Inc. (acquired by Merck & Co., Inc.), Ception Therapeutics, Inc. (acquired by Cephalon, Inc.), Transkaryotic Therapies, Inc. (acquired by Shire plc), Pharmacopeia, Inc. (acquired by Ligand, Inc.), and Cytogen Corporation (acquired by EUSA Pharma, Inc.). He was a Managing Partner at Phoenix IP Ventures, LLC from 2005-2010. From 2004-2005, he was President, North America for Dr. Reddy's Laboratories, Inc. Dr. Langer was with GlaxoSmithKline from 1994-2004, where he served as Senior Vice President, Project, Portfolio and Alliance Management, Senior Vice President, Product Development Strategy, and Senior Vice President, Healthcare Services R&D. He also served as President and CEO at Neose Technologies, Inc. from 1991-1994. Previously, Dr. Langer held R&D and marketing positions at Eli Lilly, Abbott, and Searle. During the past five years, Dr. Langer served as a Director of Dicerna Pharmaceuticals, Inc. and Pernix Therapeutics, Inc., both public companies. Dr. Langer serves on the Dean's Advisory Board of Harvard Law School. He received an M.D. from Georgetown University School of Medicine, a J.D. from Harvard Law School, and a B.A. in Biology from Columbia University.

Natalie Leong, Director. Ms. Leong has served as director of Quoin Inc. since April 2021. Ms. Leong has served as director of Quoin Ltd. since October 28, 2021. Ms. Leong has been Head of Finance and subsequently Head of Product for LoanStreet since October 2019. In this and other advisory roles for start-ups, Ms. Leong specializes in valuations, product development life cycles, financial operations and internal controls. Ms. Leong has worked with companies across Asia, Australia, Europe and the US in valuation and implementation of transactions through sale, IPO, float and raising capital from various sources. She has broad experience analyzing business plans, performing market analyses, preparing financial projections and developing valuation models to advise clients throughout the process of equity transactions, mergers and acquisitions and corporate restructurings. From May 2016 to July 2019, Ms. Leong served as the lead for the Asset Liability Committee for the US at RBC Capital Markets, liaising with Heads of businesses, US CFO, US CRO, and US Treasurer and authoring the CFO's presentation to the Board. In addition, she led FPA for fixed income and origination businesses. From October 2011 to May 2016, Ms. Leong worked as the VP of Capital Insights at National Australia Bank. During these years, Ms. Leong managed and presented at the Group Capital Committee (Group and Divisional CFOs, Treasurer, MD M&A, MD Credit. From February 2008 to October 2011, Ms. Leong specialized in internal controls across retail, corporate and wholesale banking at National Australia Bank. Ms. Leong earned her MBA at The Wharton School, University of Pennsylvania. She earned a B.Comm degree (Finance and Economics) and a B.A. degree (French and Literature) from the University of Melbourne in 2007.

Michael Sember, Director. Mr. Sember has served as director of Quoin Inc. since May 2021. Mr. Sember has served as director of Quoin Ltd. since October 28, 2021. Mr. Sember has over 40 years of global experience in the pharmaceutical industry. He is an accomplished executive, entrepreneur, leader and mentor. Sember has been the COO or CEO of seven diverse companies ranging from drug discovery tools providers to therapeutically focused biotechnology companies to medical devices. Mr. Sember has also been active as a consultant to numerous companies, as well as active in industry organizations and community affairs. Most recently he served as a mentor to companies formed from inventions discovered at the University of Arizona. Currently, Mr. Sember serves as the Chair of the Screening Panel and Board member for the Desert Angels, a Tucson based group of angel investors. Desert Angels was recently ranked as number 1 in the Southwest and number 8 in the Country based on deal activity. The foundation of Mr. Sember's career was established at Marion Laboratories (later Marion Merrell Dow). Mr. Sember performed in a wide range of functions from sales to clinical research and later to R&D program management. Following Marion Merrell Dow, Mr. Sember was Executive VP of Corporate Business Development for Élan Corporation, responsible for strategic collaborations and mergers and acquisitions. Mr. Sember has extensive public and private board experience. He has broad experience in capital raises for both established and startup companies. Mr. Sember earned a Bachelor of Science degree from the University of Pittsburgh and an MBA from Rockhurst University.

Family Relationships

There are no family relationships among any of the individuals listed in this Section A (Directors and Senior Management).

Arrangements Involving Directors and Senior Management

There are no arrangements or understandings, of which we are aware, relating to the election of our directors or the appointment of our executive officers.

Compensation

Aggregate Executive Compensation

The aggregate remuneration paid or accrued by us for the year ended December 31, 2021 to all persons listed in Section A (Directors and Senior Management) above, was approximately \$2,164,000. This sum includes \$88,000 paid for automobiles made available to our executive officers, and other fringe benefits pursuant to employment agreements with executive officers. See “— Agreements with Executive Officers” below for the description of employment agreements with our executive officers.

Dr. Myers and Ms. Carter do not receive compensation for their service as our directors. See “—Board Practices—Remuneration of Directors” below.

The term “office holder” under the Companies Law means a director, a Chief Executive Officer, or another officer who occupies a general or chief management position, or serves in a position directly secondary to or directly reporting to the Chief Executive Officer.

Individual Compensation of Executive Officers

The table below presents the compensation granted to our five most highly compensated office holders during or with respect to the year ended December 31, 2021. We refer to the three individuals currently employed as Chief Executive Officer, Chief Operating Officer and Chief Financial Officer for whom disclosure is provided herein as our “Covered Office Holders.” All amounts specified below are in terms of cost to Quoin Ltd., as recorded in our financial statements.

For purposes of the table and the summary below “compensation” includes base salary, bonuses, retirement or termination payments, benefits and perquisites such as office allowance and automobile allowance, and any undertaking to provide such compensation. No equity-based compensation was granted to our Covered Office Holders in 2021.

Name and Principal Position	Base Salary (\$)	Bonus ⁽¹⁾ (\$)	All Other Compensation ⁽²⁾ (\$)	Total ⁽³⁾ (\$)
Dr. Michael Myers, Chief Executive Officer	\$ 518,500	\$ 427,500	\$ 44,000	\$ 990,000
Denise Carter, Chief Operating Officer	\$ 416,000	\$ 342,000	\$ 44,000	\$ 802,000
Gordon Dunn, Chief Financial Officer	\$ 60,000	\$ 57,000	—	\$ 117,000

(1) Amounts reported in this column refer to cash bonuses for the year ended December 31, 2021 (including transaction cash bonuses paid in 2021). Discretionary cash bonuses are our contractual arrangements and were granted in recognition of the applicable Covered Officer Holder’s promotion of our long-term goals, strategy and operating plan, the need to form appropriate incentives for our officers, and their contribution to the achievement of our objectives in accordance with their respective corporate roles. In addition, amounts reported in this column include a transaction bonus related to the completion of the Merger and private placement transactions discussed in “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

(2) Amounts reported in this column include amounts paid as office allowance, automobile allowance.

At the 2022 AGM, our shareholders approved option grants to Dr. Myers and Ms. Carter (shareholder approval was not required for the grant to Mr. Dunn) as follows:

- an option to purchase up to 1,071,429 ADSs to Dr. Myers, at an exercise price per ADS of USD \$1.40, to vest over a four-year period, with 25% of the ADSs to be vested one year from the date of such grant, and the balance vesting on an annual basis thereafter (25% each year); and
- an option to purchase up to 1,071,429 ADSs to Ms. Carter, at an exercise price per ADS of USD \$1.40, to vest over a four-year period, with 25% of the ADSs to be vested one year from the date of such grant, and the balance vesting on an annual basis thereafter (25% each year).

In addition, our board has approved the grant of an option to purchase up to 892,857 ADSs to Mr. Dunn, at an exercise price per ADSs of USD \$1.40, to vest over a four-year period, with 25% of the ADS to be vested one year from the date of such grant, and the balance vesting on an annual basis thereafter (25% each year).

Compensation of Directors

Under our non-employee directors’ compensation program, non-employee directors are entitled to receive the following cash compensation for their services:

- each non-employee director receives an annual base retainer of \$60,000.
- each committee chairperson receives an additional retainer of \$15,000 for his or her service as a chairperson.
- each member of a standing committee receives an additional retainer of \$5,000 for such service on a standing committee.

In addition to cash compensation, our non-employee directors are also entitled to equity awards under our director compensation policy. Each non-employee director who first joins the Board of Quoin Ltd. is automatically granted an inaugural award of options to purchase ordinary shares represented by ADSs of Quoin Ltd. valued at \$165,000. In addition, each non-employee director receives an annual award of options valued at \$60,000.

Non-employee directors who joined the Board of Directors of Quoin Ltd. subsequent to the execution of the Merger Agreement received their cash and equity compensation on a prorated basis in 2021.

At the 2022 AGM, our shareholders approved, pursuant to and in line with our non-employee directors' compensation program, the following option grants to each of our non-employee directors:

- as an inaugural grant, an option to purchase 117,857 ADS under the Amended and Restated Equity Incentive Plan, at an exercise price per ADS of USD \$1.40, to vest over a three-year period, with one third of such options to be vested one year from the date of such grant and the balance vesting on annual basis thereafter (one-third every year), all in accordance with and subject to the terms and conditions of the Amended and Restated Equity Incentive Plan; and
- as an annual grant for 2022, an option to purchase 42,857 ADS under the Amended and Restated Equity Incentive Plan, at the same exercise price and as per the same vesting schedule as set forth above.

The following table sets forth information concerning the compensation awarded to, earned by or paid to non-employee directors for the year ended December 31, 2021.

Name	Fees Earned or Paid in Cash (\$)	Total (\$)
Joseph Cooper	\$ 45,000	\$ 45,000
James Culverwell	\$ 60,000	\$ 60,000
Dr. Dennis H. Langer	\$ 60,000	\$ 60,000
Natalie Leong	\$ 45,000	\$ 45,000
Michael Sember	\$ 45,000	\$ 45,000

Agreements with Executive Officers

We maintain written employment agreements with our Covered Office Holders that contain customary provisions, including non-compete and confidentiality agreements.

Dr. Myers. Pursuant to his Executive Employment Agreement with Quoin Inc., dated March 9, 2018, which was amended as of November 9, 2021 (as amended, the "Myers Agreement"), Dr. Myers is entitled to an annual base salary of \$550,000, which accrued monthly until paid by Quoin Inc. Dr. Myers may also receive, subject to employment by us on the applicable date of bonus payout, an annual target discretionary bonus of not less than 45% of his annual base salary, payable at the discretion of the board of directors after approval of our compensation committee, subject to shareholder approval by a Special Majority for Compensation Matters. See "—Board Practices—Compensation Committee and Compensation Policy." Pursuant to the Myers Agreement, Dr. Myers is also eligible to receive healthcare benefits as may be provided from time to time by us to our employees generally, and to receive paid time off annually in accordance with our policies in effect from time to time. Additionally, the Myers Agreement provides Dr. Myers with a monthly office allowance of \$2,500 and a monthly automobile allowance of \$1,500.

Ms. Carter. Pursuant to her Executive Employment Agreement with Quoin Inc., dated March 9, 2018, which was amended as of November 9, 2021 (as amended, the "Carter Agreement"), Ms. Carter is entitled to an annual base salary of \$440,000, which accrued monthly until paid by Quoin Inc. Ms. Carter may also receive, subject to employment by us on the applicable date of bonus payout, an annual target discretionary bonus of not less than 45% of her annual base salary, payable at the discretion of the board of directors after approval of our compensation committee, subject to shareholder approval by a Special Majority for Compensation Matters. See "—Board Practices—Compensation Committee and Compensation Policy." Pursuant to the Carter Agreement, Ms. Carter is also eligible to receive healthcare benefits as may be provided from time to time by us to our employees generally, and to receive paid time off annually in accordance with Quoin's policies in effect from time to time. Additionally, the Carter Agreement provides Ms. Carter with a monthly office allowance of \$2,500 and a monthly automobile allowance of \$1,500.

Mr. Dunn. Pursuant to his Service Agreement with Quoin Inc., dated November 1, 2021 (as amended, the "Dunn Agreement"), Mr. Dunn is entitled to an annual base salary of \$360,000. In addition, Mr. Dunn is entitled to receive (i) a signing bonus equal to one-twelfth of his annual base salary, and (ii) subject to employment by us on the applicable date of bonus payout, an annual target discretionary bonus of not less than 45% of his annual base salary, payable at the discretion of the Board, which will be prorated for 2021. Under the Dunn Agreement, upon our adoption of a stock option plan, we are obligated to grant an option to Mr. Dunn to purchase our ordinary shares, with \$1.25 million grant date value, subject to the terms of such plan. Mr. Dunn is also eligible to receive healthcare benefits as may be provided from time to time by us to our employees generally and paid time off annually in accordance with our policies in effect from time to time.

Compensation Upon Termination of Employment

Pursuant to each of the Myers Agreement and the Carter Agreement, Dr. Myers and Ms. Carter, respectively, are entitled to the following benefits upon termination of their employment:

- **Termination for any reason:** Upon the termination of such executive's employment for any reason, such executive will receive (i) his or her Base Salary (as defined in the Myers Agreement or the Carter Agreement, as applicable) through the Exit Date (as defined in the Myers Agreement or the Carter Agreement, as applicable), (ii) any Bonuses (as defined in the Myers Agreement or the Carter Agreement, as applicable) to which he or she is entitled and has already earned for the prior fiscal year, and (iii) any other accrued or vested benefits or reimbursements through the Exit Date to which such executive is entitled to contractually or by operation of law.
- **Termination upon death or Disability:** In the event of the executive's termination due to his or her death or Disability (as defined in the Myers Agreement or the Carter Agreement, as applicable), then, in addition to the payments set forth above, the executive will receive his or her pro rata portion of the Bonus such executive would have been entitled to receive for the fiscal year in which the Exit Date occurs, based upon the percentage of the fiscal year that elapsed through the Exit Date. Additionally, in the event of termination due to Disability, the executive will receive, for a period of 24 months following the Exit Date, such executive monthly COBRA premium.
- **Termination without Cause or for Good Reason:** In addition to the payments set forth in the first bullet above, if Dr. Myers or Ms. Carter is terminated by the Company without Cause (as defined in the Myers Agreement or the Carter Agreement, as applicable), or Dr. Myers or Ms. Carter terminates his or her employment for Good Reason (as defined in the Myers Agreement or the Carter Agreement, as applicable), he or she will be entitled to receive (i) his or her Base Salary for 2 years from the Exit Date and 2 times the current years' Bonus, and (ii) continuation of such executive's medical benefits for 2 years from the Exit Date (unless the executive becomes employed elsewhere during such 2 year period and is eligible to receive comparable medical benefits).

As a condition precedent to receiving any of the foregoing benefits, Dr. Myers and/or Ms. Carter, as applicable, must first sign a Release (as defined in the Myers Agreement or the Carter Agreement, as applicable).

Mr. Dunn, pursuant to the Dunn Agreement, is also entitled to the following benefits upon termination of his employment:

- **Garden Leave:** During any period of notice to terminate Mr. Dunn's employment, Mr. Dunn will continue to be entitled to his basic salary and contractual benefits in the usual course.
- **Payment in lieu of notice:** Upon the termination of Mr. Dunn's employment at any time, Mr. Dunn will receive payment equal to his basic salary as of the termination date which he would have been entitled to receive under the Dunn Agreement during the notice period referred to in the bullet below, less income tax and national insurance contributions. Payment in lieu of notice will not include (i) any bonus or commission payments that might otherwise have been paid to Mr. Dunn during the period for which such payment in lieu of notice is made, (ii) benefits Mr. Dunn would have been entitled to during such time, and (iii) holiday entitlement that would have accrued during such time.
- **Termination:** Subject to successful completion of the probationary employment period as set forth in the Dunn Agreement, and except in connection with certain "for cause" events, as set forth in Section 20.2 of the Dunn Agreement, the Company may terminate Mr. Dunn's employment by giving at least 12 months' prior written notice, and is obligated to continue paying Mr. Dunn his basic salary and other benefits during such notice period.

The foregoing descriptions of the Myers Agreement, the Carter Agreement and the Dunn Agreement do not purport to be complete and are qualified in their entirety by reference to the complete text of the Myers Agreement, the Carter Agreement and the Dunn Agreement, filed as exhibits to the registration statement, of which this prospectus forms a part.

Board Practices

Corporate Governance Practices

We are incorporated in Israel and therefore are subject to various corporate governance practices under the Companies Law, relating to matters such as audit and compensation committees, internal auditor and approvals of interested parties transactions. These matters are in addition to the Nasdaq rules and relevant provisions of U.S. securities laws. Under applicable Nasdaq rules, a foreign private issuer such as us may generally follow its home country rules of corporate governance in lieu of comparable Nasdaq rules, except for certain matters such as composition and responsibilities of the audit committee and the independence of its members. See “Risk Factors—As a “foreign private issuer,” we are permitted, and intend, to follow certain home country corporate governance practices instead of otherwise applicable SEC and Nasdaq requirements, which may result in less protection than is accorded to investors under rules applicable to domestic U.S. issuers.” above.

Board of Directors

Under the Companies Law and our articles of association, our board of directors directs our policy and supervises the performance of our Chief Executive Officer. Our board of directors may exercise all powers and may take all actions that are not specifically granted to our shareholders or to management. Our executive officers are responsible for our day-to-day management and have individual responsibilities established by our board of directors. Our Chief Executive Officer is appointed by, and serves at the discretion of, our board of directors. All of our other executive officers are also appointed by our board of directors, and are subject to the terms of any applicable employment or service agreements that we may enter into with them or with certain entities through which we receive their services.

All of our directors other than Dr. Michael Myers and Denise Carter, are independent under the Nasdaq rules.

Under our articles of association, our board of directors must consist of at least five and not more than eight directors (including External Directors, if and to the extent any External Directors are appointed – see External Directors below). Our board of directors currently consists of seven members.

Other than External Directors (if and to the extent “External Directors” are appointed), our directors are elected by an ordinary resolution at the annual and/or a special general meeting of our shareholders. Because our ordinary shares do not have cumulative voting rights in the election of directors, the holders of a majority of the voting rights represented at a shareholders meeting have the power to elect all of our directors, subject to the special approval requirements for External Directors, if and to the extent External Directors are appointed.

In addition, our articles of association allow our board of directors to appoint directors from time to time, until that director’s dismissal by a resolution at an annual or special general meeting of shareholders, or the conclusion of that director’s term of office in accordance with our articles of association or any applicable law, subject to the maximum number of directors allowed under our articles of association. If required to be appointed, External Directors are elected for an initial term of three years by a special majority at an annual or special general meeting of shareholders, and may be re-elected for up to two additional three-year terms and, under certain circumstances, for an indefinite number of additional three-year terms. External Directors, if required to be appointed, may be removed from office only under the limited circumstances set forth in the Companies Law.

Under the Companies Law, our board of directors must determine the minimum number of directors who are required to have “accounting and financial expertise,” as that term is defined under Section 240 of the Companies Law and regulations promulgated pursuant thereto. In determining the number of directors required to have such expertise, our board of directors must consider, among other things, the type and size of the company and the scope and complexity of its operations. Our board of directors has determined that the minimum number of directors of our company who are required to have accounting and financial expertise is three. Our board of directors has determined that James Culverwell, Joseph Cooper and Natalie Leong possess such accounting and financial expertise.

Chairman of the Board

Our articles of association provide that the Chairman of the board of directors is appointed by the members of the board of directors and serves as Chairman of the board of directors throughout his term as a director, unless resolved otherwise by the board of directors. Under the Companies Law, the Chief Executive Officer or a relative of the Chief Executive Officer may not serve as the Chairman of the board of directors, and the Chairman or a relative of the Chairman may not be vested with authorities of the Chief

Executive Officer, unless such service or the vesting of such authority is approved, for a period not greater than three years, by a majority vote of the shares present and voting at an annual or special general meeting of shareholders, provided that either:

- such majority includes at least a majority of the shares held by all shareholders who are not controlling shareholders and do not have a personal interest in such appointment, present and voting at such meeting (not including abstaining shareholders); or
- the total number of shares of non-controlling shareholders and shareholders who do not have a personal interest in such appointment voting against such appointment does not exceed 2% of the aggregate voting rights in the company.

A "controlling shareholder" under the Companies Law generally means a person (where a corporation and its affiliates, as well as an individual and family members sharing a residence or dependent upon each other for their livelihood, are deemed to be a single person), or persons acting together (whether by means of any trust, syndicate, voting arrangement or other arrangement) which, whether directly or indirectly, enjoys a *de facto* ability to direct a company's affairs, other than by exercise of official duty as a director or officer of the company or from any other position with the company, with holdings by such person or persons of 50% or more of the rights to (x) vote in a shareholders' meeting, or (y) appoint the company's directors or its chief executive officer, creating a rebuttable presumption of "control."

In addition, a person subordinated, directly or indirectly, to the Chief Executive Officer may not serve as the Chairman of the board of directors; the Chairman of the board of directors may not be vested with authorities that are granted to those subordinated to the Chief Executive Officer; and the Chairman of the board of directors may not serve in any other position in the company or a controlled company, other than as a director or Chairman of a controlled company.

Dr. Michael Myers has served as the chief executive officer and chairman of the board of Quoin Pharmaceuticals, Inc., a Delaware company and our wholly-owned subsidiary, since its inception. Effective as of the closing of the Merger on October 28, 2021, Dr. Myers was appointed to our board of directors and employed as our Chief Executive Officer, and has been acting as chairman pro tempore of our board of directors. Based on the recommendation of our nominating and governance committee, our board of directors has recommended that our shareholders ratify and approve the service of Dr. Myers as both Chief Executive Officer and Chairman of the Board, for a three-year period commencing on October 28, 2021, and which was so ratified and approved at the annual general meeting of shareholders on April 12, 2022.

External Directors

Subject to certain exceptions referred to below, under the Companies Law, an Israeli company whose shares have been offered to the public or whose shares are listed for trading on a stock exchange in or outside of Israel is required to appoint to its board of directors at least two "external directors" as that term is defined under the Companies Law ("**External Directors**"). External Directors must meet stringent standards of independence, must possess certain professional qualifications, must be elected and can only be dismissed in a prescribed manner, and may be compensated for their service only within certain defined parameters, all of the above as set forth in the Companies Law and regulations promulgated thereunder.

Regulation 5D of the Israeli Companies Regulations (Relief for Public Companies with Shares Listed for Trading on a Stock Market Outside of Israel), 5760-2000 ("Regulation 5D"), allows public companies satisfying certain conditions set out in those regulations, to "opt out" from having to appoint External Directors to its board of directors, and exempts such companies from the requirements under the Companies Law to appoint External Directors to committees of the board of directors (including the audit and compensation committees). A public company may be exempted under Regulation 5D if its securities are not listed in Israel and are listed on certain foreign exchanges, including Nasdaq, and the company: (x) satisfies the laws and regulations (including listing standards) regarding the appointment of independent directors and the composition of audit and compensation committees which apply to companies that are organized in the country in which the qualified foreign exchange operates; and (y) has no controlling shareholder, *provided that* (z) if at the time of the election or appointment of any director the members of the Board are of one gender, a director of the opposite gender shall be elected or appointed.

For so long as we do not have a controlling shareholder, we believe we will satisfy the conditions set out in Regulation 5D and, accordingly, pursuant to a resolution of our board of directors adopted on March 3, 2022, we have "opted out" from the requirements of the Companies Law that would otherwise have required us to appoint External Directors to our board of directors and appoint External Directors to various committees of the board.

At any point in time, should we cease to satisfy the conditions set out in Regulation 5D, or should our board adopt a resolution to cease to avail ourselves of Regulation 5D, we will then convene a general meeting of shareholders to elect External Directors to our board of directors as required under the Companies Law, and following such election, we will re-constitute the membership of our audit committee, compensation committee, and any other committees exercising a power of our board of directors (to the extent necessary and applicable), in the manner prescribed under the Companies Law.

We set down below certain of the rules and requirements under the Companies Law relating to External Directors in the event we cease to satisfy the conditions set out in Regulation 5D or in the event, due to a board resolution, we decide to "opt-in" to the appointment of External Directors.

According to the Companies Law and the regulations promulgated thereunder, an External Director must have either "accounting and financial expertise" or "professional expertise," as those terms are defined in such regulations. At least one of our External Directors (if and to the extent we are required to appoint External Directors), must have "financial and accounting expertise" as defined under the Companies Law, unless a member of the audit committee, who is an independent director with financial and accounting expertise under the Nasdaq Capital Market rules and has independence from any controlling shareholder of the Company in the manner required of External Directors, has "financial and accounting expertise." An External Director is considered to have "professional expertise" if he or she holds an academic degree in certain fields or has at least five years of experience in certain senior positions.

The provisions of the Companies Law set out special approval requirements for the election and term of service of External Directors. External Directors must be elected by a majority vote of the shares present and voting at a general meeting of shareholders, provided that either:

- such majority includes at least a majority of the shares held by all shareholders who are not controlling shareholders and do not have a personal interest in the election of the External Director (other than a personal interest not deriving from a relationship with a controlling shareholder) that are voted at the meeting, excluding abstentions; or
- the total number of shares voted by shareholders who are not controlling shareholders and who do not have a personal interest in the election of the External Director (other than a personal interest not deriving from a relationship with a controlling shareholder), against the election of the External Director, does not exceed 2% of the aggregate voting rights in the company.

The initial term of an External Director is three years. Thereafter, an External Director may be reelected by shareholders to serve in that capacity for up to two additional three-year terms, except as provided below, provided that either:

- his or her service for each such additional term is recommended by one or more shareholders holding at least 1% of the company's aggregate voting rights and is approved at a shareholders meeting by a majority of those shareholders who are not controlling shareholders and do not have a personal interest in such election (other than a personal interest not deriving from a relationship with a controlling shareholder), provided that the total number of shares held by shareholders voting for such re-election who are not controlling shareholders and do not have a personal interest in such re-election (other than a personal interest not deriving from a relationship with a controlling shareholder) exceeds 2% of the aggregate voting rights in the company. In such event, the External Director so reappointed may not be a Related or Competing Shareholder, as defined below, or a relative of such shareholder, at the time of the appointment, and is not and has not had any affiliation with a Related or Competing Shareholder, at such time or during the two years preceding such person's reappointment to serve an additional term as external director. The term "Related or Competing Shareholder" means a shareholder proposing the reappointment or a shareholder holding 5% or more of the outstanding shares or voting rights of the company, provided that, at the time of the reappointment, such shareholder, the controlling shareholder of such shareholder, or a company controlled by such shareholder, have a business relationship with the company or are competitors of the company; or
- his or her service for each such additional term is recommended by the board of directors and is approved at a shareholders meeting by the same majority required for the initial election of an External Director (as described above).

The term of office for External Directors for Israeli companies traded on certain foreign stock exchanges, including the Nasdaq Capital Market, may be extended for an indefinite number of additional three-year terms, in each case provided that the audit committee and the board of directors of the company confirm that, in light of the External Director's expertise and special contribution to the work of the board of directors and its committees, the reelection for such additional period(s) is beneficial to the company, and

provided that the External Director is re-elected subject to the same shareholder vote requirements as if elected for the first time (as described above). Prior to the approval of the re-election of the External Director at a general meeting of shareholders, the company's shareholders must be informed of the term previously served by him or her and of the reasons why the board of directors and audit committee recommended the extension of his or her term.

An External Director may be removed from office before the expiration of his or her term only upon his or her disqualification to serve as a director of the Company, or by the determination of either: (1) a court, or (2) a special general meeting of shareholders acting to dismiss the External Director by the same shareholder vote percentage required for the External Director's election, that the statutory qualifications required of an External Director have ceased to apply, or that the External Director has violated his or her duty of loyalty to the company. If any of the conditions which the Companies Laws requires of an External Director ceases to exist, that External Director must inform the Company forthwith, and his or her term will expire effective from the Company's receipt of such notice. If an External Directorship becomes vacant and there are fewer than two External Directors on the board of directors at the time, then the board of directors is required under the Companies Law to call a shareholders meeting as soon as practicable to appoint a replacement External Director.

External Directors may be compensated only in accordance with regulations adopted under the Companies Law.

Each committee of the board of directors that is authorized to exercise the powers of the board of directors must include at least one External Director; the audit committee and the compensation committee must include all External Directors then serving on the board of directors, and the audit and compensation committee must meet certain composition requirements (as will be described below), all of the above being applicable to us only in the event that we cease to satisfy the conditions set out in Regulation 5D, or if our board of directors adopts a resolution to cease to avail ourselves of Regulation 5D.

Committees of the Board of Directors

Our board of directors has established three standing committees, the audit committee, the compensation committee and the nominating and governance committee.

Audit Committee

Our audit committee consists of James Culverwell, Joseph Cooper and Natalie Leong. James Culverwell serves as Chairman of the audit committee.

Under the Companies Law and our articles of association, the audit committee must be comprised of at least three directors. The audit committee elects its own Chairman. The audit committee may not include the Chairman of the board of directors, a controlling shareholder of the company, certain relatives of a controlling shareholder, a director employed by or providing services on a regular basis to a controlling shareholder or to an entity controlled by a controlling shareholder, or a director most of whose livelihood depends on a controlling shareholder.

If we cease to satisfy the conditions set out in Regulation 5D, or if our board resolution adopts a resolution to cease to avail ourselves of Regulation 5D, then the Chairman of the audit committee must be an External Director, all the External Directors must be members of the audit committee, and a majority of the audit committee's members must be either External Directors or independent directors (either as "independent director" is defined under the Companies Law, or in keeping with Nasdaq Capital Market rules regarding independent directors, provided that such independent director has independence from any controlling shareholder of the Company in the manner required of External Directors).

Under the Nasdaq corporate governance rules, we are required to maintain an audit committee consisting of at least three independent directors, each of whom is financially literate and one of whom has accounting or related financial management expertise.

All members of our audit committee meet the requirements for financial literacy under the applicable rules and regulations of the SEC and Nasdaq corporate governance rules. Our board of directors has determined that each member of the audit committee is an audit committee financial expert, as defined by the SEC rules, and have the requisite financial sophistication as required by the Nasdaq Capital Market corporate governance rules.

Each of the members of the audit committee is deemed "independent" as such term is defined in Rule 10A-3(b)(1) under the Exchange Act, according to which an audit committee member is barred from accepting any consulting, advisory or other

compensatory fee from the company or any subsidiary thereof, other than in the member's capacity as a member of the board of directors, and may not be an affiliated person of the company or any subsidiary of the company apart from his or her capacity as a member of the board of directors and any committee of the board of directors.

On March 3, 2022, our board of directors adopted an amended and restated audit committee charter that sets forth the responsibilities of the audit committee consistent with the rules of the SEC and Nasdaq listing rules, as well as the requirements for such committee under the Companies Law, including the following:

- overseeing our independent registered public accounting firm and recommending the engagement, compensation or termination of engagement of our independent registered public accounting firm to the board of directors in accordance with Israeli law;
- recommending the engagement or termination of the person filling the office of our internal auditor; and
- recommending the terms of audit and non-audit services provided by the independent registered public accounting firm for pre-approval by our board of directors.

Our audit committee provides assistance to our board of directors in fulfilling its legal and fiduciary obligations in matters involving our accounting, auditing, financial reporting, internal control and legal compliance functions by pre-approving the services performed by our independent accountants and reviewing their reports regarding our accounting practices and systems of internal control over financial reporting. Our audit committee also oversees the audit efforts of our independent accountants and takes those actions that it deems necessary to satisfy itself that the accountants are independent of management.

Under the Companies Law, our audit committee is responsible for:

- determining whether there are deficiencies in the business management practices of our company, including in consultation with our internal auditor or the independent auditor, and making recommendations to the board of directors to improve such practices;
- determining the approval process for transactions that are 'non-negligible' (i.e., transactions with a controlling shareholder that are classified by the audit committee as non-negligible, even though they are not deemed extraordinary transactions), as well as determining which types of transactions would require the approval of the audit committee, which determination may be based on annually pre-determined criteria;
- determining whether to approve certain related party transactions (including transactions in which an office holder has a personal interest and whether such transaction is extraordinary or material under the Companies Law) (see "—Approval of Related Party Transactions under Israeli Law");
- examining the work plan of the internal auditor before its submission to our board of directors and proposing amendments thereto or, upon a decision of the board of directors, acting as the corporate body to approve such work plan;
- examining our internal controls and internal auditor's performance, including whether the internal auditor has sufficient resources and tools at his disposal to fulfill his responsibilities;
- examining the scope of our external auditor's work and compensation and submitting a recommendation with respect thereto to our board of directors; and
- establishing procedures for the handling of employees' complaints as to the management of our business and the protection to be provided to such employees.

Compensation Committee and Compensation Policy

Under the Companies Law, the board of directors of a public company must appoint a compensation committee. Under the corporate governance rules of Nasdaq, we are required to maintain a compensation committee consisting of at least two independent directors .

On March 3, 2022, our board of directors adopted an amended and restated compensation committee charter that sets forth the responsibilities of the compensation committee consistent with the rules of the SEC and Nasdaq listing rules, as well as the requirements for such committee under the Companies Law.

If we cease to satisfy the conditions set out in Regulation 5D, or if due to a resolution adopted by the board of directors we cease to avail ourselves of Regulation 5D, then:

- the compensation committee must consist of no less than three members;
- all the External Directors must be members of the compensation committee,
- a majority of the compensation committee's members must be External Directors,
- the chairman of the compensation committee must be an External Director; and
- any person not qualified to be a member of the audit committee (as described above) will not be qualified to be a member of the compensation committee, and the compensation of any member serving on the compensation committee will be subject to the same regulations governing the compensation payable to External Directors.

Our compensation committee consists of Dennis Langer and Michael Sember. Dennis Langer serves as Chairman of the compensation committee.

- Under the Companies Law and Nasdaq rules, our compensation committee is responsible for, among other things: recommending to our board of directors a policy regarding the terms of engagement of the company's office holders, to which we refer as a "compensation policy";
- recommending whether the compensation policy should continue in effect, if the then-current policy has a term of greater than three years (approval of either a new compensation policy or the continuation of an existing compensation policy must in any case occur every three years);
- recommending to the board of directors updates to the compensation policy from time to time;
- assessing implementation of the compensation policy;
- the initial approval of transactions regarding the terms of compensation for all office holders, subject to further approvals that may be required by the board of directors and/or a general meeting of shareholders, depending on the circumstances;
- deciding, under the special circumstances set forth in the Companies Law, whether to exempt the approval of terms and conditions of a Chief Executive Officer's service from the requirement of shareholder approval;
- approving non-material amendments to the compensation arrangement of an office holder who is not a director;
- making other determinations that the Companies Law assigns to a compensation committee;
- reviewing and recommending for approval by the board of directors the overall compensation policies with respect to our Chief Executive Officer and other executive officers;
- reviewing and recommending for approval by the board of directors the corporate goals and objectives relevant to the compensation of our Chief Executive Officer and other executive officers;
- evaluating the performance of our Chief Executive Officer and other executive officers in light of such goals and objectives;
- reviewing and approving the granting of options and other incentive awards, including the exercise of authorities delegated by the board of directors regarding the grant of equity incentives under our equity compensation plans;

- reviewing, evaluating and making recommendations regarding the compensation and benefits for our non-employee directors;
- overseeing our compliance with SEC and Nasdaq rules related to shareholder approval of certain executive compensation matters and equity compensation plans;
- considering and implementing policies with respect to oversight, assessment and management of risks associated with our compensation policies; and
- reviewing and establishing appropriate insurance coverage for our office holders.

Under Israeli law, the compensation policy serves as the basis for decisions concerning the financial terms of employment or engagement of office holders, including exculpation, insurance, indemnification or any monetary payment or obligation of payment in respect of employment or engagement. The compensation policy must relate to certain factors, including advancement of the company's objectives, the company's business plan and its long-term strategy, and creation of appropriate incentives for office holders. It also considers, among other things, the company's risk management, size and the nature of its operations. The compensation policy further provides a framework for the consideration of, among other things, the following additional factors:

- the knowledge, skills, expertise and accomplishments of the relevant office holder;
- the office holder's roles and responsibilities and prior compensation agreements with him or her;
- the ratio between the cost of the terms of employment of an office holder and the cost of the compensation of the other employees of the company, including those employed through manpower companies, in particular the ratio between such cost and the average and median compensation of the other employees of the company, as well as the impact such disparities may have on the work relationships in the company;
- the possibility of reducing variable compensation, if any, at the discretion of the board of directors; and the possibility of setting a limit on the exercise value of non-cash variable equity-based compensation; and
- as to severance compensation, if any, the period of service of the office holder, the terms of his or her compensation during such service period, the company's performance during that period of service, the person's contribution towards the company's achievement of its goals and the maximization of its profits, and the circumstances under which the person is leaving the company.

The compensation policy must also include:

- a link between variable compensation and long-term performance and measurable criteria;
- the relationship between variable and fixed compensation, and the ceiling for the value of variable compensation;
- the conditions under which an office holder would be required to repay compensation paid to him or her if it was later shown that the data upon which such compensation was based was inaccurate and was required to be restated in the company's financial statements;
- the minimum holding or vesting period for variable, equity-based compensation; and
- maximum limits for severance compensation.

The compensation policy must be approved by the company's board of directors after considering the recommendations of the compensation committee. In addition, the compensation policy needs to be approved by the company's shareholders by a simple majority, provided that (1) such majority includes a majority of the votes cast by the shareholders who are not controlling shareholders and who do not have a personal interest in the matter, present and voting (abstentions are disregarded) or (2) the votes cast by shareholders who are not controlling shareholders and who do not have a personal interest in the matter and voted against the

compensation policy, constitute two percent or less of the aggregate voting rights in the company (a "Special Majority for Compensation Matters").

If and to the extent the compensation policy is not approved by a Special Majority for Compensation Matters at a duly convened general meeting of shareholders, it may be possible under the Companies Law for the company to approve such compensation policy by the compensation committee and the board of directors making a determination, after re-examining the compensation policy and based on detailed reasoning that, notwithstanding the opposition or lack of approval by the general meeting of shareholders, the adoption of the compensation policy is nonetheless in the company's best interest.

A compensation policy that is for a period of more than three years must be approved in accordance with the above procedure every three years. A compensation policy does not, in and of itself, grant any rights to our directors or officers.

Following the recommendation of our compensation committee, our board of directors has approved the compensation policy for our office holders by way of a board resolution dated March 4, 2022, subject to that policy's approval by a Special Majority for Compensation Matters, and, that policy, in turn, was so approved by the Company's shareholders at our annual general meeting held on April 12, 2022.

Our compensation policy is designed to promote retention and motivation of directors and executive officers, incentivize superior individual excellence, align the interests of our directors and executive officers with our long-term performance and provide a risk management tool. To that end, a portion of our executive officer compensation package is targeted to reflect our short- and long-term goals, as well as the executive officer's individual performance. On the other hand, our compensation policy includes measures designed to reduce the executive officer's incentives to take excessive risks that may harm us in the long-term, such as limits on the value of cash bonuses and equity-based compensation, limitations on the ratio between the variable and the total compensation of an executive officer and minimum vesting periods for equity-based compensation.

Our compensation policy also addresses our executive officers' individual characteristics (such as their respective position, education, scope of responsibilities and contribution to the attainment of our goals) as the basis for compensation variation among our executive officers and considers the internal ratios between compensation of our executive officers and directors and other employees. Pursuant to our compensation policy, the compensation that may be granted to an executive officer may include: base salary, annual bonuses and other cash bonuses (such as a signing bonus and special bonuses with respect to any special achievements, such as outstanding personal achievement, outstanding personal effort or outstanding company performance), equity-based compensation, benefits and retirement and termination of service arrangements.

Nominating and Governance Committee

Our nominating and governance committee consists of Natalie Leong and Joseph Cooper, with Natalie Leong serving as chairperson. Our board of directors adopted, on March 3, 2022, an amended and restated nominating and governance committee charter, consistent with the rules of the SEC and Nasdaq listing rules, setting forth the responsibilities of the committee, which include:

- evaluating our corporate leadership structure, and reviewing important issues and developments in corporate governance, and developing appropriate recommendations for the Board; and
- overseeing and assisting our board in reviewing and recommending nominees for election as directors and members of committees of our board.

Internal Auditor

Under the Companies Law, the board of directors of an Israeli public company must appoint an internal auditor in accordance with the recommendation of the audit committee. An internal auditor may not be:

- a person (or a relative of a person) who holds more than 5% of the company's outstanding shares or voting rights;
- a person (or a relative of a person) who has the power to appoint a director or the chief executive officer of the company;
- an office holder (including a director) of the company (or a relative thereof); or

- a member of the company's independent accounting firm, or anyone on his or her behalf.

The role of the internal auditor is to examine, among other things, our compliance with applicable law and orderly business procedures. The audit committee is required to oversee the activities and to assess the performance of the internal auditor as well as to review the internal auditor's work plan. On March 6, 2022, we appointed Edo Pollack as our internal auditor. Edo Pollack is a Certified Public Accountant (CPA) and partner-in-charge of the Israel office of Eisner Advisory Group LLC.

The Chairman of the board of directors is the direct supervisor of the internal auditor, unless the board of directors shall determine otherwise, in accordance with our articles of association and the Companies Law (and, in this regard, we have not determined otherwise). The internal auditor is required to submit his or her findings to the Chairman of the Board, the Chief Executive Officer, and the Chairman of the audit committee. The internal auditor may not be dismissed or suspended without his consent, other than by a decision of the board of directors requiring a quorum of the majority of the members of the board, after the board of directors has heard the audit committee's position on the matter and the internal auditor has been afforded a reasonable opportunity to bring his position before the audit committee and the board of directors.

Approval of Related Party Transactions under Israeli Law

Fiduciary Duties of Directors and Executive Officers

The Companies Law codifies the fiduciary duties that office holders owe to a company. An "office holder" under the Companies Law means a director, a Chief Executive Officer, or other officer who occupies a general or chief management position, or serves in a position directly secondary to or directly reporting to the Chief Executive Officer. Each person listed in the table under "Directors and Senior Management" above is an office holder.

An office holder's fiduciary duties consist of a duty of care and a duty of loyalty. The duty of care requires an office holder to act with the level of care with which a reasonable office holder in the same position would have acted under the same circumstances. The duty of loyalty requires that an office holder act in good faith and in the best interests of the company.

The duty of care includes a duty to use reasonable means to obtain:

- information on the advisability of a given action brought for his or her approval or performed by virtue of his or her position; and
- all other important information pertaining to any such action.

The duty of loyalty includes a duty to:

- refrain from any conflict of interest between the performance of his or her duties to the company and his or her other duties or personal affairs;
- refrain from any activity that is competitive with the company;
- refrain from exploiting any business opportunity of the company to receive a personal gain for himself or herself or others; and
- disclose to the company any information or documents relating to the company's affairs which the office holder received as a result of his or her position as an office holder.

Disclosure of Personal Interests of an Office Holder and Approval of Certain Transactions

The Companies Law requires that an office holder promptly disclose to the board of directors any personal interest that he or she may be aware of and all related material information or documents concerning any existing or proposed transaction with the company. An interested office holder's disclosure must be made promptly and in any event no later than the first meeting of the board of directors at which the transaction is considered. As used in the context of the Companies Law, a "personal interest" includes an interest of any person in an act or transaction of a company, including a personal interest of such person's "relative," or of a corporate body in which such person or a relative of such person is a 5% or greater shareholder, director or chief executive officer, or in which

he or she has the right to appoint at least one director or the chief executive officer, but excluding a personal interest stemming from ownership of shares in the company. A "personal interest" is furthermore deemed to include, in a proposal brought before a meeting of shareholders, the personal interest of a shareholder for whom a vote is being cast by power of attorney, as well as the personal interest of a person voting by virtue of a power of attorney, even if the person granting such power of attorney has no personal interest in the matter. A "relative" (in this context, and generally in the context of the Companies Law) means (a) a spouse, sibling, parent, grandparent, child or descendant, (b) a spouse's child or descendant, parent or sibling, or (c) the spouse of any of the foregoing. An office holder is not, however, obligated to disclose a personal interest if it derives solely from the personal interest of his or her relative in a transaction that is not considered an "extraordinary transaction."

Under the Companies Law, an "extraordinary transaction" is defined as any of the following:

- a transaction other than in the ordinary course of business;
- a transaction that is not on market terms; or
- a transaction that may have a material impact on a company's profitability, assets or liabilities.

A director and any other office holder who has a personal interest in a transaction which is considered at a meeting of the board of directors or the audit committee may generally (unless it is with respect to a transaction which is not an extraordinary transaction) not be present at such a meeting or vote on that matter, unless a majority of the directors or members of the audit committee, as applicable, have a personal interest in the matter. If a majority of the members of the audit committee or the board of directors have a personal interest in the matter, then all of the directors may participate in the deliberations of the audit committee or board of directors, as applicable, with respect to such transaction and vote on the approval thereof and, in such case, shareholder approval is also required.

Generally speaking, any transaction between the Company and an office holder, or between the Company and a person or entity in whom the office holder has a personal interest, requires approval by the board of directors; if such transaction is an extraordinary transaction, it requires approval first by the company's audit committee, and subsequently by the board of directors. A transaction regarding the terms of compensation of an office holder who is not a director requires approval first by the company's compensation committee, then by the company's board of directors, and, if such compensation transaction is not consistent with the company's compensation policy, or if the office holder is the Chief Executive Officer, the subsequent approval of a Special Majority for Compensation Matters at a general meeting of shareholders- as defined in *Compensation Committee and Compensation Policy* above. Arrangements regarding the terms of compensation of a director require the approval of the compensation committee, followed by the board of directors, followed by a simple majority at a general meeting of shareholders; however, under certain circumstances, a Special Majority for Compensation Matters is required.

Disclosure of Personal Interests of Controlling Shareholders and Approval of Certain Transactions

Under Israeli law, the disclosure requirements regarding personal interests that apply to directors and other office holders also apply to a controlling shareholder of a public company, and certain transactions with controlling shareholders, transactions in which a controlling shareholder has a personal interest, and arrangements regarding the terms of service or employment of a controlling shareholder require certain specified approvals. For these purposes (and throughout this section regarding the disclosure of personal interests and approval of transactions regarding controlling shareholders), a "controlling shareholder" is deemed to include any shareholder holding 25% or more of the voting rights in the company if no other shareholder owns more than 50% of the voting rights in the company, and two or more shareholders with a personal interest in the approval of the same transaction are deemed to be one shareholder for such purpose. The approval of the audit committee or the compensation committee, as the case may be, followed by the board of directors and further followed by a general meeting of shareholders of the company, in that order, is required for (a) extraordinary transactions with a controlling shareholder or in which a controlling shareholder has a personal interest, (b) the engagement with a controlling shareholder or his or her relative, directly or indirectly, for the provision of services to the company, (c) the terms of engagement and compensation of a controlling shareholder or his or her relative as an office holder, (d) the employment of a controlling shareholder or his or her relative by the company, other than as an office holder, or (e) a private placement in which a controlling shareholder has a personal interest. The approval by the shareholders of such transactions at a general meeting requires one of the following special majorities:

- at least a majority of the shares held by all shareholders who do not have a personal interest in the transaction and who are present and voting at the meeting approving the transaction, excluding abstentions; or

- the shares voted against the transaction by shareholders who have no personal interest in the transaction and who are present and voting at the meeting do not exceed 2% of the aggregate voting rights in the company.

To the extent that any such transaction with a controlling shareholder is for a period extending beyond three years, approval is required once every three years, unless, with respect to certain transactions, the audit committee determines that the duration of the transaction is reasonable given the circumstances related to that transaction.

Transactions regarding the terms of compensation of a controlling shareholder to be approved in accordance with the procedure described above may not be inconsistent with the company's compensation policy.

Under the Companies Regulations (Relief from Related Party Transactions), 5760-2000, the following types of extraordinary transactions require approval of the audit committee and board of directors only, and do not require shareholder approval: (i) the extension of a previously approved extraordinary transaction, which does not involve any significant change in the terms of the existing transaction, other than a change solely for the benefit of the company; (ii) an extraordinary transaction from which the company stands only to benefit; (iii) an extraordinary transaction is in accordance with the terms of a framework agreement, which itself was duly approved in the manner of an extraordinary transaction with a controlling shareholder; (iv) an extraordinary transaction with a controlling shareholder or a person in which the controlling shareholder has a personal interest, the purpose of which is a transaction of theirs with a third party or a joint proposal to enter into a transaction with a third party, and the terms of the transaction that apply to the company are not significantly different from the terms that apply to the controlling shareholder or an entity controlled by him or her (taking into account the extent their respective portions in the transaction); (v) an extraordinary transaction by and among companies controlled by the controlling shareholder, or between the company and the controlling shareholder or a person in which the controlling shareholder has a personal interest, and the transaction is on market terms, within the ordinary course of business, and is without injury to the company's interests; or (vi) at the time of the extraordinary transaction's approval by the audit committee and the board of directors, the aggregate voting rights of shareholders who do not have personal interest in the approval of such transaction do not exceed 2% of the voting rights in the company. Employment and compensation arrangements for an office holder who is a controlling shareholder of a public company, or the provision of directors and officers insurance for the chief executive officer, do not require shareholder approval if certain criteria regarding caps on compensation are met. Furthermore, these relief regulations allow for a company to enter an insurance policy for its office holders by approval of the compensation committee alone, if such insurance policy is consistent with the company's existing and duly approved compensation policy, is under market terms, and is not likely to substantially impact the company's assets, liabilities or profitability.

Shareholder Duties

Under the Companies Law, a shareholder has a duty to act in good faith and in a customary manner toward the company and other shareholders and to refrain from abusing his or her power in the company, including, among other things, in voting at a general meeting or class meeting of shareholders with respect to the following matters:

- an amendment to the company's articles of association;
- an increase of the company's authorized share capital;
- a merger; or
- the approval of related party transactions and acts of office holders that require shareholder approval.

In addition, a shareholder also has a general duty to refrain from taking advantage of other shareholders.

Certain shareholders also have a duty of fairness toward the company. These shareholders include any controlling shareholder, any shareholder who is aware that his or her vote would determine the outcome of a shareholder vote at a general meeting or class meeting of shareholders, and any shareholder who, by virtue of the articles of association, has the power to appoint or to prevent the appointment of an office holder of the company or other power regarding the company. The Companies Law does not define (and there is little Israeli case law defining) the substance of the duty of fairness, except that the Companies Law states that the remedies generally available upon a breach of contract will also apply in the event of a breach of the duty to act with fairness.

Exculpation, Insurance and Indemnification of Directors and Officers

Under the Companies Law, a company may not exculpate an office holder from liability for a breach of the duty of loyalty. An Israeli company may exculpate an office holder in advance from liability to the company, in whole or in part, for damages caused to the company as a result of a breach of duty of care but only if a provision authorizing such exculpation is included in its articles of association. Our articles of association include such a provision. The company may not exculpate in advance a director from liability arising out of a prohibited dividend or distribution to shareholders.

Under the Companies Law, a company may indemnify an office holder in respect of the following liabilities and expenses incurred for acts performed by him or her as an office holder, either pursuant to an undertaking made in advance of an event or following an event, provided its articles of association include a provision authorizing such indemnification, which ours do:

- financial liability imposed on him or her in favor of another person pursuant to a judgment, including a settlement or arbitrator's award approved by a court. However, if an undertaking to indemnify an office holder with respect to such liability is provided in advance, then such an undertaking must be limited to events which, in the opinion of the board of directors, can be reasonably foreseen based on the company's activities when the undertaking to indemnify is given, and to an amount or according to criteria determined by the board of directors as reasonable under the circumstances, and such undertaking shall detail the abovementioned foreseen events and amount or criteria;
- reasonable litigation expenses, including attorneys' fees, incurred by the office holder (1) as a result of an investigation or proceeding instituted against him or her by an authority authorized to conduct such investigation or proceeding, provided that (a) no indictment was filed against such office holder as a result of such investigation or proceeding; and (b) no financial liability, such as a criminal penalty, was imposed upon him or her as a substitute for the criminal proceeding as a result of such investigation or proceeding or, if such financial liability was imposed, it was imposed with respect to an offense that does not require proof of criminal intent; and (2) in connection with a monetary sanction; and
- reasonable litigation expenses, including attorneys' fees, incurred by the office holder or imposed by a court in proceedings instituted against him or her by the company, on its behalf, or by a third party, or in connection with criminal proceedings in which the office holder was acquitted, or as a result of a conviction for an offense that does not require proof of criminal intent.

Under the Companies Law and the Israeli Securities Law 5728-1968 (the "Israeli Securities Law"), a company may insure an office holder against the following liabilities incurred for acts performed by him or her as an office holder if and to the extent provided in the company's articles of association:

- a breach of the duty of loyalty to the company, provided that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm the company;
- a breach of duty of care to the company or to a third party, to the extent such a breach arises out of the negligent conduct of the office holder; and
- financial liability imposed on the office holder in favor of a third party.

Under our articles of association, we may insure an office holder against the aforementioned liabilities as well as the following liabilities:

- a breach of duty of care to the company or to a third party;
- any other action against which we are permitted by law to insure an office holder;
- expenses incurred and/or paid by the office holder in connection with an administrative enforcement procedure under any applicable law including Parts 8(3), 8(4) and 9(1) of the Israeli Securities Law, and a proceeding according to Section D of Chapter 4 in Part 9 of the Companies Law, including reasonable litigation expenses and attorney fees;
- a payment to a person injured by a violation of Section 52BBB(a)(1)(a) of the Israeli Securities Law; and

- expenses incurred in connection with a proceeding under the Economic Competition Law 5748-1988, including reasonable litigation expenses and attorney fees.

Under the Companies Law, a company may not indemnify, exculpate or insure an office holder against any of the following:

- a breach of the duty of loyalty, except for indemnification and insurance for a breach of the duty of loyalty to the company to the extent that the office holder acted in good faith and had a reasonable basis to believe that the act would not harm the company;
- a breach of duty of care committed intentionally or recklessly, excluding a breach arising solely out of the negligent conduct of the office holder;
- an act or omission committed with intent to derive illegal personal benefit; or
- a fine, civil fine, or other financial sanction levied against the office holder.

Under the Companies Law, exculpation, indemnification and insurance of office holders in a public company must be approved by the compensation committee and the board of directors and, with respect to certain office holders or under certain circumstances, also by the shareholders. See “—Approval of Related Party Transactions under Israeli Law.”

Our articles of association permit us to exculpate, indemnify and insure our office holders to the fullest extent permitted or to be permitted by the Companies Law and the Israeli Securities Law.

Upon the recommendation of our compensation committee, our board of directors has approved, and our shareholders have approved, at the annual general meeting held on April 12, 2022, the form of indemnification and release agreement to be entered into with each of our current and future directors and executive officers exculpating them, to the fullest extent permitted by law and our articles of association, and undertaking to indemnify them to the fullest extent permitted by law and our articles of association. This indemnification will be limited to events determined as foreseeable by the board of directors based on our activities, and to an amount or according to criteria determined by the board of directors and our compensation committee as reasonable under the circumstances.

Under the form of indemnification and release agreement so approved, the maximum indemnification amount will be limited to an amount which shall not exceed the greater of (a) 25% of our total shareholders’ equity according to our most recent financial statements as of the time of the actual payment of the indemnification and (b) \$35 million. Such maximum amount is in addition to any amount paid (if paid) under insurance and/or by a third-party pursuant to an indemnification arrangement.

In the opinion of the SEC, indemnification of directors and officers for liabilities arising under the Securities Act, however, is against public policy and therefore unenforceable.

We have obtained directors’ and officers’ liability insurance for the benefit of our office holders and intend to continue to maintain such coverage and pay all premiums thereunder to the fullest extent permitted by the Companies Law.

Employees.

As of December 31, 2021, we had four full-time employees. These employees are comprised of Dr. Michael Myers, Chief Executive Officer, Denise Carter, Chief Operating Officer, Gordon Dunn, Chief Financial Officer, and an administrative assistant. Our employees are not represented by any collective bargaining agreements, and we have never experienced an organized work stoppage. Gordon Dunn is located in the United Kingdom. Our other employees are located in the United States of America.

Share Ownership

Stock Option Plans

Amended and Restated Equity Incentive Plan

Upon the recommendation of our Compensation Committee, our board of directors, and our shareholders at the 2022 AGM, have approved and adopted an amendment and restatement of our 2014 Global Incentive Option Scheme, which has been renamed as our

Amended and Restated Equity Incentive Plan (the “Equity Incentive Plan”). The number of shares reserved for issuance under the Equity Incentive Plan has been increased to 15% of our outstanding ordinary shares on a fully-diluted basis, and will provide for the grant of options to our directors, officers, employees, consultants, advisers and service providers. The approved changes to the 2014 Global Incentive Option Scheme related to (i) the number of shares authorized for issuance under this plan, as described above, and (ii) the name of the plan, as well as certain related conforming changes.

As of April 12, 2022, options to purchase 1,606,133,600 ordinary shares were outstanding and up to 220,858,000 ordinary shares were available for issuance under the Equity Incentive Plan. Of such outstanding options, options to purchase 23,276,800 ordinary shares were exercisable as of April 12, 2022, with a weighted average exercise price of \$0.05 per ordinary share.

The Equity Incentive Plan provides for options to be granted at the determination of our board of directors, which has the power to administer the Equity Incentive Plan, either directly or upon the recommendation of the Compensation Committee of the Board of Directors in accordance with applicable law and Quoin’s Amended and Restated Articles of Association. Upon termination of employment for any reason, other than in the event of death or disability or for “Cause” (as defined in the Equity Incentive Plan), all unvested options will expire and all vested options at time of termination will generally be exercisable for 90 days following termination, subject to the terms of the Equity Incentive Plan and the governing option agreement. If we terminate a grantee for Cause the grantee’s right to exercise all vested and unvested the options granted to him or her will expire immediately. Upon termination of employment due to death or disability, all the vested options at the time of termination will be exercisable for 12 months after date of termination, subject to the terms of the Equity Incentive Plan and the governing option agreement.

Options granted under the Equity Incentive Plan are subject to applicable vesting schedules.

In the event that options allocated under the Equity Incentive Plan expire or otherwise terminate in accordance with the provisions of the Equity Incentive Plan, such expired or terminated options will become available for future grant awards and allocations under the Equity Incentive Plan.

Material Contracts

We have not entered into any material contract within the two years prior to the date of the registration statement of which this prospectus forms a part, other than contracts entered into in the ordinary course of business, contracts entered into in connection with the Merger and related private placements, as described in Forms 6-K filed with the SEC, or as otherwise described herein in (i) “Prospectus Summary” above, (ii) this “Business” section, (iii) “Management” above, (iv) “Principal Shareholders” below, (v) “Certain Relationships and Related Transactions” below, and (vi) “Index to Consolidated Financial Statements” below.

PRINCIPAL SHAREHOLDERS

The following table sets forth information relating to the beneficial ownership of our ordinary shares as of April 12, 2022 by:

- each person, or group of affiliated persons, known by us to own beneficially 5% or more of our outstanding ordinary shares;
- each of our directors and executive officers; and
- all of our directors and officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC and generally means sole or shared power to vote or direct the voting or to dispose or direct the disposition of any ordinary shares. Unless otherwise indicated in the footnotes to this table, we believe that each of the persons named in this table has sole voting and investment power with respect to the shares indicated as being beneficially owned.

Except as indicated by footnote, the beneficial ownership information is based upon 3,354,653,999 ordinary shares outstanding as of April 12, 2022. Ordinary shares that may be acquired by a person within 60 days of April 12, 2022, pursuant to the exercise of options or warrants, are deemed to be outstanding for purpose of computing the percentage ownership of such person, but are not deemed to be outstanding for purposes of computing the percentage ownership of ordinary shares of any other person shown in the table. Each ADS represents 400 ordinary shares of Quoin Ltd.

<u>Name</u>	<u>Number of Ordinary Shares Beneficially Owned</u>	<u>Percentage Owned</u>
<i>Principal Shareholders:</i>		
Altium Growth Fund, LP ⁽¹⁾	6,783,977,200	9.99 %
Goldman Sachs & Co. LLC ⁽²⁾	580,219,600	17.3 %
<i>Executive Officers and Directors:</i>		
Michael Myers ⁽³⁾	600,730,400	17.9 %
Denise Carter ⁽³⁾	600,730,400	17.9 %
Gordon Dunn	—	*
James Culverwell ⁽⁴⁾	19,074,800	*
Joseph Cooper	—	*
Dennis Langer ⁽⁵⁾	21,006,400	*
Natalie Leong	—	*
Michael Sember	—	*
All directors and officers as a group (8 persons)	1,241,542,000	36.6 %

* Less than 1%

- (1) Altium Capital Management, LP (“Altium Capital”), the investment manager of Altium Growth Fund, LP (the “Fund”), has voting and investment power over these securities. Jacob Gottlieb is the managing member of Altium Capital Growth GP, LLC (“Altium Growth”), which is the general partner of the Fund. Each of the Fund and Jacob Gottlieb disclaims beneficial ownership over these shares. Consists of 1,238,429 ADSs issuable upon exercise of Investor Exchange Warrants, 6,665,922 ADSs issuable upon exercise of Series A Warrant (including 2,389,670 ADSs issuable upon exercise of an additional Series A Warrant issuable upon the cash exercise of the Series C Warrant), 6,665,992 ADSs issuable upon exercise of Series B Warrant (including 2,389,670 ADSs issuable upon exercise of an additional Series B Warrant issuable upon the cash exercise of the Series C Warrant), and 2,389,670 ADSs issuable upon exercise of the Series C Warrant, issued pursuant to the terms of the Securities Purchase Agreement entered into between the Fund, Collect and Quoin Inc. The Fund cannot exercise the Investor Exchange Warrants or the Series A Warrant to the extent the Fund, together with its affiliates, would beneficially own, after any such exercise, more than 4.99% of the outstanding ordinary shares (the “4.99% Warrant Blocker”). In addition, the Fund cannot exercise the Series B Warrant or the Series C Warrant to the extent the Fund, together with its affiliates, would beneficially own, after any such exercise, more than 9.99% of the outstanding ordinary shares (the “9.99% Warrant Blocker”, and together with the 4.99%, the “Warrant Blockers”). The percentage set forth in this table gives effect to the Warrant Blockers, but the number of ordinary shares beneficially owned by the Fund set forth in this table does not give effect to the Warrant Blockers. The address of the Fund, Altium Capital and Altium Growth is c/o Altium Capital Management, LP, 152 West 57th Street, 20th Floor, New York, NY 10019.
- (2) Based on Schedule 13G/A filed with the SEC on March 10, 2022 by The Goldman Sachs Group, Inc. (“GS Group”) and Goldman Sachs & Co. LLC (“GS LLC”). The securities are held directly by GS LLC, a broker or dealer registered under Section 15 of the Investment Company Act of

1940 and an investment adviser registered under Section 203 of the Investment Advisers Act of 1940. GS LLC is a subsidiary of GS Group, and GS Group may be deemed to beneficially own the securities. The address of GS Group and GS LLC is 200 West Street, New York, NY 10282.

- (3) Includes ADSs held in escrow.
- (4) Consists of 7,119 ADSs outstanding and 40,568 ADSs issuable upon exercise of warrants
- (5) Consists of 7,831 ADSs outstanding and 44,685 ADSs issuable upon exercise of warrants.

At the closing of the Merger on October 28, 2021 and pursuant to the terms of the Merger Agreement, the former holders of common stock of Quoin Inc. (including shares acquired by, and held in escrow on behalf of, Altium Growth Fund, LP) owned in the aggregate approximately 88% of the ordinary shares, with Collect's stockholders immediately prior to the Merger owning approximately 12% of the ordinary shares.

Bank of New York Mellon, or BNY, is the holder of record for our ADR program, pursuant to which each ADS represents 400 ordinary shares. As of April 12, 2022, BNY held 3,354,291,340 ordinary shares representing 99.99% of the outstanding share capital held at that date. Certain of these ordinary shares were held by brokers or other nominees. As a result, the number of holders of record or registered holders in the United States is not representative of the number of beneficial holders or of the residence of beneficial holders.

None of our shareholders has different voting rights from other shareholders. To our knowledge, we are not owned or controlled, directly or indirectly, by another corporation or by any foreign government. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of us.

SELLING SHAREHOLDERS

The selling shareholders will acquire the ordinary shares represented by ADSs being registered for resale pursuant to this prospectus upon exercise of the Warrants acquired under the Purchase Agreement and the 2020 Notes. We are registering the ordinary shares represented by ADSs in order to permit the selling shareholders to offer the ordinary shares represented by ADSs for resale from time to time. Except as described in this prospectus, none of the selling shareholders has had any material relationship with us within the past three years. See “Prospectus Summary–Issuance of Warrants.”

The table below lists the selling shareholders and other information regarding the beneficial ownership of ordinary shares represented by ADSs by the selling shareholders. The second column lists the number of ordinary shares beneficially owned by each selling shareholder, based on such holder’s ownership of the ADSs and the Warrants, as of April 12, 2022, assuming exercise of the Warrants held by such selling shareholder on that date, without regard to any limitations on exercises. The third column lists the ordinary shares represented by ADSs being offered by this prospectus by each selling shareholder.

In accordance with the terms of the Registration Rights Agreement with the Investor, this prospectus generally covers the resale of sum of the (i) maximum number of ADSs issued and issuable upon exercise of the Series A Warrants and assuming that the Series C Warrant has been exercised in full by paying the Aggregate Exercise Price (as defined in such warrant) in cash (without giving effect to any limitation on exercise set forth therein), (ii) maximum number of ADSs issued and issuable upon exercise of the Series B Warrants and assuming that the Series C Warrant has been exercised in full by paying the Aggregate Exercise Price (as defined in such warrant) in cash (without giving effect to any limitation on exercise set forth therein), and (iii) maximum number of ADSs issued and issuable upon exercise of the Series C Warrant by paying the Aggregate Exercise Price (as defined in such warrant) in cash (without giving effect to any limitation on exercise set forth therein), in each case, determined as if the outstanding Warrants were exercised in full as of as of April 12, 2022. The fourth column assumes the sale of all of the shares offered by the Investor pursuant to this prospectus.

Under the terms of the Investor Warrants, Altium may not exercise the Warrants to the extent such exercise would cause such selling shareholder, together with its affiliates, to beneficially own a number of ordinary shares (including, for the avoidance of doubt, any ordinary shares represented by ADSs) which would exceed 4.99% or 9.99%, as applicable, of our then outstanding ordinary shares following such exercise, excluding for purposes of such determination ADSs issuable upon exercise of the warrants which have not been exercised. The number of shares in the second column reflects this limitation. The selling shareholders may sell all, some or none of their shares in this offering. See “Plan of Distribution.”

Name of Selling Shareholder	Ordinary Shares Beneficially Owned Prior to Offering		Maximum Number of Ordinary Shares to be Sold Pursuant to this Prospectus	Ordinary Shares Owned Immediately After Sale of Maximum Number of Ordinary Shares in This Offering	
	Number	Percentage		Number	Percentage
Altium Growth Fund, LP (1)	6,783,977,200	9.99 %	6,288,605,600	495,371,600	4.8 %
Anthony Wild (2)	95,338,000	2.8 %	81,099,600	14,238,400	*
Dennis Langer (3)	21,006,400	*	17,874,000	3,132,400	*
James Culverwell (4)	19,074,800	*	16,227,200	2,847,600	*
Beauchamp Ventures Limited (5)	18,509,200	*	15,661,600	2,847,600	*
Hugh Bett (6)	18,927,600	*	16,080,000	2,847,600	*

* Indicates beneficial ownership of less than 1% of the total outstanding ordinary shares.

- (1) Altium Capital Management, LP (“Altium Capital”), the investment manager of Altium Growth Fund, LP (the “Fund”), has voting and investment power over these securities. Jacob Gottlieb is the managing member of Altium Capital Growth GP, LLC (“Altium Growth”), which is the general partner of the Fund. Each of the Fund and Jacob Gottlieb disclaims beneficial ownership over these shares. Consists of 1,238,429 ADSs issuable upon exercise of Investor Exchange Warrants, 6,665,922 ADSs issuable upon exercise of Series A Warrant (including 2,389,670 ADSs issuable upon exercise of an additional Series A Warrant issuable upon the cash exercise of the Series C Warrant), 6,665,992 ADSs issuable upon exercise of Series B Warrant (including 2,389,670 ADSs issuable upon exercise of an additional Series B Warrant issuable upon the cash exercise of the Series C Warrant), and 2,389,670 ADSs issuable upon exercise of the Series C Warrant, issued pursuant to the terms of

the Securities Purchase Agreement entered into between the Fund, Collect and Quoin Inc. The Fund cannot exercise the Investor Exchange Warrants or the Series A Warrant to the extent the Fund, together with its affiliates, would beneficially own, after any such exercise, more than 4.99% of the outstanding ordinary shares (the "4.99% Warrant Blocker"). In addition, the Fund cannot exercise the Series B Warrant or the Series C Warrant to the extent the Fund, together with its affiliates, would beneficially own, after any such exercise, more than 9.99% of the outstanding ordinary shares (the "9.99% Warrant Blocker", and together with the 4.99%, the "Warrant Blockers"). The percentage set forth in this table gives effect to the Warrant Blockers, but the number of ordinary shares beneficially owned by the Fund set forth in this table does not give effect to the Warrant Blockers.

- (2) Consists of 35,596 ADSs outstanding and 202,749 ADSs issuable upon exercise of outstanding Noteholder Warrants.
- (3) Consists of 7,831 ADSs outstanding and 44,685 ADSs issuable upon exercise of outstanding Noteholder Warrants.
- (4) Consists of 7,119 ADSs outstanding and 40,568 ADSs issuable upon exercise of outstanding Noteholder Warrants.
- (5) Consists of 7,119 ADSs outstanding and 39,154 ADSs issuable upon exercise of outstanding Noteholder Warrants.
- (6) Consists of 7,119 ADSs outstanding and 40,200 ADSs issuable upon exercise of outstanding Noteholder Warrants.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

The following is a description of the transactions with related parties, to which we are party and which have been in effect within the past three fiscal years and up to the date of the registration statement of which this prospectus forms a part.

We believe that we have executed all of our transactions with related parties on terms no less favorable to us than those we could have obtained from unaffiliated third parties. See “Board Practices—Approval of Related Party Transactions under Israeli Law.”

On October 2, 2020, Quoin Inc. commenced an offering of convertible notes and warrants. From October through December 2020, Quoin Inc. received an aggregate of approximately \$910,000 in the initial bridge financing, and issued 2020 Notes with an aggregate face value of \$1,213,333. Approximately 22% of the initial bridge financing was received from parties who are related to or affiliated with members of our board of directors. See “Management’s Discussion and Analysis of Financial Condition and Results of Operations” above for additional information about 2020 Notes.

During 2021, Quoin Inc. incurred \$108,000 of consulting expenses, primarily from a related party company controlled by Dennis Langer, our director, with approximately \$8,000 paid to Dr. Myers’ son, who consults Quoin Inc. on research and development matters from time to time.

Due to the limited funding of Quoin Inc. prior to the Merger and private placements, as described in this prospectus, the compensation, including salary, office and car allowances and other benefits, due to Dr. Myers Ms. Carter under their respective employment agreements, as well as reimbursement of expenses and other amounts paid by Dr. Myers and Ms. Carter to third parties on behalf of Quoin Inc., were not paid by Quoin Inc. to Dr. Myers and Ms. Carter, and have been accruing as indebtedness to Dr. Myers and Ms. Carter. Following the closing of the Merger and private placements, Quoin Inc. began making payments of \$25,000 per month to each of Dr. Myers and Ms. Carter to repay the above-described non-interest-bearing indebtedness. After taking into account \$125,000 repaid to each of Dr. Myers and Ms. Carter from October 28, 2021 until February 2022, Quoin Inc. was indebted to each of Dr. Myers and Ms. Carter in the aggregate amount of \$ 2,508,701 and \$2,115,032, respectively.

Indemnification Agreements

Our articles of association permit us to exculpate, indemnify and insure our directors and other office holders to the fullest extent permitted by the Companies Law and we have obtained and maintain directors’ and officers’ insurance covering our directors and other office holders. Upon the recommendation of our compensation committee, our board of directors has approved, and our shareholders have approved at the Annual General Meeting held on April 12, 2022, the form of indemnification and release agreement to be entered into with each of our current and future directors and other office holders, exculpating them to the fullest extent permitted by the law and our articles of association and undertaking to indemnify them to the fullest extent permitted by the law and our articles of association, including with respect to liabilities resulting from this offering, to the extent such liabilities are not covered by insurance. See “Exculpation, Insurance and Indemnification of Directors and Officers.”

Employment Agreements and Bonuses

We have employment agreements with our Chief Executive Officer, Chief Operating Officer and Chief Financial Officer, and granted bonuses to such officers. See “Management—Compensation.”

Options

In April 2022, we granted options to purchase our ordinary shares to certain of our officers and directors. See “Management—Compensation” and “Principal Shareholders.” We describe our option plan under “Management—Share Ownership” and “Principal Shareholders.”

Descriptions provided above are summaries of the terms of agreements (if any) and do not purport to be complete and are qualified in their entirety by the complete agreements.

DESCRIPTION OF SHARE CAPITAL

The following are summaries of material provisions of our articles of association and the Israeli Companies Law, as amended (the “Companies Law”), insofar as they relate to the material terms of our ordinary shares.

Purposes and Objects of the Company

Our purpose is set forth in Section 2 of our articles of association and includes every lawful purpose.

Voting Rights

Holders of our ordinary shares have one vote for each ordinary share held on all matters submitted to a vote of shareholders at a shareholders meeting. Shareholders may vote at shareholders meetings either in person, by proxy or by written ballot. Israeli law does not allow public companies to adopt shareholder resolutions by means of written consent in lieu of a shareholders meeting. The board of directors shall determine and provide a record date for each shareholders meeting and all shareholders at such record date may vote. Unless stipulated differently in the Companies Law or in the articles of association, all shareholders’ resolutions shall be approved by a simple majority vote. As a general rule, an amendment to our articles of association requires the prior approval of a simple majority of our shares represented and voting at a general meeting.

Transfer of Shares

Our ordinary shares that are fully paid for are issued in registered form and may be freely transferred under our articles of association, unless the transfer is restricted or prohibited by applicable law or the rules of a stock exchange on which the shares are traded. The ownership or voting of our ordinary shares by non-residents of Israel is not restricted in any way by our articles of association or Israeli law, except for ownership by nationals of some countries that are, or have been, in a state of war with Israel.

Amendment of Share Capital

Our articles of association enable us to increase or reduce our share capital. Any such changes are subject to the provisions of the Companies Law and must be approved by a resolution duly passed by our shareholders at a general or special meeting by voting on such change in the capital. In addition, transactions that have the effect of reducing capital, such as the declaration and payment of dividends in the absence of sufficient retained earnings and profits, or an issuance of shares for less than their nominal value (which would be applicable to our company should our articles be changed so as to permit the issue of shares having a nominal value, however our shares currently have no nominal value), require a resolution of our board of directors and court approval.

Dividends

Under Israeli law, we may declare and pay dividends only if, upon the determination of our board of directors, there is no reasonable concern that the distribution will prevent us from being able to meet the terms of our existing and foreseeable obligations as they become due. Under the Companies Law, the distribution amount is further limited to the greater of retained earnings or earnings generated over the two most recent years legally available for distribution according to our then last reviewed or audited financial statements, provided that the date of the financial statements is not more than six months prior to the date of distribution. In the event that we do not have retained earnings or earnings generated over the two most recent years legally available for distribution, we may seek the approval of the court in order to distribute a dividend. The court may approve our request if it determines that there is no reasonable concern that the payment of a dividend will prevent us from satisfying our existing and foreseeable obligations as they become due.

Shareholders Meetings

Under Israeli law, we are required to hold an annual general meeting of our shareholders once every calendar year and in any event no later than 15 months after the date of the previous annual general meeting. All meetings other than the annual general meeting of shareholders are referred to as special meetings. Our board of directors may call special meetings whenever it sees fit, at such time and place, within or outside of Israel, as it may determine. In addition, the Companies Law and our articles of association provide that our board of directors is required to convene a special meeting upon the written request of (1) any two of our directors or one quarter of the directors then in office; or (2) one or more shareholders holding, in the aggregate either (a) 5% of our issued share capital and 1% of our outstanding voting rights, or (b) 5% of our outstanding voting rights.

Subject to the provisions of the Companies Law and the regulations promulgated thereunder, shareholders entitled to participate and vote at general meetings of a company are the shareholders of record on a date to be decided by the board of directors which for us, as a company listed on an exchange outside Israel, may be between four and forty days prior to the date of the meeting.

The Companies Law and our articles of association require that resolutions regarding the following matters must be passed at a general meeting of our shareholders:

- amendments to our articles of association;
- appointment or termination of our auditors;
- appointment and dismissal of External Directors, if and to the extent any are required to be appointed;
- approval of acts and transactions requiring general meeting approval pursuant to the Companies Law;
- increases or reductions of our authorized share capital;
- a merger; and
- authorizing the Chairman of the board of directors or his relative to serve as the company's Chief Executive Officer or be vested with such authority; or authorizing the company's Chief Executive Officer or his relative to serve as the Chairman of the board of directors or be vested with such authority.

Under the Companies Law and our articles of association, notice of any annual or special shareholders meeting be provided at least 14 days prior to the meeting, and if the agenda of the meeting includes the appointment or removal of directors, the approval of office holders' compensation or transactions with office holders or interested or related parties, approval of a merger, or authorization of the Chairman of the board or his relative to serve as or be vested with authorities of the Chief Executive Officer, or of the Chief Executive Officer to serve as or be vested with authorities of the Chairman of the board, notice must be provided at least 35 days prior to the meeting.

Quorum

The quorum required for our general meetings of shareholders consists of two or more shareholders present in person, by proxy or by other voting instrument in accordance with the Companies Law and our articles of association, who hold or represent, in the aggregate, at least 25% of the total outstanding voting rights, within half an hour from the time the meeting was designated to start.

A meeting adjourned for lack of a quorum will be adjourned for one week, to the same day in the following week and at the same time and place, or to a later date if so specified in the notice of the meeting, or to another day or place determined by our board of directors in a notice to shareholders. At the reconvened meeting, if a quorum is not present within half an hour from the scheduled time, any number of our shareholders present in person or by proxy shall constitute a lawful quorum.

Resolutions

Our articles of association provide that all resolutions of our shareholders require a simple majority vote, unless otherwise required by applicable law. Under the Companies Law, certain actions require the approval of a special majority, including: (i) an extraordinary transaction with a controlling shareholder or in which a controlling shareholder has a personal interest, or any transaction regarding the terms of employment or other engagement of a controlling shareholder or a controlling shareholder's relative, other than certain exceptions as provided by regulatory relief – all as described in *“Approval of Related Party Transactions under Israeli Law – Disclosure of Personal Interest of Controlling Shareholders and Approval of Certain Transactions”* above, (ii) matters related to the compensation of our Chief Executive Officer, other than special circumstances under which our compensation committee can exempt such transactions from shareholder approval, as described in *“Board Practices – Compensation Committee and Compensation Policy”* above, (iii) the adoption of a compensation policy, as described in *“Compensation Committee and Compensation Policy”* above, (iv) compensation arrangements or grants that are exceptions to the guidelines under our compensation policy, (v) authorization of our Chief Executive Officer to serve as or be vested with the authorities of the Chairman of our board of directors, or for the Chairman of our board of directors to serve as or be vested with the authorities of our Chief Executive Officer, and (vi) appointment of External Directors, if any are appointed (see *“Management—Board Practices—External Directors”* above).

The Companies Law provides that a shareholder, in exercising his or her rights and performing his or her obligations toward the company and its other shareholders, must act in good faith and in a customary manner, and avoid abusing his or her power. See “— Shareholder Duties” above for more details.

Dissolution

Generally under Israeli law, a resolution for the voluntary winding up of a company requires the approval of holders of 75% of the voting rights represented at the meeting, in person, by proxy or by written ballot and voting on the resolution.

In the event of our liquidation, after satisfaction of liabilities to creditors, our assets will be distributed to the holders of our ordinary shares (including holders of entitlements to shares, after deducting the nominal value (if any) of such shares and the price which would have been paid in order to exercise the right to such shares), in proportion to their shareholdings. This right, as well as the right to receive dividends, may be affected by the grant of preferential dividend or distribution rights to the holders of a class of shares with preferential rights that may be authorized in the future.

Access to Corporate Records

Under the Companies Law, all shareholders of a company generally have the right to review minutes of the company's general meetings, its register of shareholders and material shareholders, articles of association, financial statements and any document it is required by law to file publicly with the Israeli Companies Registrar. Any of our shareholders may request to review any document in our possession that relates to any action or transaction with a related party, interested party, or office holder that requires shareholder approval under the Companies Law. We may deny a request to review a document if we determine that the request was not made in good faith, that the document contains a trade secret or patent, or that the document's disclosure may otherwise prejudice our interests.

Acquisitions under Israeli Law

Full Tender Offer

A person wishing to acquire shares of a public Israeli company, and who would as a result hold over 90% of the target company's issued and outstanding share capital, is required by the Companies Law to make a tender offer to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company. A person wishing to acquire shares of a public Israeli company, and who would as a result hold over 90% of the issued and outstanding share capital of a certain class of shares, is required to make a tender offer to all of the shareholders who hold shares of that class for the purchase of all of the issued and outstanding shares of that class. If the shareholders who do not accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law, provided that a majority of the offerees that do not have a personal interest in such tender offer, have accepted the tender offer. Alternatively, if shareholders who do not accept the tender offer represent less than 2% of the company's issued and outstanding share capital (or less than 2% of the applicable class of shares), approval by a majority of the offerees that do not have a personal interest in such tender offer is not required to complete the tender offer. A shareholder whose shares are so transferred may petition the court regarding the fair value to be paid in consideration of such shares, within six months from the date of acceptance of the full tender offer; this right of petition applies to all offeree shareholders, unless the acquirer stipulated in the tender offer that a shareholder accepting the offer may not seek appraisal rights, and prior to the acceptance of the full tender offer, the acquirer and the company disclosed the information required by law in connection with a full tender offer. To the extent a court so petitioned determines that the offered value was less than the fair value per share, the court may order the difference to be paid.

Special Tender Offer

The Companies Law provides that an acquisition of shares of an Israeli public company must be made by means of a "special tender offer" complying with the relevant provisions of the Companies Law if, as a result of the acquisition, the purchaser would become a holder of 25% or more of the voting rights in the company, if there did not previously exist a holder of 25% or more of the voting rights in the company, or if, as a result of the acquisition, the purchaser would become a holder of more than 45% of the voting rights in the company, if there did not previously exist a holder of more than 45% of the voting rights in the company. This requirement does not apply if the acquisition: (a) occurs in the context of a private placement by the company that received shareholder approval as a private placement giving the offeree 25% or 45% of the company's voting rights (as the case may be); (b) is from a holder of 25% or more of the voting rights in the company and results in the acquirer becoming a holder of 25% or more of the

voting rights in the company; or (c) is from a holder of more than 45% of the voting rights in the company and results in the acquirer becoming a holder of more than 45% of the voting rights in the company.

In the event that a special tender offer is made, the target company's board of directors is required to express its opinion on the advisability of the offer, or may abstain from expressing any opinion if it is unable to do so, provided that it gives the reasons for its abstention.

A special tender offer must be directed to all offerees, and the offerees may give notice of their agreement or opposition to the special tender offer. The special tender offer will be consummated only if: (a) at least 5% of the voting rights attached to the company's outstanding shares will be acquired by the offeror, and (b) among those shareholders who gave notice of their position (excluding any controlling shareholders of the offeror, holders of 25% or more of the voting rights in the target company, and any person having a personal interest in the acceptance of the tender offer, including relatives or corporations under the control of any of the above), the number of shares whose holders agreed to the offer exceeds the number of shares whose holders objected to the offer.

If a special tender offer is accepted by the procedure described above, then shareholders who did not respond to or who objected the offer may accept the offer within four days of the last day set for the acceptance of the offer.

An office holder in a company which is the target of a special tender offer who, in his or her capacity as an office holder, performs an act or omits to act for in order to cause the failure of an existing or foreseeable special tender offer, or to impair the likelihood of its acceptance, is liable to the offeror and offerees for damages, unless such office holder acted in good faith and had reasonable grounds to believe that such act or omission was beneficial to the company. As a safe harbor, office holders of the target company may negotiate with a potential purchaser in order to improve the terms of a special tender offer, or negotiate with third parties in order to obtain a competing offer.

In the event that a special tender offer is accepted, the purchaser, any person or entity controlling or controlled by the purchaser, or under common control with the purchaser, may not make a subsequent tender offer for the purchase of shares of the target company, and may not enter into a merger with the target company, for a period of one year from the date of the offer, unless the purchaser or such person or entity undertakes to effect such an offer or merger as a special tender offer in compliance with the Companies Law requirements.

Under regulations enacted pursuant to the Companies Law, the above special tender offer requirements may not apply to companies whose shares are listed for trading on a foreign stock exchange if, among other things, the relevant foreign laws or the rules of the stock exchange include provisions limiting the percentage of control which may be acquired, or provide that the purchaser is required to make a tender offer to the public. However, the opinion of the Israeli Securities Authority (the "ISA") is that such exemption does not apply with respect to companies whose shares are listed for trading on stock exchanges in the United States, including Nasdaq, which, in the ISA's opinion, do not provide for sufficient legal restrictions on obtaining control or an obligation to make a tender offer to the public.

Merger

The Companies Law permits merger transactions if approved by each party's board of directors and, unless certain conditions described under the Companies Law are met, by each party's shareholders by a majority vote as described below.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the shares voted at the shareholders meeting held by shareholders who are not the other party to the merger, or held by any person who holds 25% or more of the outstanding shares or the right to appoint 25% or more of the directors of the other party to the merger (including relatives or entities in control of the above), vote against the merger. If the transaction would have been approved but for the separate approval of each class or the exclusion of the votes of certain shareholders as provided above, a court may still approve the merger upon the request of holders of at least 25% of the voting rights of a company, if the court holds that the merger is fair and reasonable, taking into account the relative value of the merger parties and the consideration offered to the shareholders. If the non-surviving entity of the merger has more than one class of shares, the merger must be approved by each class of shareholders. If a merger is with a company's controlling shareholder, or if a controlling shareholder has a personal interest in the merger, then the merger will be subject to the special majority approval required for an extraordinary transaction with a controlling shareholder (see: *Approval of Related Party Transactions under Israeli Law – Declaration of Personal Interest of Controlling Shareholders and Approval of Certain Transactions*). In the context of mergers (as well as other related party transactions), a "controlling shareholder" under Israeli law is deemed to include any shareholder holding 25% or more of the voting rights in the company if no other

shareholder owns more than 50% of the voting rights in the company, and two or more shareholders with a personal interest in the approval of the same transaction are deemed to be one shareholder for such purpose.

The Companies Law requires the board of directors of a merging company to discuss and determine whether, in its view, there exists a reasonable concern that as a result of the proposed merger, the surviving company will not be able to satisfy its obligations towards its creditors, and if not, the board of directors may not approve the merger. The Companies Law requires each merging company to inform its secured creditors of the proposed merger plan. Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that, as a result of the merger, the surviving company will be unable to satisfy the obligations of any of the parties to the merger, and may further give instructions to secure the rights of creditors.

A merger may not be completed unless at least 50 days have passed from the date that a proposal for approval of the merger is filed with the Israeli Registrar of Companies, and 30 days have passed from the date the merger was approved by the shareholders of each merging company.

Antitakeover Measures

The Companies Law allows us to create and issue shares having rights different from those attached to our ordinary shares, including shares providing certain preferred rights, distributions or other matters, and shares having preemptive rights. As of the date of the registration statement of which this prospectus forms a part, we do not have any authorized or issued classes of shares other than our ordinary shares. In the future, if we do create and issue a class of shares other than ordinary shares, such class of shares, depending on the specific rights that may be attached to them, may delay or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their ordinary shares. The authorization of a new class of shares will require an amendment to our articles of association which requires the prior approval of the holders of a majority of our shares at a general meeting. Shareholders voting in such meeting will be subject to the restrictions provided in the Companies Law as described above.

DESCRIPTION OF AMERICAN DEPOSITARY SHARES

The Bank of New York Mellon (the “Depositary”), as depositary, has registered and delivered American Depositary Shares, also referred to as ADSs. Each ADS represents four hundred (400) ordinary shares (or a right to receive four hundred (400) ordinary shares) deposited with The Bank of New York Mellon in Manchester, United Kingdom, as custodian for the Depositary. The Depositary’s corporate trust office at which the ADSs will be administered is located at 240 Greenwich Street, New York, New York 10286. The Bank of New York Mellon’s principal executive office is located at 240 Greenwich Street, New York, New York 10286.

ADSs may be held either (a) directly (1) by having an American Depositary Receipt, also referred to as an ADR, which is a certificate evidencing a specific number of ADSs or (2) by having uncertificated ADSs, or (b) indirectly by holding a security entitlement in ADSs through a broker or other financial institution that is a direct or indirect participant in The Depositary Trust Company, also called DTC. If ADSs are held directly by the holder, then that holder is registered as such, and is referred to in our description here as an ADS holder. An indirect holder of ADSs indirectly must rely on the procedures of the holder’s broker or other financial institution to assert the rights of ADS holder described in this Exhibit.

Registered holders of uncertificated ADSs will receive statements from the depositary confirming their holdings.

We will not treat registered ADS holders as one of our shareholders, and they will not have shareholder rights. Israeli law governs shareholder rights. The depositary will be the holder of the ordinary shares underlying ADSs. A registered holder of ADSs will have ADS holder rights. A deposit agreement among us, the depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs.

The following is a summary of the material provisions of the deposit agreement. For more complete information, you should read the entire deposit agreement and the form of ADR.

Dividends and Other Distributions

How will you receive dividends and other distributions on the shares?

The depositary has agreed to pay or distribute to ADS holders the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities, upon payment or deduction of its fees and expenses. You will receive these distributions in proportion to the number of ordinary shares your ADSs represent.

Cash. The depositary will convert any cash dividend or other cash distribution we pay in non-U.S. currency on the ordinary shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the United States. If that is not possible or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency, and it will not be liable for any interest.

Before making a distribution, the depositary will deduct any withholding taxes, or other required governmental charges. See “Certain Material U.S. Federal Income Tax Considerations” below. The depositary will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, you may lose some or all of the value of the distribution.

Shares. The depositary may distribute additional ADSs representing any ordinary shares we distribute as a dividend or free distribution. The depositary will only distribute whole ADSs. It will sell ordinary shares which would require it to deliver a fraction of an ADS (or ADSs representing those shares) and distribute the net proceeds in the same way as it does with cash. If the depositary does not distribute additional ADSs, the outstanding ADSs will also represent the new shares. The depositary may sell a portion of the distributed ordinary shares (or ADSs representing those shares) sufficient to pay its fees and expenses in connection with that distribution.

Rights to purchase additional shares. If we offer holders of our securities any rights to subscribe for additional ordinary shares or any other rights, the depositary may (1) exercise those rights on behalf of ADS holders, (2) distribute those rights to ADS holders or (3) sell those rights and distribute the net proceeds to ADS holders, in each case after deduction or upon payment of its fees and expenses. To the extent the depositary does not do any of those things, it will allow the rights to lapse. In that case, you will receive no

value for them. The depositary will exercise or distribute rights only if we ask it to and provide satisfactory assurances to the depositary that it is legal to do so. If the depositary will exercise rights, it will purchase the securities to which the rights relate and distribute those securities or, in the case of ordinary shares, new ADSs representing the new ordinary shares, to subscribing ADS holders, but only if ADS holders have paid the exercise price to the depositary. U.S. securities laws may restrict the ability of the depositary to distribute rights or ADSs or other securities issued on exercise of rights to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

Other Distributions. The depositary will send to ADS holders anything else we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with non-U.S. currency. Alternatively, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory evidence from us that it is legal to make that distribution. The depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution. U.S. securities laws may restrict the ability of the depositary to distribute securities to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. This means that you may not receive the distributions we make on our ordinary shares or any value for them if it is illegal or impractical for us to make them available to you.

Deposit, Withdrawal and Cancellation

How are ADSs issued?

The depositary will deliver ADSs upon deposits of ordinary shares or evidence of rights to receive ordinary shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

How can ADS holders withdraw the deposited securities?

ADS holders may surrender ADSs for the purpose of withdrawal at the Depositary's account at DTCC (BNYM's DTC participant #2504). Upon payment of its cancellation fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the ordinary shares and any other deposited securities underlying the ADSs to the ADS holder or a person the ADS holder designates in accordance with the Cancellation Instruction provided to The Bank of New York Mellon.

How do ADS holders interchange between certificated ADSs and uncertificated ADSs?

ADS holders may surrender ADS to the depositary for the purpose of exchanging ADS for uncertificated ADSs. The depositary will cancel that ADS and will send to the ADS holder a statement confirming that the ADS holder is the registered holder of uncertificated ADSs. Upon receipt by the depositary of a proper instruction from a registered holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to the ADS holder an ADS evidencing those ADSs.

Voting Rights

ADS holders may instruct the depositary how to vote the number of deposited ordinary shares their ADSs represent. If we request the depositary to solicit your voting instructions (and we are not required to do so), the depositary will notify you of a shareholders' meeting and send or make voting materials available to you. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they must reach the depositary by a date set by the depositary.

The depositary will try, as far as practical, subject to the laws of Israel and the provisions of our articles of association or similar documents, to vote or to have its agents vote the ordinary shares or other deposited securities as instructed by ADS holders. If we do

not request the depositary to solicit your voting instructions, you can still send voting instructions, and, in that case, the depositary may try to vote as you instruct, but it is not required to do so.

Except by instructing the depositary as described above, ADS holders will not be able to exercise voting rights, unless they surrender your ADSs and withdraw the ordinary shares. However, ADS holders may not know about the meeting sufficiently in advance to withdraw the ordinary shares. In any event, the depositary will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed.

We cannot assure that ADS holders will receive the voting materials in time to ensure that they can instruct the depositary to vote ordinary shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. This means that ADS holders may not be able to exercise voting rights and there may be nothing they can do if your ordinary shares are not voted as requested.

In order to give ADS holders a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to deposited securities, if we request the Depositary to act, we agree to give the depositary notice of any such meeting and details concerning the matters to be voted upon at least thirty days in advance of the meeting date.

Fees and Expenses

Persons depositing or withdrawing shares or ADS holders must pay:

\$5.00 (or less) per 400 ADSs (or portion of 400 ADSs)

\$0.05 (or less) per ADS

A fee equivalent to the fee that would be payable if securities distributed to you had been ordinary shares and the ordinary shares had been deposited for issuance of ADSs

\$0.05 (or less) per ADSs per calendar year

Registration or transfer fees

Expenses of the Depositary

Taxes and other governmental charges the Depositary or the custodian have to pay on any ADS or share underlying an ADS, for example, stock transfer taxes, stamp duty or withholding taxes

Any charges incurred by the Depositary or its agents for servicing the deposited securities

For:

Issuance of ADSs, including issuances resulting from a distribution of ordinary shares or rights or other property
Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates

Any cash distribution to ADS holders

Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders

Depositary services

Transfer and registration of ordinary shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw ordinary shares

Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement); converting foreign currency to U.S. dollars

As necessary

As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing ordinary shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary or share

revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

Payment of Taxes

ADS holders are responsible for any taxes or other governmental charges payable on their ADSs or on the deposited securities represented by any of their ADSs. The depositary may refuse to register any transfer of ADSs or allow a withdrawal of the deposited securities represented by your ADSs, until such taxes or other charges are paid. It may apply payments owed to the ADS holder or sell deposited securities represented by the ADSs to pay any taxes owed and the ADS holder will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.

Tender and Exchange Offers; Redemption, Replacement or Cancellation of Deposited Securities

The depositary will not tender deposited securities in any voluntary tender or exchange offer unless instructed to do by an ADS holder surrendering ADSs and subject to any conditions or procedures the depositary may establish.

If deposited securities are redeemed for cash in a transaction that is mandatory for the depositary as a holder of deposited securities, the depositary will call for surrender of a corresponding number of ADSs and distribute the net redemption money to the holders of called ADSs upon surrender of those ADSs.

If there is any change in the deposited securities such as a sub-division, combination or other reclassification, or any merger, consolidation, recapitalization or reorganization affecting the issuer of deposited securities in which the depositary receives new securities in exchange for or in lieu of the old deposited securities, the depositary will hold those replacement securities as deposited securities under the deposit agreement. However, if the depositary decides it would not be lawful and to hold the replacement securities because those securities could not be distributed to ADS holders or for any other reason, the depositary may instead sell the replacement securities and distribute the net proceeds upon surrender of the ADSs.

If there is a replacement of the deposited securities and the depositary will continue to hold the replacement securities, the depositary may distribute new ADSs representing the new deposited securities or ask you to surrender your outstanding ADRs in exchange for new ADSs identifying the new deposited securities.

If there are no deposited securities underlying ADSs, including if the deposited securities are cancelled, or if the deposited securities underlying ADSs have become apparently worthless, the depositary may call for surrender or of those ADSs or cancel those ADSs upon notice to the ADS holders.

Amendment and Termination

How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the ADSs without consent of the ADS holders for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depositary for registration fees, facsimile costs, delivery charges or similar items, or prejudices a substantial right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depositary notifies ADS holders of the amendment. At the time

an amendment becomes effective, ADS holders are considered, by continuing to hold your ADSs, to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended.

How may the deposit agreement be terminated?

The depositary will initiate termination of the deposit agreement if we instruct it to do so. The depositary may initiate termination of the deposit agreement if

- 60 days have passed since the depositary told us it wants to resign but a successor depositary has not been appointed and accepted its appointment;
- we delist our ordinary shares from an exchange on which they were listed and do not list the ordinary shares on another exchange;
- we appear to be insolvent or enter insolvency proceedings all or substantially all the value of the deposited securities has been distributed either in cash or in the form of securities;
- there are no deposited securities underlying the ADSs or the underlying deposited securities have become apparently worthless; or
- there has been a replacement of deposited securities.

If the deposit agreement will terminate, the depositary will notify ADS holders at least 90 days before the termination date. At any time after the termination date, the depositary may sell the deposited securities. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement, unsegregated and without liability for interest, for the pro rata benefit of the ADS holders that have not surrendered their ADSs. Normally, the depositary will sell as soon as practicable after the termination date.

After the termination date and before the depositary sells, ADS holders can still surrender their ADSs and receive delivery of deposited securities, except that the depositary may refuse to accept a surrender for the purpose of withdrawing deposited securities if it would interfere with the selling process. The depositary may refuse to accept a surrender for the purpose of withdrawing sale proceeds until all the deposited securities have been sold. The depositary will continue to collect distributions on deposited securities, but, after the termination date, the depositary is not required to register any transfer of ADSs or distribute any dividends or other distributions on deposited securities to the ADSs holder (until they surrender their ADSs) or give any notices or perform any other duties under the deposit agreement except as described in this paragraph.

Limitations on Obligations and Liability

Limits on our Obligations and the Obligations of the Depositary; Limits on Liability to Holders of ADSs

The deposit agreement expressly limits our obligations and the obligations of the depositary. It also limits our liability and the liability of the depositary. We and the depositary:

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith;
- are not liable if we are or it is prevented or delayed by law or circumstances beyond our or its control from performing our or its obligations under the deposit agreement;
- are not liable if we or it exercises discretion permitted under the deposit agreement;
- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement;

- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on your behalf or on behalf of any other person;
- are not liable for the acts or omissions of any securities depository, clearing agency or settlement system; and
- may rely upon any documents we believe or it believes in good faith to be genuine and to have been signed or presented by the proper person.

In the deposit agreement, we and the depository agree to indemnify each other under certain circumstances.

Requirements for Depository Actions

Before the depository will deliver or register a transfer of ADSs, make a distribution on ADSs, or permit withdrawal of shares, the depository may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any ordinary shares or other deposited securities;
- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and
- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depository may refuse to deliver ADSs or register transfers of ADSs when the transfer books of the depository or our transfer books are closed or at any time if the depository or we think it advisable to do so.

Right to Receive the Ordinary Shares Underlying ADSs

ADS holders have the right to cancel their ADSs and withdraw the underlying ordinary shares at any time except:

- when temporary delays arise because: (1) the depository has closed its transfer books or we have closed our transfer books; (2) the transfer of ordinary shares is blocked to permit voting at a shareholders meeting; or (3) we are paying a dividend on our shares;
- when you owe money to pay fees, taxes and similar charges; or
- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of ordinary shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Pre-release of ADSs

The deposit agreement permits the depository to deliver ADSs before deposit of the underlying shares. This is called a pre-release of the ADSs. The depository may also deliver ordinary shares upon cancellation of pre-released ADSs (even if the ADSs are canceled before the pre-release transaction has been closed out). A pre-release is closed out as soon as the underlying ordinary shares are delivered to the depository. The depository may receive ADSs instead of ordinary shares to close out a pre-release. The depository may pre-release ADSs only under the following conditions: (1) before or at the time of the pre-release, the person to whom the pre-release is being made represents to the depository in writing that it or its customer owns the ordinary shares or ADSs to be deposited; (2) the pre-release is fully collateralized with cash or other collateral that the depository considers appropriate; and (3) the depository must be able to close out the pre-release on not more than five business days' notice. In addition, the depository will limit the number of ADSs that may be outstanding at any time as a result of pre-release, although the depository may disregard the limit from time to time if it thinks it is appropriate to do so.

Direct Registration System

In the deposit agreement, all parties to the deposit agreement acknowledge that the Direct Registration System, or DRS, and Profile Modification System, or Profile, will apply to the ADSs. DRS is a system administered by DTC that facilitates interchange between registered holdings of uncertificated ADSs and holdings of security entitlements in ADSs through DTC and a DTC participant. Profile is a feature of DRS that allows a DTC participant, claiming to act on behalf of a registered holder of ADSs, to direct the depository to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that DTC participant without receipt by the depository of prior authorization from the ADS holder to register that transfer.

In connection with and in accordance with the arrangements and procedures relating to DRS/Profile, the parties to the deposit agreement understand that the depository will not determine whether the DTC participant that is claiming to be acting on behalf of an ADS holder in requesting registration of transfer and delivery as described in the paragraph above has the actual authority to act on behalf of the ADS holder (notwithstanding any requirements under the Uniform Commercial Code). In the deposit agreement, the parties agree that the depository's reliance on and compliance with instructions received by the depository through the DRS/Profile system and in accordance with the deposit agreement will not constitute negligence or bad faith on the part of the depository.

Shareholder communications; inspection of register of holders of ADSs

The depository will make available for your inspection at its office all communications from us that we make generally available to holders of deposited securities. The depository will send you copies of those communications or otherwise make those communications available to you upon our request. You have a right to inspect the register of holders of ADSs, but not for the purpose of contacting those holders about a matter unrelated to our business or the ADSs.

CERTAIN MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS

THE FOLLOWING SUMMARY IS INCLUDED HEREIN FOR GENERAL INFORMATION AND IS NOT INTENDED TO BE, AND SHOULD NOT BE CONSIDERED TO BE, LEGAL OR TAX ADVICE. EACH HOLDER SHOULD CONSULT WITH HIS OR HER OWN TAX ADVISOR AS TO THE PARTICULAR U.S. FEDERAL INCOME TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP AND SALE OF ORDINARY SHARES, AMERICAN DEPOSITORY SHARES AND WARRANTS, INCLUDING THE EFFECTS OF APPLICABLE STATE, LOCAL, FOREIGN OR OTHER TAX LAWS AND POSSIBLE CHANGES IN THE TAX LAWS.

Subject to the limitations described in the next paragraph, the following discussion summarizes the material U.S. federal income tax consequences to a “U.S. Holder” arising from the purchase, ownership and disposition of the ordinary shares, ADSs and warrants. For this purpose, a “U.S. Holder” is a beneficial owner of ordinary shares or ADSs or warrants that is: (1) an individual citizen or resident of the United States, including an alien individual who is a lawful permanent resident of the United States or meets the substantial presence residency test under U.S. federal income tax laws; (2) a corporation (or entity treated as a corporation for U.S. federal income tax purposes) created or organized under the laws of the United States, any state therein, or the District of Columbia; (3) an estate, the income of which is includable in gross income for U.S. federal income tax purposes regardless of source; (4) a trust if a court within the United States is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust; and (5) a trust that has a valid election in effect to be treated as a U.S. person to the extent provided in U.S. Treasury regulations. A “non-U.S. Holder” is a beneficial owner of ordinary shares or ADSs or warrants that is not a U.S. Holder.

This summary is for general information purposes only and does not purport to be a comprehensive description of all of the U.S. federal income tax considerations that may be relevant to a decision to purchase our ordinary shares or ADSs or warrants. This summary generally considers only U.S. Holders that will own our ordinary shares or ADSs or warrants as capital assets (generally, property held for investment). Except to the limited extent discussed below, this summary does not consider the U.S. federal tax consequences to a person that is a non-U.S. Holder, nor does it describe the rules applicable to determine a taxpayer’s status as a U.S. Holder. This summary is based on the provisions of the Code, final, temporary and proposed U.S. Treasury regulations promulgated thereunder, administrative and judicial interpretations thereof, and the Convention Between the Government of the United States of America and the Government of the State of Israel with Respect to Taxes on Income (the “U.S.-Israel Double Tax Treaty”), all as in effect as of the date hereof and all of which are subject to change, possibly on a retroactive basis, and all of which are open to differing interpretations. We will not seek a ruling from the Internal Revenue Service, or IRS, with regard to the U.S. federal income tax treatment of an investment in our ordinary shares or ADSs or warrants and, therefore, can provide no assurances that the IRS will agree with the conclusions set forth below.

This discussion does not address all of the tax considerations that may be relevant to a particular U.S. Holder based on such holder’s particular circumstances, or to U.S. Holders that are subject to special treatment under U.S. federal income tax law, including: (1) banks, life insurance companies, regulated investment companies, or other financial institutions or “financial services entities”; (2) brokers or dealers in securities or foreign currency; (3) persons who acquired our ordinary shares or ADSs or warrants in connection with employment or other performance of services; (4) U.S. Holders that are subject to the U.S. alternative minimum tax; (5) U.S. Holders that hold our ordinary shares or ADSs or warrants as a hedge or as part of a hedging, straddle, conversion or constructive sale transaction or other risk-reduction transaction for U.S. federal income tax purposes; (6) tax-exempt entities; (7) real estate investment trusts; (8) U.S. Holders that expatriate out of the United States or former long-term residents of the United States; or (9) U.S. Holders having a functional currency other than the U.S. dollar. This discussion does not address the U.S. federal income tax treatment of a U.S. Holder that owns, directly, indirectly or constructively, at any time, ordinary shares or ADSs or warrants representing 10% or more of our voting power or value. This discussion also does not address any U.S. state or local or non-U.S. tax considerations, any U.S. federal estate, gift, generation-skipping, transfer, or alternative minimum tax considerations, or any U.S. federal tax consequences other than U.S. federal income tax consequences.

If an entity or arrangement treated as a partnership for U.S. federal income tax purposes holds our ordinary shares or ADSs or warrants, the tax treatment of such entity or arrangement treated as a partnership and each person treated as a partner thereof generally will depend upon the status and activities of the entity and such person. A holder that is treated as a partnership for U.S. federal income tax purposes and partners thereof should consult their own tax advisors regarding the U.S. federal income tax considerations applicable to the purchase, ownership and disposition of our ordinary shares or ADSs or warrants.

Each prospective investor is advised to consult his or her own tax adviser for the specific tax consequences to that investor of purchasing, holding or disposing of our ordinary shares or ADSs or warrants, including the effects of applicable state, local, foreign or other tax laws and possible changes in the tax laws.

U.S. Tax Status of the Company

Although the Company is incorporated under Israeli law, as a result of the consummation of the Merger, the Company should be treated, pursuant to Section 7874 of the Code, as a U.S. corporation for all purposes under the Code. As a result, since the Company is and will be treated as a U.S. corporation for U.S. federal income tax purposes and, we do not intend to treat the Company as a “passive foreign investment company,” as such rules apply only to non-U.S. corporations that are treated as such for U.S. federal income tax purposes. Since the Company is a taxable corporation in Israel, it would likely be subject to income taxation in both the United States and Israel on the same income, which could reduce the amount of income available for distribution to shareholders. The ability of the Company to take foreign tax credits against its U.S. tax liability in respect of taxes paid in Israel may be limited.

The remainder of this discussion assumes that the Company is treated as a U.S. corporation for all U.S. federal income tax purposes. If, for some reason (e.g., future repeal of Section 7874 of the Code), we were no longer treated as a U.S. corporation under the Code, the U.S. federal income tax consequences described herein could be materially and adversely affected.

Taxation of Dividends Paid on Ordinary Shares or ADSs

We do not intend to pay dividends in the foreseeable future. In the event that we do pay dividends, a U.S. Holder will be required to include in gross income as ordinary income the amount of any distribution paid on ordinary shares or ADSs (including the amount of any Israeli tax withheld on the date of the distribution), to the extent that such distribution does not exceed our current or accumulated earnings and profits, as determined for U.S. federal income tax purposes. The amount of a distribution which exceeds our current and accumulated earnings and profits will be treated first as a non-taxable return of capital, reducing the U.S. Holder’s tax basis for the ordinary shares or ADSs to the extent thereof, and then as capital gain. Corporate holders generally will not be allowed a deduction for dividends received.

In general, preferential tax rates for “qualified dividend income” and long-term capital gains are applicable for U.S. Holders that are individuals, estates or trusts. For this purpose, “qualified dividend income” means, inter alia, dividends received from a “domestic corporation.” As indicated above, we believe we should be treated as a domestic corporation and our dividends will therefore be qualified dividend income. A U.S. Holder will not be entitled to the preferential rate: (1) if the U.S. Holder has not held our ordinary shares or ADSs for at least 61 days of the 121-day period beginning on the date which is 60 days before the ex-dividend date, or (2) to the extent the U.S. Holder is under an obligation to make related payments on substantially similar property. Any days during which the U.S. Holder has diminished its risk of loss on our ordinary shares or ADSs are not counted towards meeting the 61-day holding period. Finally, U.S. Holders who elect to treat the dividend income as “investment income” pursuant to Code section 163(d)(4) will not be eligible for the preferential rate of taxation.

The amount of a distribution with respect to our ordinary shares or ADSs will be measured by the amount of the fair market value of any property distributed, and for U.S. federal income tax purposes, the amount of any Israeli taxes withheld therefrom. Cash distributions paid by us in NIS will be included in the income of U.S. Holders at a U.S. dollar amount based upon the spot rate of exchange in effect on the date the dividend is includible in the income of the U.S. Holder, and U.S. Holders will have a tax basis in such NIS for U.S. federal income tax purposes equal to such U.S. dollar value. If the U.S. Holder subsequently converts the NIS into U.S. dollars or otherwise disposes of it, any subsequent gain or loss in respect of such NIS arising from exchange rate fluctuations will be U.S. source ordinary exchange gain or loss.

U.S. Holders’ eligibility to claim a foreign tax credit with respect to any Israeli withholding tax imposed on dividends paid by us may be limited. The foreign tax credit rules are complex, and their application in connection with Section 7874 of the Code in the presence of the U.S.-Israel Double Tax Treaty, are not entirely clear at this time. U.S. Holders should consult their own tax advisors with respect to any benefits they may be entitled to under the foreign tax credit rules and the U.S.-Israel Double Tax Treaty, and to determine whether, and to what extent, they are entitled to such credits.

Taxation of the Disposition of Ordinary Shares or ADSs or Warrants

Upon the sale, exchange or other taxable disposition of our ordinary shares or ADSs or warrants, a U.S. Holder generally will recognize capital gain or loss in an amount equal to the difference between such U.S. Holder’s tax basis for the ordinary shares or

ADSs or warrants in U.S. dollars and the amount realized on the disposition in U.S. dollars (or its U.S. dollar equivalent determined by reference to the spot rate of exchange on the date of disposition, if the amount realized is denominated in a foreign currency). The gain or loss realized on the sale, exchange or other disposition of ordinary shares or ADSs or warrants will be long-term capital gain or loss if the U.S. Holder has a holding period of more than one year at the time of the disposition. U.S. Holders should consult their own tax advisors regarding the U.S. federal income tax consequences of receiving currency other than U.S. dollars upon the disposition of their ordinary shares.

Gain realized by a U.S. Holder on a sale, exchange or other disposition of ordinary shares or ADSs or warrants will generally be treated as U.S. source income for U.S. foreign tax credit purposes. A loss realized by a U.S. Holder on the sale, exchange or other disposition of ordinary shares or ADSs or warrants is generally allocated to U.S. source income. The deductibility of a loss realized on the sale, exchange or other disposition of ordinary shares or ADSs or warrants is subject to limitations.

A U.S. Holder's eligibility to claim a foreign tax credit with respect to any Israeli withholding tax imposed on gain from the sale or other disposition of our ordinary shares or ADSs or warrants may be limited. The foreign tax credit rules are complex, and their application in connection with Section 7874 of the Code in the presence of the U.S.-Israel Double Tax Treaty are not entirely clear at this time. U.S. Holders should consult their own tax advisors with respect to any benefits they may be entitled to under the foreign tax credit rules and the U.S.-Israel Double Tax Treaty.

Exercise or Lapse of a Warrant

Except as discussed below with respect to a cashless exercise of a warrant, a U.S. Holder generally will not recognize gain or loss upon the exercise of a warrant for cash. An ordinary share or ADS acquired pursuant to the exercise of a warrant for cash generally will have a tax basis equal to the U.S. Holder's tax basis in the warrant, increased by the amount paid to exercise the warrant. The holding period of such share or ADS generally begins on the day after the date of exercise of the warrant and will not include the period during which the U.S. Holder held the warrant.

The tax consequences of a cashless exercise of a warrant are not clear under current tax law. A cashless exercise may be tax-free, either because the exercise is not a gain realization event or because the exercise is treated as a recapitalization for U.S. federal income tax purposes. In either tax-free situation, a U.S. Holder's basis in the ordinary shares or ADSs received upon exercise of a warrant would equal the holder's basis in the warrant. If the cashless exercise were not treated as a gain realization event, a U.S. Holder's holding period in the ordinary shares or ADSs received upon exercise of a warrant would be treated as commencing on the date following the date of exercise (or possibly the date of exercise) of the warrant. If the cashless exercise were treated as a recapitalization, the holding period of the ordinary shares or ADSs received upon exercise of a warrant would include the holding period of the warrant.

It is also possible that a cashless exercise could be treated in part as a taxable exchange in which gain or loss would be recognized. In such event, a U.S. Holder would recognize gain or loss with respect to the portion of the exercised warrants treated as surrendered to pay the exercise price of the warrants (the "surrendered warrants"). The U.S. Holder would recognize capital gain or loss in an amount equal to the difference between the fair market value of the surrendered warrants and the U.S. Holder's tax basis in such warrants. In this case, a U.S. Holder's tax basis in the ordinary shares or ADSs received upon exercise of a warrant would equal the sum of the fair market value of the surrendered warrants and the U.S. Holder's tax basis in the warrants exercised (except for any such tax basis allocable to the surrendered warrants). A U.S. holder's holding period for the ordinary shares or ADSs received upon exercise of a warrant would commence on the date following the date of exercise (or possibly the date of exercise) of the warrant.

Due to the absence of authority on the U.S. federal income tax treatment of a cashless exercise, there can be no assurance which, if any, of the alternative tax consequences and holding periods described above would be adopted by the IRS or a court. Accordingly, U.S. Holders should consult their tax advisors regarding the tax consequences of a cashless exercise.

If a warrant is allowed to lapse unexercised, a U.S. Holder generally will recognize a capital loss equal to such holder's tax basis in the warrant. U.S. Holders should consult their own tax advisors regarding the U.S. federal income tax consequences of the exercise of a warrant, including with respect to whether the exercise is a taxable event, and their holding period and tax basis in the ordinary shares or ADSs received.

Tax on Investment Income

U.S. Holders who are individuals, estates or trusts will generally be required to pay a 3.8% Medicare tax on their net investment income (including dividends on and gains from the sale or other disposition of our ordinary shares and ADSs or warrants), or in the case of estates and trusts on their net investment income that is not distributed. In each case, the 3.8% Medicare tax applies only to the extent the U.S. Holder's total adjusted income exceeds applicable thresholds.

Tax Consequences for Non-U.S. Holders of Ordinary Shares or ADSs or Warrants

Taxation of Dividends Paid on Ordinary Shares or ADSs

In general, any distributions we make to a non-U.S. Holder on ordinary shares or ADSs, to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles), will constitute dividends for U.S. federal income tax purposes and, provided such dividends are not effectively connected with the non-U.S. Holder's conduct of a trade or business within the United States, we will be required to withhold tax from the gross amount of the dividend at a rate of 30%, unless such non-U.S. Holder is eligible for a reduced rate of withholding tax under an applicable income tax treaty and provides proper certification of its eligibility for such reduced rate (usually on an IRS Form W-8BEN or W-8BEN-E, as applicable). Any distribution on our ordinary shares or ADSs not constituting a dividend for U.S. federal income tax purposes will be treated first as reducing (but not below zero) the non-U.S. Holder's adjusted tax basis in its shares of such stock and, to the extent such distribution exceeds the non-U.S. Holder's adjusted tax basis in such stock, as gain realized from the sale or other disposition of such stock, which will be treated as described under "Gain on Sale, Exchange or Other Taxable Disposition of Ordinary Shares, ADSs, and Warrants" below. The full amount of any distributions to you may, however, be subject to U.S. withholding tax unless the applicable withholding agent elects to withhold a lesser amount based on a reasonable estimate of the amount of the distribution that would be treated as a dividend for U.S. federal income tax purposes. In addition, if we determine that we are classified as a "United States real property holding corporation" (see "—Gain on Sale, Exchange or Other Taxable Disposition of Ordinary Shares, ADSs, and Warrants" below), we will withhold 15% of any distribution that exceeds our current and accumulated earnings and profits.

Dividends we pay to a non-U.S. Holder that are effectively connected with such non-U.S. Holder's conduct of a trade or business within the United States (and if a tax treaty applies are attributable to a U.S. permanent establishment or fixed base maintained by the non-U.S. Holder) will generally not be subject to U.S. withholding tax, provided such non-U.S. Holder complies with certain certification and disclosure requirements (usually by providing an IRS Form W-8ECI). Instead, such dividends will generally be subject to U.S. federal income tax, net of certain deductions, at the same graduated individual or corporate rates applicable to U.S. Holders. If the non-U.S. Holder is a corporation, dividends that are effectively connected income may also be subject to a "branch profits tax" at a rate of 30% (or such lower rate as may be specified by an applicable income tax treaty).

Exercise or Lapse of a Warrant

The U.S. federal income tax treatment of a non-U.S. Holder's exercise of a warrant or the lapse of a warrant held by a non-U.S. Holder generally will correspond to the U.S. federal income tax treatment of the exercise or lapse of a warrant by a U.S. Holder, as described under "Exercise of a Warrant" above. Accordingly, a non-U.S. Holder generally will not be subject to U.S. federal income tax on the exercise of a warrant in exchange for ordinary shares or ADSs. However, if a cashless exercise of warrants results in a taxable exchange, as described above in "Exercise of a Warrant" above, the rules described below under "—Gain on Sale, Exchange or Other Taxable Disposition of Ordinary Shares, ADSs, and Warrants" would apply.

Gain on Sale, Exchange or Other Taxable Disposition of Ordinary Shares, ADSs, and Warrants

A non-U.S. Holder generally will not be subject to U.S. federal income or withholding tax on the proceeds from the disposition of, our ordinary shares or ADSs or warrants, unless:

- the gain is effectively connected with the conduct of a trade or business by the non-U.S. Holder within the United States (and, if an applicable tax treaty so requires, is attributable to a U.S. permanent establishment or fixed base maintained by the non-U.S. Holder);
- the non-U.S. Holder is an individual who is present in the United States for 183 days or more in the taxable year of disposition and certain other conditions are met; or

- we are or have been a “United States real property holding corporation” for U.S. federal income tax purposes at any time during the shorter of the five-year period ending on the date of disposition or the period that the non-U.S. Holder held our ordinary shares or ADSs, and, in the case where our ordinary shares or ADSs are regularly traded on an established securities market, the non-U.S. Holder has owned, directly or constructively, more than 5% of our regularly-traded stock at any time within the shorter of the five-year period preceding the disposition or such non-U.S. Holder’s holding period for the stock disposed of by the non-U.S. holder. There can be no assurance that our ordinary shares or ADSs will be treated as regularly traded on an established securities market for this purpose.

Gain described in the first bullet point above will be subject to tax at generally applicable U.S. federal income tax rates. Any gains described in the first bullet point above of a non-U.S. Holder that is a foreign corporation may also be subject to an additional “branch profits tax” at a 30% rate (or lower applicable treaty rate). Gain described in the second bullet point above will generally be subject to a flat 30% U.S. federal income tax, although the gain may be offset by some United States source capital losses realized during the same taxable year. Non-U.S. Holders are urged to consult their tax advisors regarding possible eligibility for benefits under income tax treaties.

If the third bullet point above applies to a non-U.S. Holder, gain recognized by such holder on the sale, exchange or other disposition of our ordinary shares, ADSs, or warrants will be subject to tax at generally applicable U.S. federal income tax rates. In addition, a buyer of our ordinary shares, ADSs, or warrants from such holder may be required to withhold U.S. income tax at a rate of 15% of the amount realized upon such disposition. We will be classified as a United States real property holding corporation if the fair market value of our “United States real property interests” equals or exceeds 50% of the sum of the fair market value of our worldwide real property interests plus our other assets used or held for use in a trade or business, as determined for U.S. federal income tax purposes. Non-U.S. Holders are urged to consult their own tax advisors regarding the application of these rules.

Payments to Foreign Financial Institutions

The Foreign Account Tax Compliance Act (“FATCA”) generally provides that a 30% withholding tax may be imposed on payments of U.S. source income, such as U.S. source dividends, to certain non-U.S. entities unless such entities enter into an agreement with the IRS to disclose the name, address and taxpayer identification number of certain U.S. persons that own, directly or indirectly, interests in such entities, as well as certain other information relating to such interests. Non-U.S. Holders are encouraged to consult with their own tax advisors regarding the possible implications and obligations of FATCA. While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of ordinary shares or ADSs on or after January 1, 2019, recently proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Information Reporting and Withholding

A U.S. Holder may be subject to backup withholding at a rate of 24% with respect to dividends and proceeds from a disposition of ordinary shares or ADSs or warrants. In general, backup withholding will apply only if a U.S. Holder fails to comply with specified identification procedures. Backup withholding will not apply with respect to payments made to designated exempt recipients, such as corporations and tax-exempt organizations.

In general, non-U.S. Holders will not be subject to backup withholding with respect to the payment of dividends and proceeds from a disposition of ordinary shares or ADSs or warrants, provided that the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person, and the holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any payments of dividends on our ordinary shares or ADSs paid to the non-U.S. holder, regardless of whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our ordinary shares or ADSs or warrants within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person, or the holder otherwise establishes an exemption. Proceeds of a disposition of our ordinary shares or ADSs or warrants conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Backup withholding is not an additional tax and may be claimed as a credit against the U.S. federal income tax liability of a holder, provided that the required information is timely furnished to the IRS.

CERTAIN MATERIAL ISRAELI TAX CONSIDERATIONS

The following description is not intended to constitute a complete analysis of all tax consequences relating to the ownership or disposition of our ordinary shares or ADSs or warrants (all referred to in this section as “the Shares”). You should consult your own tax advisor concerning the tax consequences of your particular situation, as well as any tax consequences that may arise under the laws of any state, local, foreign, including Israeli, or other taxing jurisdiction.

The following is a summary of the material tax consequences under Israeli law concerning the purchase, ownership and disposition of our Shares.

This discussion does not purport to constitute a complete analysis of all potential tax consequences applicable to investors upon purchasing, owning or disposing of our Shares. In particular, this discussion does not take into account the specific circumstances of any particular investor (such as tax-exempt entities, financial institutions, certain financial companies, broker-dealers, investors that own, directly or indirectly, 10% or more of our outstanding voting rights, all of whom are subject to special tax regimes not covered under this discussion). To the extent that issues discussed herein are based on legislation that has yet to be subject to judicial or administrative interpretation, there can be no assurance that the views expressed herein will accord with any such interpretation in the future.

You are urged to consult your own tax advisors as to the Israeli or other tax consequences of the purchase, ownership, and disposition of the Shares, including, in particular, the effect of any foreign, state or local taxes.

General Corporate Tax Structure in Israel

Israeli companies are generally subject to corporate tax on their taxable income at the rate of 23% for the 2022 tax year.

Taxation of Shareholders

Capital Gains

Capital gains tax is imposed on the disposition of capital assets by an Israeli resident and on the disposition of such assets by a non-Israeli resident if those assets are either (i) located in Israel; (ii) are shares or a right to a share in an Israeli company, or (iii) represent, directly or indirectly, rights to assets located in Israel, unless an exemption is available or unless an applicable double tax treaty between Israel and the seller's country of residence provides otherwise. The Israeli Income Tax Ordinance distinguishes between “Real Gain” and the “Inflationary Surplus”. “Real Gain” is the excess of the total capital gain over Inflationary Surplus generally computed on the basis of the increase in the Israeli Consumer Price Index between the date of purchase and the date of disposition. Inflationary Surplus is not subject to tax.

Taxable capital gain accrued by individuals on the sale of the Shares are taxed at the rate of 25%. However, if the individual shareholder is a “Substantial Shareholder” at the time of sale or at any time during the preceding 12-month period, such gain will be taxed at the rate of 30%. In this regard, broadly, a “Substantial Shareholder” is considered to be a person who alone, or together with his relative or another person who collaborates with him on a regular basis, holds, directly or indirectly, at least 10% of any our means of control. In this context “means of control” generally includes the right to vote, receive profits, nominate a director or an officer, receive assets upon liquidation, or instruct someone who holds any of these rights regarding the manner in which he or she is to exercise such right(s), and all regardless of the source of such rights).

The term “Israeli resident” is generally defined under Israeli tax legislation with respect to individuals as a person whose center of life is in Israel. The Ordinance provides that in order to determine the center of life of an individual, account will be taken of the individual's family, economic and social connections, including: (a) place of permanent home; (b) place of residential dwelling of the individual and the individual's immediate family; (c) place of the individual's regular or permanent occupation or the place of his permanent employment; (d) place of the individual's active and substantial economic interests; and (e) place of the individual's activities in organizations, associations and other institutions. The center of life of an individual will be presumed to be in Israel if: (a) the individual was present in Israel for 183 days or more in the tax year; or (b) the individual was present in Israel for 30 days or more in the tax year, and the total period of the individual's presence in Israel in that tax year and the two previous tax years is 425 days or more. The presumption in this paragraph may be rebutted either by the individual or by the assessing officer.

Capital gains derived by corporations are subject to tax at the same rate as the corporate tax rate. Under Israeli tax legislation, a corporation will be considered as an “Israeli Resident” if it meets one of the following criteria: (a) it was incorporated in Israel; or (b) the control and management of its business are exercised in Israel.

Despite the above, capital gains generated from the sale of our Shares by a non-Israeli shareholder may be exempt from Israeli tax under the Israeli Income Tax Ordinance provided that the following cumulative conditions are met: (i) the Shares were purchased by the selling shareholder upon or after the registration of the Shares on the non-Israeli stock exchange (on July 29, 2016) and (ii) the selling shareholder does not have a permanent establishment in Israel to which the generated capital gain is attributed. However, a seller of our Shares that is a non-Israeli resident corporation will not be entitled to this exemption if Israeli residents: (i) hold a 25% or more interest in such non-Israeli corporation or (ii) are the beneficiaries of, or are entitled to, 25% or more of the income or profits of such non-Israeli corporation, whether directly or indirectly. In addition, this exemption would not be available to a person whose gains from selling or otherwise disposing of our Shares are deemed to be business income.

Likewise, capital gains generated from the sale of our Shares by a non-Israeli shareholder who purchased the Shares before the registration of the Shares on the non-Israeli stock exchange may also be exempt from Israeli tax under the Israeli Income Tax Ordinance provided that the following cumulative conditions are met: (i) the Shares were purchased on January 1, 2009 or afterwards; (ii) the Shares were not purchased from a related party (as defined for this purpose) and were not purchased as part of an exempted reorganization for Israeli tax purposes; (iii) the Shares are not registered for trade on an Israeli stock exchange at the date of the sale; and (iv) on the day of the purchase of the Shares and in the two years preceding its sale – the bulk of the value of the assets held by the Israeli company, directly or indirectly, are not rights in, or attached or related to, or in connection with the use of or proceeds from, immovable property or natural resources in Israel.

In addition, the sale of the Shares may be also exempt from Israeli capital gains tax under the provisions of an applicable double tax treaty. For example, the U.S.-Israel Double Tax Treaty should exempt a U.S. resident from Israeli capital gain tax in connection with the sale of our Shares, provided that: (i) the U.S. resident owned, directly or indirectly, less than 10% of our voting power at any time within the 12-month period preceding such sale; (ii) the U.S. resident, being an individual, is present in Israel for a period or periods of less than 183 days during the taxable year; and (iii) the capital gain from the sale was not derived through a permanent establishment of the U.S. resident in Israel. A U.S. resident not exempt from Israeli capital gains tax may be limited under U.S. law in its ability to claim a credit for such taxes against the U.S. federal income tax imposed with respect to such sale, exchange or disposition even if such U.S. resident is eligible for benefits under the U.S.-Israel Double Tax Treaty. The U.S.-Israel Double Tax Treaty does not relate to U.S. state or local taxes.

There may be some other circumstances in which exemptions (or partial exemptions) may apply, so that any non-Israeli shareholder who does not meet the aforementioned exemption criteria (whether under the Israeli internal tax law or the relevant tax treaty) should consult their own tax advisors.

Payers of consideration for the purchase of our Shares, including the actual purchaser, the Israeli stockbroker or the financial institution through which the Shares are held, may be obligated to withhold tax upon the sale of Shares at a rate of 25% (for individuals) or 23% (for corporations) of the consideration. However, where the seller of our Shares is a non-Israeli resident, there is usually an exemption from such withholding duty (based on a declaration of tax status to be provided by the seller).

Upon the sale of traded securities, a detailed return, including a computation of the tax due, must be filed and an advance payment must be paid to the Israeli Tax Authority on January 31 and July 31 of every tax year in respect of sales of traded securities made within the previous six months. This will apply to the sale of our Shares. However, if all tax due was withheld at source according to applicable provisions of the Israeli Income Tax Ordinance and regulations promulgated thereunder, such return need not be filed, and no advance payment must be paid. Capital gains are also reportable on annual income tax returns.

Dividends

Dividends distributed by an Israeli company to a shareholder who is an Israeli resident individual will generally be subject to income tax at a rate of 25%. However, a 30% tax rate will apply if the dividend recipient is a Substantial Shareholder, as defined above, at the time of distribution or at any time during the preceding 12-month period. If the recipient of the dividend is an Israeli resident corporation, dividends will generally be exempted from Israeli income tax provided that the income from which such dividend is distributed was derived or accrued within Israel.

Dividends distributed by an Israeli company to a non-Israeli resident (either an individual or a corporation) are generally subject to Israeli withholding tax at the rate of 25% (30% if the dividend recipient is a Substantial Shareholder at the time of distribution or at any time during the preceding 12-month period). These rates may be reduced under the provisions of an applicable double tax treaty. For example, under the U.S.-Israel Double Tax Treaty, the following tax rates will apply in respect of dividends distributed by an Israeli resident company to a U.S. resident: (i) if the U.S. resident is a corporation that holds during that portion of the taxable year which precedes the date of payment of the dividend and during the whole of its prior taxable year (if any), at least 10% of the outstanding shares of the voting stock of the Israeli company paying the dividend and not more than 25% of the gross income of such Israeli company for such prior taxable year (if any) consists of certain types of interest or dividends the tax rate is 12.5%; (ii) if both the conditions mentioned in clause (i) above are met and the dividend is paid from an Israeli resident company's income which was entitled to a reduced tax rate under The Law for the Encouragement of Capital Investments, 1959, the tax rate is 15%; and (iii) in most other cases, the tax rate is 25%. The aforementioned lower rates under the U.S.-Israel Double Tax Treaty will not apply if the dividend income is attributed to a permanent establishment of the U.S. resident in Israel.

Surtax

Individual holders who are subject to tax in Israel (whether any such individual is an Israeli resident or non-Israeli resident) and who have taxable income that exceeds a certain threshold in a tax year ((NIS 663,240 for 2022, linked to the Israeli Consumer Price Index) will be subject to an additional tax at the rate of 3% on his or her taxable income for such tax year that is in excess of such amount. For this purpose, taxable income includes taxable capital gains from the sale of securities and taxable income from interest and dividends, subject to the provisions of an applicable double tax treaty.

Estate and Gift Tax

Israel does not currently impose estate or gift taxes if the Israeli Tax Authority is satisfied that the gift was made by an Israeli resident individual in good faith and on condition that the recipient of the gift is not a non-Israeli resident. If the gift giver is a non-Israeli resident individual, then he should be exempted under the aforementioned capital gains tax exemptions provided for a regular sale of shares.

YOU SHOULD CONSULT YOUR OWN TAX ADVISOR REGARDING THE PARTICULAR ISRAELI TAX CONSEQUENCES OF PURCHASING, HOLDING, AND DISPOSING OF OUR SHARES, INCLUDING THE CONSEQUENCES OF ANY PROPOSED CHANGE IN APPLICABLE LAWS.

PLAN OF DISTRIBUTION

We are registering ordinary shares represented by ADSs issued and issuable upon exercise of the Warrants to permit the resale of these ordinary shares represented by ADSs by the selling shareholders from time to time after the date of this prospectus. We will not receive any of the proceeds from the sale by the selling shareholders of ordinary shares represented by ADSs. We will bear all fees and expenses incident to our obligation to register ordinary shares represented by ADSs.

Each selling shareholder may sell all or a portion of ordinary shares represented by ADSs beneficially owned by it and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If ordinary shares represented by ADSs are sold through underwriters or broker-dealers, such selling shareholder will be responsible for underwriting discounts or commissions or agent's commissions. The ordinary shares represented by ADSs may be sold in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions,

- on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale;
- in the over-the-counter market;
- in transactions otherwise than on these exchanges or systems or in the over-the-counter market;
- through the writing of options, whether such options are listed on an options exchange or otherwise;
- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- sales pursuant to Rule 144;
- broker-dealers may agree with the selling securityholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

If a selling shareholder effects such transactions by selling ordinary shares represented by ADSs to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from such selling shareholder or commissions from purchasers of ordinary shares represented by ADSs for whom they may act as agent or to whom they may sell as principal (which discounts, concessions or commissions as to particular underwriters, broker-dealers or agents may be in excess of those customary in the types of transactions involved). In connection with sales of ordinary shares represented by ADSs or otherwise, the selling shareholders may enter into hedging transactions with broker-dealers, which may in turn engage in short sales of ordinary shares represented by ADSs in the course of hedging in positions they assume. The selling shareholders may also sell ordinary shares represented by ADSs short and deliver ordinary shares represented by ADSs covered by this prospectus to close out short positions and to return borrowed shares in connection with such short sales. The selling shareholders may also loan or pledge ordinary shares represented by ADSs to broker-dealers that in turn may sell such shares.

Each selling shareholder may pledge or grant a security interest in some or all of the warrants or ordinary shares represented by ADSs owned by it and, if it defaults in the performance of its secured obligations, the pledgees or secured parties may offer and sell ordinary shares represented by ADSs from time to time pursuant to this prospectus or any amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act of 1933, as amended, amending, if necessary, the list of selling shareholders to include the pledgee, transferee or other successors in interest as selling shareholders under this prospectus. The selling shareholders also may transfer and donate ordinary shares represented by ADSs in other circumstances in which case the transferees, donees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

The selling shareholders and any broker-dealer participating in the distribution of ordinary shares represented by ADSs may be deemed to be “underwriters” within the meaning of the Securities Act, and any commission paid, or any discounts or concessions allowed to, any such broker-dealer may be deemed to be underwriting commissions or discounts under the Securities Act. At the time a particular offering of ordinary shares represented by ADSs is made, a prospectus supplement, if required, will be distributed which will set forth the aggregate amount of ordinary shares represented by ADSs being offered and the terms of the offering, including the name or names of any broker-dealers or agents, any discounts, commissions and other terms constituting compensation from the selling shareholders and any discounts, commissions or concessions allowed or reallocated or paid to broker-dealers.

Under the securities laws of some states, ordinary shares represented by ADSs may be sold in such states only through registered or licensed brokers or dealers. In addition, in some states ordinary shares represented by ADSs may not be sold unless such shares have been registered or qualified for sale in such state or an exemption from registration or qualification is available and is complied with.

There can be no assurance that the selling shareholders will sell any or all of ordinary shares represented by ADSs registered pursuant to the registration statement, of which this prospectus forms a part.

The selling shareholders and any other person participating in such distribution will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including, without limitation, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of ordinary shares represented by ADSs by the selling shareholders and any other participating person. Regulation M may also restrict the ability of any person engaged in the distribution of ordinary shares represented by ADSs to engage in market-making activities with respect to ordinary shares represented by ADSs. All of the foregoing may affect the marketability of ordinary shares represented by ADSs and the ability of any person or entity to engage in market-making activities with respect to ordinary shares represented by ADSs.

We will pay all expenses of the registration of ordinary shares represented by ADSs pursuant to the Registration Rights Agreement, estimated to be \$234,730.07 in total, including, without limitation, SEC filing fees and expenses of compliance with state securities or “blue sky” laws; provided, however, that the selling shareholders will pay all underwriting discounts and selling commissions, if any. We will indemnify Altium against liabilities, including some liabilities under the Securities Act of 1933, as amended (the “Securities Act”), in accordance with the Registration Rights Agreement, or Altium will be entitled to contribution. We may be indemnified by Altium against civil liabilities, including liabilities under the Securities Act, that may arise from any written information furnished to us by Altium specifically for use in this prospectus, in accordance with the Registration Rights Agreement, or we may be entitled to contribution.

Once sold under the registration statement, of which this prospectus forms a part, ordinary shares represented by ADSs will be freely tradable in the hands of persons other than our affiliates. Although ADSs are listed on the Nasdaq Capital Market, we cannot assure you that a regular trading market for our ADSs will sustain or continue to exist. We do not expect that a trading market will develop for our ordinary shares not represented by the ADSs.

EXPENSES RELATED TO THIS OFFERING

Set forth below is an itemization of the total expenses that we expect to incur in connection with this offering. With the exception of the SEC registration fee, all amounts are estimates.

SEC registration fee	\$ 1,730.07
Legal fees and expenses	\$ 203,000.00
Accounting fees and expenses	\$ 15,000.00
Printing expenses	\$ 10,000.00
Miscellaneous expenses	\$ 5,000.00
Total	\$ 234,730.07

LEGAL MATTERS

The validity of our ordinary shares offered by this prospectus will be passed upon for us by S. Horowitz & Co., our Israeli counsel. We are being represented by Blank Rome LLP with respect to certain matters of U.S. federal law.

EXPERTS

The financial statements included in this prospectus have been audited by Friedman LLP, an independent registered public accounting firm, as stated in their report appearing herein. Such financial statements are included in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

ENFORCEABILITY OF CIVIL LIABILITIES

To the extent any of our shareholders may seek to enforce a U.S. judgment in Israel against us or our executive officers and directors, or to assert U.S. securities law claims in Israel, shareholders may have difficulties enforcing such a U.S. judgment, including judgments based upon the civil liability provisions of the U.S. federal securities laws, in Israel.

We have been informed by our legal counsel in Israel that it may be difficult to assert claims under U.S. securities laws in original actions instituted in Israel or obtain a judgment based on the civil liability provisions of U.S. federal securities laws. Israeli courts may refuse to hear a claim based on a violation of U.S. securities laws against us or our officers and directors because Israel may not be the most appropriate forum to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel addressing the matters described above. Israeli courts might not enforce judgments rendered outside Israel, which may make it difficult to collect on judgments rendered against us or our officers and directors.

Moreover, among other reasons, including but not limited to fraud or absence of due process, or the existence of a judgment which is at variance with another judgment that was given in the same matter if a suit in the same matter between the same parties was pending before a court or tribunal in Israel, an Israeli court will not enforce a foreign judgment if it was given in a state whose laws do not provide for the enforcement of judgments of Israeli courts (subject to exceptional cases) or if its enforcement is likely to prejudice the sovereignty or security of the State of Israel.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We are subject to the reporting requirements of the Exchange Act that are applicable to a foreign private issuer. Under the Exchange Act, we file annual reports on Form 20-F and other information with the SEC. We also furnish to the SEC under cover of Form 6-K material information required to be made public in our home country, filed with and made public by any stock exchange on which we are listed or distributed by us to our shareholders. As a foreign private issuer, we are exempt from, among other things, the rules under the Exchange Act prescribing the furnishing and content of proxy statements and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act.

The SEC maintains a web site that contains reports and information statements and other information about issuers, such as us, who file electronically with the SEC. The address of that website is www.sec.gov.

This prospectus is part of a registration statement on Form F-1 that we filed with the SEC and does not contain all of the information in the registration statement. The full registration statement may be obtained from the SEC or us, as provided below. Forms of the documents establishing the terms of the offered securities are or may be filed as exhibits to the registration statement, of which this prospectus forms a part. Statements in this prospectus about these documents are summaries and each statement is qualified in all respects by reference to the document to which it refers. You should refer to the actual documents for a more complete description of the relevant matters. You may inspect a copy of the registration statement through the SEC's website, as provided above.

We also maintain a website at <https://quoinpharma.com> through which you can access our SEC filings. The information set forth on our website is not part of this prospectus.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Shareholders and the Board of Directors of Quoin Pharmaceuticals Ltd.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Quoin Pharmaceuticals Ltd. (the “Company”) as of December 31, 2021 and 2020, the related statements of operations, and shareholders’ equity (deficit), and cash flows for the years then ended, and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2021 and 2020, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on the Company’s financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of a critical audit matter does not alter in any way our opinion on the financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing a separate opinion on the critical audit matters or on the accounts or disclosures to which they relate.

Assessment of the measurement of fair value of Warrants:

As discussed in Notes 4 and 5 to the financial statements, the Company issued warrants in connection with the Convertible Notes Payable and the Bridge Financing. The warrants were initially classified as liabilities. The warrants estimated fair value upon their dates of issuance, as well as from those issuance dates to either the warrant exchange on October 28, 2021 or December 31, 2021, as applicable, was \$12.8 million and recorded on the statement of operations as warrant liability expense. The Company utilizes a Monte Carlo simulation model to estimate the fair value.

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We identified the assessment of the measurement of warrant fair value as a critical audit matter that is challenging due to the high degree of judgment, including the involvement of professionals with specialized skills and knowledge, as well as the complex valuation methodology that incorporates assumptions to estimate the fair value.

The primary procedures we performed to address this critical audit matter included evaluating the design of the internal control related to the Company's process to measure the fair value and testing the valuation methodology and corresponding inputs used by the valuation professionals with specialized skills including:

- Evaluating the model and methodology used to calculate the fair value of the warrants
- Evaluating and comparing the expected price volatility against a volatility range that was independently developed using peer group volatility information, and
- Independently developed a range of the fair value of the warrants

Contracted Research & Development Cost Recognition:

As discussed in Note 3 to the financial statements, the Company records costs for clinical trial activities based upon estimates of costs incurred through the balance sheet date for services performed by contract research organizations, clinical study sites and other vendors.

Auditing the recognition of pre-clinical and clinical trial costs associated with contracted organizations is challenging due to the significant judgment required to determine the nature and level of services that have been received, including determining the progress to completion of specific tasks and activities conducted in relation to what has been invoiced and recorded.

The primary procedures we performed to address this critical audit matter included:

- Obtained an understanding of the design and operating effectiveness of internal controls for pre-clinical and clinical cost recognition
- Tested the completeness and accuracy of the underlying data used in the estimates including, but not limited to, the estimated costs per project milestone and duration
- Assessed the reasonableness of the significant assumptions, corroborated the progress of the pre-clinical and clinical trials with the Company's operations personnel and to information obtained by the Company directly from third parties, and to information in contracts or statements of work including costs for those activities and project duration
- Examined subsequent invoicing received from such third parties

/s/ Friedman LLP

We have served as the Company's auditor since 2020.

East Hanover, New Jersey

April 13, 2022

QUOIN PHARMACEUTICALS LTD.**Consolidated Balance Sheets**

	December 31,	
	2021	2020
ASSETS		
Current assets:		
Cash	\$ 7,482,773	\$ 323,832
Prepaid expenses	1,015,474	—
Deferred offering costs	—	141,338
Total current assets	<u>8,498,247</u>	<u>465,170</u>
Intangible assets, net	808,604	912,648
Other assets	50,000	—
Total assets	<u>\$ 9,356,851</u>	<u>\$ 1,377,818</u>
LIABILITIES AND SHAREHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	\$ 923,239	\$ —
Accrued expenses	1,685,409	960,848
Accrued license acquisition	250,000	875,000
Accrued interest and amounts due under convertible notes payable	743,840	47,041
Due to officers	4,723,732	4,888,913
Convertible notes payable	—	1,213,313
Warrant liability	373,599	—
Total liabilities	<u>8,699,819</u>	<u>7,985,115</u>
Commitments and contingencies		
Shareholders' equity (deficit):		
Ordinary shares, no par value, 12,500,000,000 ordinary shares authorized – 3,354,650,799 and 1,201,460,800 (8,386,627 and 3,003,651 ADSs) ordinary shares issued and outstanding at December 31, 2021 and 2020, respectively	—	—
Treasury Stock, 2,641,693 ordinary shares, at cost	(2,932,000)	—
Additional paid in capital	31,659,017	100
Accumulated deficit	<u>(28,069,985)</u>	<u>(6,607,397)</u>
Total shareholders' equity (deficit)	<u>657,032</u>	<u>(6,607,297)</u>
Total liabilities and shareholders' equity (deficit)	<u>\$ 9,356,851</u>	<u>\$ 1,377,818</u>

The accompanying footnotes are an integral part of these statements

QUOIN PHARMACEUTICALS LTD.**Consolidated Statements of Operations**

	Years Ended December 31,		
	2021	2020	2019
Revenue	\$ —	\$ —	\$ —
Operating expenses			
General and administrative	4,499,923	1,425,855	1,514,751
Research and development	1,562,927	244,155	45,650
Total operating expenses	6,062,850	1,670,010	1,560,401
Other expenses			
Fair value adjustment to convertible notes payable	1,250,000	378,333	—
Warrant liability expense	12,784,329	—	—
Financing expense	275,000	—	—
Interest expense	1,090,409	47,021	—
Total other expense	15,399,738	425,354	—
Net loss	\$ (21,462,588)	\$ (2,095,364)	\$ (1,560,401)
Loss per ADS and ordinary share			
Loss per ADS			
Basic	\$ (5.42)	\$ (0.70)	\$ (0.52)
Fully-diluted	\$ (5.42)	\$ (0.70)	\$ (0.52)
Weighted average number of ADSs outstanding			
Basic	3,962,264	3,003,652	3,003,652
Fully-diluted	3,962,264	3,003,652	3,003,652
Loss per ordinary share			
Basic	\$ (0.01)	\$ (0.70)	\$ (0.52)
Fully-diluted	\$ (0.01)	\$ (0.70)	\$ (0.52)
Weighted average number of ordinary shares outstanding			
Basic	1,584,905,594	1,201,460,800	1,201,460,800
Fully-diluted	1,584,905,594	1,201,460,800	1,201,460,800

The accompanying footnotes are an integral part of these statements

QUOIN PHARMACEUTICALS LTD.

Consolidated Statements of Shareholders' Equity (Deficit)
Years ended December 31, 2021, 2020 and 2019

	Ordinary Shares	No Par Value	ADSs	Treasury Stock	Additional Paid in Capital	Accumulated Deficit	Total
Balance at December 31, 2018	1,201,460,800	\$ —	3,003,652		\$ 100	\$ (2,951,632)	\$ (2,951,532)
Net loss						(1,560,401)	(1,560,401)
Balance at December 31, 2019	1,201,460,800	—	3,003,652		100	(4,512,033)	(4,511,933)
Net loss						(2,095,364)	(2,095,364)
Balance at December 31, 2020	1,201,460,800	—	3,003,652		100	(6,607,397)	(6,607,297)
Net loss						(21,462,588)	(21,462,588)
Conversion of "2020 Notes" into ordinary shares	25,913,600		64,784		1,213,313		1,213,313
Sale of equity securities, including conversion of "Bridge Notes"	1,710,500,800		4,276,252		17,000,000		17,000,000
Costs associated with sale of equity securities					(1,897,126)		(1,897,126)
Merger recapitalization of Collect	416,775,599		1,041,939	(2,932,000)	2,932,000		—
Reclassification of warrants upon issuance of exchange warrants					12,410,730		12,410,730
Balance at December 31, 2021	<u>3,354,650,799</u>	<u>\$ —</u>	<u>8,386,627</u>	<u>(2,932,000)</u>	<u>\$ 31,659,017</u>	<u>\$ (28,069,985)</u>	<u>\$ 657,032</u>

The accompanying footnotes are an integral part of these statements

QUOIN PHARMACEUTICALS LTD.**Consolidated Statements of Cash Flows**

	Years Ended December 31,		
	2021	2020	2019
Cash flows provided by (used in) operating activities			
Net loss	\$ (21,462,588)	\$ (2,095,364)	\$ (1,560,401)
Fair value adjustment to convertible notes payable	1,250,000	378,333	—
Warrant liability expense	12,784,329	—	—
Financing expense	275,000	—	—
Amortization of intangibles	104,043	104,043	20,710
Changes in assets and liabilities:			
Increase in accounts payable and accrued expenses	1,347,801	227,313	240,833
Increase in accrued interest	696,799	47,042	—
Increase in prepaid expenses	(715,474)	—	—
Net cash used in operating activities	(5,720,090)	(1,338,633)	(1,298,858)
Cash flows used in investing activities			
Payment for license acquisition	(625,000)	(125,000)	—
Net cash used in investing activities	(625,000)	(125,000)	—
Cash flows provided by financing activities:			
Increase (decrease) in deferred offering costs	141,338	(141,338)	—
Increase in other assets	(50,000)	—	—
Increase in due to officers	139,285	1,068,823	1,298,818
Payments of amounts due to officers	(304,466)	(50,000)	—
Proceeds from issuance of “Bridge Notes”, net	3,475,000	909,980	—
Proceeds from sale of equity securities, net	10,102,874	—	—
Net cash provided by financing activities	13,504,031	1,787,465	1,298,818
Net change in cash	7,158,941	323,832	(40)
Cash - beginning of year	323,832	—	40
Cash - end of year	<u>\$ 7,482,773</u>	<u>\$ 323,832</u>	<u>\$ —</u>
Supplemental information:			
License acquisition payable	\$ —	\$ —	\$ 1,000,000
Interest paid	393,611	—	—
Exchange of “2020 Notes” for Ordinary shares	\$ 1,213,313	—	—
Exchange of “Bridge Notes” for Ordinary shares	\$ 5,000,000	—	—
Reclassification of warrant liability to equity upon issuance of “Exchange Warrants”	\$ 12,410,730	—	—

The accompanying footnotes are an integral part of these statements

QUOIN PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements
December 31, 2021, 2020 and 2019

NOTE 1 – ORGANIZATION, BUSINESS AND BASIS OF PRESENTATION

Quoin Pharmaceuticals Ltd. (“Quoin Ltd.” or the “Company”), formerly known as Collect Biotechnology Ltd. (“Collect”), is the holding company for Quoin Pharmaceuticals, Inc., a Delaware corporation (“Quoin Inc.”). On October 28, 2021, Collect completed the business combination with Quoin Inc., in accordance with the terms of the Agreement and Plan of Merger and Reorganization, dated as of March 24, 2021 (the “Merger Agreement”), by and among Collect, Quoin Inc. and CellMSC, Inc., a Delaware corporation and wholly-owned subsidiary of Collect (“Merger Sub”), pursuant to which Merger Sub merged with and into Quoin Inc., with Quoin Inc. surviving as a wholly-owned subsidiary of Collect (the “Merger”). Immediately after completion of the Merger, Collect changed its name to “Quoin Pharmaceuticals Ltd.” The Company has accounted for the transaction as a reverse recapitalization with Quoin Inc. as the accounting acquirer. Because Quoin Inc. is the accounting acquirer, its historical financial statements became the Company’s historical financial statements and such assets and liabilities continued to be recorded at their historical carrying values. The impact of the recapitalization has been retroactively applied to all periods presented. All equity related disclosures are presented in American Depositary Shares (“ADSs”), unless the context indicates otherwise. One ADS represents 400 ordinary shares of the Company.

Quoin Inc. was incorporated in Delaware on March 5, 2018. Quoin Inc. is a specialty pharmaceutical company focused on developing and commercializing therapeutic products that treat rare and orphan diseases. The first lead product is QRX003, a once daily, topical lotion comprised of a broad-spectrum serine protease inhibitor, formulated with the proprietary Invisicare® technology, to treat Netherton Syndrome (NS). In addition, the Company intends to pursue the clinical development of QRX003 in additional rare dermatological diseases, including Peeling Skin Syndrome, SAM Syndrome and Palmoplantar Keratoderma.

To date, no products have been commercialized and revenue has not been generated. The majority of the operating expenses since inception have been associated with completing due diligence on various technologies, asset technology acquisitions, negotiating and finalizing potential funding agreements, costs related to the Merger and building the pipeline of preclinical product candidates. The founders of Quoin Inc. funded all related expenditures through September 2020.

On October 28, 2021, Collect sold the entire share capital of its subsidiary, Collect Biotherapeutics Ltd., which essentially included all of Collect’s then existing net assets, to EnCellX Inc. (“EnCellX”), a newly formed U.S. privately held company based in San Diego, CA (the “Share Transfer”), pursuant to an Amended and Restated Share Transfer Agreement. Quoin Ltd. has no interests in EnCellX subsequent to the closing of the Merger. See Note 12.

On October 28, 2021, the Company completed the private placement transaction with an investor (the “Investor”) for an aggregate purchase price of approximately \$17.0 million (comprised of the set off of approximately \$5 million of senior secured notes issued in connection with the bridge loan that the Investor previously made to Quoin Inc. and approximately \$12 million in cash from the Investor (the “Primary Financing”). See Note 5 .

Immediately after the closing of the Merger, there were approximately 8,386,627 ADSs issued and outstanding. The former holders of common stock of Quoin Inc. (including shares delivered to the Investor and the escrow account for the Investor) owned, in the aggregate, approximately 88% of the ordinary shares, with Collect’s shareholders immediately prior to the Merger owning approximately 12% of ordinary shares.

NOTE 2 - LIQUIDITY RISKS AND UNCERTAINTIES AND GOING CONCERN

The Company has incurred net losses every year since inception and had an accumulated deficit of approximately \$28.1 million at December 31, 2021. The Company funded its operations through the issuance of the 2020 Notes (as defined below) and the Bridge Financing (as defined below) prior to the Merger and the Primary Financing completed on October 28, 2021, whereby the Company received funding of approximately \$12 million (\$10.1 million after offering costs) at the

QUOIN PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements
December 31, 2021, 2020 and 2019

closing of the Merger. Further, the Company expects to receive additional funding through the mandatory exercise provision of the Series C Warrant issued to the Investor in March 2022 which would result in proceeds of approximately \$9.5 million. In the event the requirements of the mandatory exercise provision of such warrant are not met (see Note 5), the Company has a written commitment from the Investor to provide funding equal to the \$9.5 million expected upon exercise of the Series C Warrant, at prevailing market rates. As such, the Company believes that it has sufficient resources to affect its business plan for at least one year from the issuance of these consolidated financial statements. The Company is also in the process of negotiating a line of credit with a bank which has not yet been closed as of the financial statement filing date and is likely to be conditional on additional equity funding which could be satisfied by the aforementioned Investor funding, as well as the achievement of clinical development milestones.

Additional financing will be required to complete the research and development of the Company's therapeutic targets and its other operating requirements, which may not be available at acceptable terms, if at all. If the Company is unable to obtain the additional funding when it becomes necessary, the development of its product candidates will be impacted and the Company would likely be forced to delay, reduce, or terminate some or all of its development programs, all of which could have a material adverse effect on the Company's business, results of operations and financial condition.

NOTE 3 - SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation:

The accompanying consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States ("U.S. GAAP"), which have been consistently applied, reflecting the operations of Quoin Inc. since inception and include the accounts of Quoin Ltd. since the date of the Merger.

Use of estimates:

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts in the financial statements and accompanying notes. Actual results could materially differ from those estimates. Management considers many factors in selecting appropriate financial accounting policies and controls, and in developing the estimates and assumptions that are used in the preparation of these financial statements. In addition, other factors may affect estimates, including: expected business and operational changes, sensitivity and volatility associated with the assumptions used in developing estimates, and whether historical trends are expected to be representative of future trends. The estimation process often may yield a range of potentially reasonable estimates of the ultimate future outcomes and management must select an amount that falls within that range of reasonable estimates. Estimates are used in the following areas, among others: settlement of debt or other obligations, fair value of debt instruments and warrants, research and development expense recognition, intangible asset estimated useful lives and impairment assessments, allowances of deferred tax assets, contingency recognition, and cash flow assumptions regarding going concern considerations.

Other risks and uncertainties:

The Company is subject to risks common to development stage biopharmaceutical companies including, but not limited to, new technological innovations, dependence on key personnel, protection of proprietary technology, compliance with government regulations, product liability, pre-clinical and clinical trial outcome risks, regulatory approval risks, uncertainty of market acceptance and additional financing requirements.

The Company's products require approval or clearance from the U.S. Food and Drug Administration ("FDA") prior to commencing commercial sales in the United States. There can be no assurance that the Company's products will receive

QUOIN PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements
December 31, 2021, 2020 and 2019

all of the required approvals or clearances. Approvals or clearances are also required in foreign jurisdictions in which the Company may license or sell its products.

There can be no assurance that the Company's products, if approved, will be accepted in the marketplace, nor can there be any assurance that any future products can be developed or manufactured at an acceptable cost and with appropriate performance characteristics, or that such products will be successfully marketed.

The Company is also dependent on several third party suppliers, in some cases single-source suppliers which include the supplier of the active pharmaceutical ingredient (API) as well as the contract manufacturer of the drug substance for the expected clinical development.

A novel strain of coronavirus ("COVID-19") created a global pandemic, which commenced in 2020. The Company's operations, to date, have not been dramatically affected by COVID-19. However, the extent of any future impact on the Company's operational and financial performance will depend on the possibility of a resurgence and resulting severity of COVID-19 with respect to the Company's access to API and drug substance, the potential disruption in global freight networks, as well as our ability to safely and efficiently conduct planned clinical trials.

Cash and cash equivalents:

The Company considers all highly liquid investments and short-term debt instruments with original maturities of three months or less to be cash equivalents. The Company, from time to time during the periods presented, has had bank account balances in excess of federally insured limits where substantially all cash is held in the United States. The Company has not experienced losses in such accounts. The Company believes that it is not subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

Long-lived assets:

Long-lived assets are comprised of acquired technology and licensed rights to use technology, which are considered platform technology with alternative future uses beyond the current products in development. Such intangible assets are being amortized on a straight-line basis over their expected useful life of 10 years.

The Company assesses the impairment for long-lived assets whenever events or circumstances indicate the carrying value may not be recoverable. Factors we consider that could trigger an impairment review include the following:

- Significant changes in the manner of our use of the acquired assets or the strategy for our overall business,
- Significant underperformance relative to expected historical or projected development milestones,
- Significant negative regulatory or economic trends, and
- Significant technological changes which could render the platform technology obsolete.

The Company recognizes impairment when the sum of the expected undiscounted future cash flows is less than the carrying amount of the asset. Impairment losses, if any, are measured as the excess of the carrying amount of the asset over its estimated fair value. During the years ended December 31, 2021, 2020 and 2019, there were no impairment indicators which required an impairment loss measurement.

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Deferred Offering Costs:

Deferred offering costs are expenses directly related to the Primary Financing. These costs consisted of legal, accounting, printing, and filing fees that the Company capitalized which were offset against the proceeds upon completion of the Primary Financing.

Research and development:

Research and development costs are expensed as incurred. Research and development expenses include personnel costs associated with research and development activities, including third-party contractors to perform research, conduct clinical trials and manufacture drug supplies and materials. The Company accrues for costs incurred by external service providers, including contract research organizations and clinical investigators, based on its estimates of service performed and costs incurred. These estimates include the level of services performed by third parties, patient enrollment in clinical trials when applicable, administrative costs incurred by third parties, and other indicators of the services completed. Based on the timing of amounts invoiced by service providers, the Company may also record payments made to those providers as prepaid expenses that will be recognized as expense in future periods as the related services are rendered.

Income taxes:

The Company accounts for its income taxes using the asset and liability method. Accordingly, deferred tax assets and liabilities are recognized for future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and tax credit carry-forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. The Company maintains a full valuation allowance on its existing deferred tax assets.

The Company also accounts for uncertain tax positions using the more-likely-than-not threshold for financial statement recognition and measurement of a tax position taken in the Company's income tax returns. As of December 31, 2021 and 2020, the Company had no uncertain tax positions which affected its financial position and its results of operations or its cash flows and will continue to evaluate for uncertain tax positions in the future. If at any time the Company should record interest and penalties in connection with income taxes, the interest and the penalties will be expensed within the interest and general and administrative expenses, respectively.

Fair value of financial instruments:

The Company considers its cash, accounts payable, accrued expenses and the convertible and bridge notes payable to meet the definition of financial instruments. The convertible and bridge notes payable are recorded at fair value, see Notes 4, 5 and 6. The warrants are recorded at fair value, see Notes 4, 5 and 6. The carrying amounts of the remaining financial instruments approximated their fair values due to the short maturities.

The Company measures fair value as required by ASC Topic 820, *Fair Value Measurements and Disclosures* ("ASC Topic 820"). ASC Topic 820 defines fair value, establishes a framework and gives guidance regarding the methods used for measuring fair value, and expands disclosures about fair value measurements. ASC Topic 820 clarifies that fair value is an exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants.

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Earnings (loss) per share:

The Company reports loss per share in accordance with ASC 260-10, *Earnings Per Share*, which provides for calculation of “basic” and “diluted” earnings per share. Basic earnings per share includes no dilution and is computed by dividing net income or loss available to common shareholders by the weighted average common shares outstanding for the period. Diluted earnings per share reflect the potential dilution of securities that could share in the earnings of an entity. The calculation of diluted net earnings (loss) per share gives effect to ordinary shares equivalents; however, potential common shares are excluded if their effect is anti-dilutive.

For the year ended December 31, 2021, the number of shares excluded from the diluted net earnings (loss) per share included outstanding warrants to purchase 1,787,844 ADS or 715,137,600 Ordinary Shares and warrants to purchase 15,721,514 ADS or 6,288,605,600 Ordinary Shares issuable pursuant to Primary Financing.

For the year ended December 31, 2020, the number of shares issuable upon the conversion of both the Convertible Notes Payable (as defined below) and the Bridge Notes (as defined below) as well as the warrants issued in connection with both of these convertible instruments are not included in the denominator since their inclusion would be anti-dilutive.

New accounting pronouncements:

The Company has evaluated all recent accounting pronouncements and believes that none of them will have a material effect on the Company’s financial position, results of operations or cash flows except as discussed below.

Debt with Conversion and Other Options and Derivatives and Hedging

The FASB recently issued ASU 2020-06, *Debt – Debt with Conversion and Other Options (Subtopic 470- 20) and Derivatives and Hedging – Contracts in Entity’s Own Equity (Subtopic 815-40): Accounting for Convertible Instruments and Contracts in an Entity’s Own Equity*, to reduce complexity in applying GAAP to certain financial instruments with characteristics of liabilities and equity. The guidance in ASU 2020-06 simplifies the accounting for convertible debt instruments and convertible preferred stock by removing the existing guidance that requires entities to account for beneficial conversion features and cash conversion features in equity, separately from the host convertible debt or preferred stock. The guidance in ASC 470-20 applies to convertible instruments for which the embedded conversion features are not required to be bifurcated from the host contract and accounted for as derivatives. In addition, the amendments revise the scope exception from derivative accounting in ASC 815-40 for freestanding financial instruments and embedded features that are both indexed to the issuer’s own stock and classified in shareholders’ equity, by removing certain criteria required for equity classification. These amendments are expected to result in more freestanding financial instruments qualifying for equity classification (and, therefore, not accounted for as derivatives), as well as fewer embedded features requiring separate accounting from the host contract. The amendments in ASU 2020-06 further revise the guidance in ASC 260, *Earnings Per Share*, to require entities to calculate diluted earnings per share (EPS) for convertible instruments by using the if-converted method. In addition, entities must presume share settlement for purposes of calculating diluted EPS when an instrument may be settled in cash or shares. The amendments in ASU 2020-06 are effective for public entities, excluding smaller reporting companies as defined, for fiscal years beginning after December 15, 2021. For all other entities, the amendments are effective for fiscal years beginning after December 15, 2023. Early adoption is permitted, but no earlier than fiscal years beginning after December 15, 2020. The Company is currently evaluating the impact this standard will have on its financial statements.

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Earnings Per Share

In May 2021, the FASB issued ASU 2021-04, *Earnings Per Share* (Topic 260), *Debt-Modifications and Extinguishments* (Subtopic 470-50), *Compensation-Stock Compensation* (Topic 718), and *Derivatives and Hedging-Contracts in Entity's Own Equity* (Subtopic 815-40). The new ASU addresses issuer's accounting for certain modifications or exchanges of freestanding equity-classified written call options. This amendment is effective for all entities, for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early adoption is permitted. The Company does not believe the impact of the adoption of this pronouncement is significant to the consolidated financial statements.

Recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the Securities and Exchange Commission did not or are not believed by management to have a material impact on the Company's present or future consolidated financial statement presentation or disclosures.

NOTE 4 – CONVERTIBLE NOTES PAYABLE

On October 2, 2020, Quoin Inc. commenced an offering of promissory notes (the "2020 Notes" or "Convertible Notes Payable") and warrants. The 2020 Notes were issued at a 25% original issue discount and bear interest at a rate of 20% per annum. The 2020 Notes are due one year from their respective dates of issuance. In October through December 2020, Quoin Inc. received an aggregate of approximately \$910,000 pursuant to this offering, resulting in the issuance of 2020 Notes with an aggregate face value of \$1,213,313 and an original issue discount of \$303,333. Approximately 23% of such financing was received from parties who are related to or affiliated with members of Quoin Inc.'s board of directors. No additional funding from the 2020 Notes was received in the year ended December 31, 2021.

Based upon the terms agreed to in March 2021 in the Primary Financing (see Note 5), the 2020 Notes were mandatorily convertible into 64,784 ADSs in the Primary Financing, subject to adjustment.

The Company elected to account for the Convertible Notes Payable using the fair value model due to the short maturity and likely conversion at the date of the Merger. The fair value of the Convertible Notes Payable was estimated to be approximately \$1.2 million at the date of issuance, resulting in a \$378,000 expense recognized in the fourth quarter of 2020. There was no material change in the fair value from issuance until the conversion to equity on the Merger date.

The noteholders also were entitled to receive warrants exercisable at any time after the issuance date for a number of shares of Quoin Inc.'s common stock that equates to 100% of the "as if converted" shares as if the 2020 Notes principal and interest were convertible at the lowest price any securities are sold, convertible, or exercisable into in the Primary Financing or the next round of financing (whichever is lower). The exercise price was based on a valuation equal to the next financing round and since the number of shares issuable upon the exercise of the warrants and exercise price were not knowable at the time of the financing and as of December 31, 2020 they were not recognized. After entering into the Merger Agreement in March 2021, the terms of the warrants became measurable and were exercisable for 367,356 ADSs at an initial exercise price of \$3.98 per ADS.

The Company determined that these warrants met the criteria to be recorded as a liability instrument. Each holder agreed to exchange its warrant for warrants on substantially the same terms as the Investor Exchange Warrants (See Note 5) with the same number of shares issuable upon the exercise of an Exchange Warrant as upon the exercise of the original warrant and the same exercise price as under the original warrant and have a contractual term of 5 years

At the closing of the Merger, 64,784 ADSs were issued upon the conversion of the principle of the Convertible Notes Payable. In addition, effective as of March 13, 2022, the Company exchanged noteholders' warrants for warrants on substantially the same terms as the Investor Exchange Warrants (See Note 5), exercisable for 367,356 ADSs, in the

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aggregate, at the exercise price of \$3.98 per ADS. The Exchange Warrants have been determined to warrant equity classification and, as such, the fair value change through the exchange date will be included in warrant liability expense in the accompanying statement of operations.

In December 2021, the Company concluded that the calculation of ADSs due to the 2020 Noteholders did not account for accrued interest due when the ADSs were issued. The Company reached cash settlements with, and plans to issue additional ADSs to, the 2020 Noteholders to account for this. The estimated amount required to settle these obligations was determined to be approximately \$744,000 at December 31, 2021 and is included in accrued liabilities in the accompanying consolidated balance sheet and in interest expense in the accompanying consolidated statement of operations.

Interest expense, at the stated interest rate, recognized in the year ended December 31, 2021, 2020 and 2019 was approximately \$202,000, \$47,000, and \$0, respectively. Accrued interest and estimated settlement costs at December 31, 2021, 2020 and 2019 was approximately \$744,000, \$47,000, and \$0, respectively, of which \$697,000 was recognized in the year ended December 31, 2021.

NOTE 5 – BRIDGE FINANCING AND SECURITIES PURCHASE AGREEMENT (Primary Financing)

Bridge Financing

In connection with the Merger Agreement and the Securities Purchase Agreement (described below), Quoin Inc. entered into a “Bridge Purchase Agreement” on March 24, 2021 with the Investor, pursuant to which the Investor agreed to purchase, and Quoin Inc. agreed to issue notes (the “Bridge Notes”) in the aggregate principal amount of up to \$5.0 million in exchange for an aggregate purchase price of up to \$3.8 million together with warrants. The Bridge Notes were purchased in three closings: (i) the first purchase of \$2.0 million on March 25, 2021 (Quoin Inc. received proceeds of \$1.5 million less fees of \$90,000); (ii) the second purchase of \$1.7 million in April 2021 (Quoin Inc. received proceeds of \$1.25 million); and (iii) a third purchase of \$1.3 million in May 2021 (Quoin Inc. received proceeds of \$1.0 million less fees of \$185,000). The Bridge Notes were secured by a lien on Quoin Inc.’s current and future assets, were senior to all other outstanding and future indebtedness of Quoin Inc. and included covenants limiting future indebtedness, among others.

The Bridge Notes were issued with a 25% original issue discount, at an interest rate of 15% per annum and had a maturity date of the earliest to occur of: (i) December 25, 2021, (ii) the date on which Quoin Inc.’s equity is registered under the Exchange Act or is exchanged for equity so registered or (iii) immediately prior to the closing of the Merger

The Investor and Quoin Inc. agreed that if the Primary Financing is consummated, the Investor may, at its election, offset the purchase price otherwise payable by Investor to Quoin Inc. pursuant to the Securities Purchase Agreement related to the Primary Financing, by an amount equal to the outstanding amount under this Bridge Note, and, upon such set-off, the portion of this Bridge Note shall be deemed to have been paid in its entirety and all obligations thereunder shall be deemed to be fully satisfied without any further obligations on, or liability to, Quoin Inc.

The Company elected to account for the Bridge Notes using the fair value model due to the short maturity and likely conversion at the closing of the Merger. The cumulative fair value of the Bridge Notes was estimated to be approximately \$5.0 million at the date of issuances, resulting in an increase in the fair value of approximately \$1,250,000, which was recognized in the statement of operations for the year ended December 31, 2021. The fair value adjustments also included \$275,000 of debt issuance costs which was also immediately recognized as a component of other expense. Management has estimated that the fair value had not significantly changed from issuance to the Merger date. See Note 6.

The Bridge Notes were offset against the purchase price under the Securities Purchase Agreement related to the Primary Financing and converted into 1,257,721 ADSs (including shares held in escrow for the benefit of the Investor) upon the

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closing of the Primary Financing. The accrued interest amounting to \$393,611 was paid in cash. Interest expense, at the stated interest rate, recognized in the year ended December 31, 2021 was \$393,611.

Warrants

Upon the funding of each Bridge Note tranches described above, the Investor received warrants (the “Bridge Warrants”) to purchase a number of shares of Quoin Inc.’s common stock equal to the aggregate principal amount of the Bridge Notes. The Bridge Warrants have a term of five years from the date all of the shares underlying the Bridge Warrants are freely tradable. The Bridge Warrants also contain certain rights with regard to asset distributions and fundamental transactions. Quoin Inc. issued a total of 1,238,429 Bridge Warrants in the year ended December 31, 2021.

Following the closing date of the Merger, on each of the tenth trading day, the forty-fifth day, the ninetieth day, and the one hundred thirty-fifth day thereafter (each, a “Reset Date”), if the initial exercise price of the Bridge Warrants is greater than the arithmetic average of 85% of the three lowest weighted average prices of the post-Merger ordinary shares of the combined company during the ten trading day period immediately preceding the applicable Reset Date (the “Reset Price”), the exercise price of the Bridge Warrants will be reset to the Reset Price. Furthermore, the number of shares underlying Bridge Warrants will be adjusted such that the aggregate number of shares of common stock issuable to the Investor reflects the Reset Price instead of the initial exercise price. Adjustments to the exercise price and number of warrant shares are available to the Investor until the second anniversary of the Registration Date, as defined in the Bridge Warrants. Upon the occurrence of a Fundamental transaction, as defined in the Bridge Warrants, the warrant holder has the right to elect a cash settlement for the value of the warrant base on the Black Scholes options pricing model.

The Company determined that the warrants met the criteria to be recorded as a liability instrument through the exchange date upon the closing of the Primary Financing. The fair value of warrants was determined by a MonteCarlo simulation model to be approximately \$1.6 million at the date of issuance of the 495,374 warrants in connection with the first closing and \$2.2 million at the date of issuance of the 743,055 (post exchange ratio) in connection with the second and third closing of the Bridge Notes See Note 6.

Upon the closing of the Primary Financing, the Bridge Warrants were exchanged for warrants to purchase 1,238,429 ADSs at a fixed per share exercise price of \$3.98 (“Investor Exchange Warrants”), as amended, which replaced the reset provisions and modified the fundamental transaction requirements of the Bridge Warrants. The Investor Exchange Warrants and ordinary shares underlying the Investor Exchange Warrants were registered with the SEC on the Registration Statement on Form F-4. An amendment to the Investor Exchange Warrants was entered into in September 2021, which replaced the reset provisions with a fixed number of shares and exercise price.

Primary Financing

On October 28, 2021, the Company completed the private placement transaction with the Investor for an aggregate purchase price of approximately \$17.0 million (comprised of (x) the set off of approximately \$5 million of Bridge Notes, and (y) approximately \$12 million in cash from the Investor) (the “Primary Financing”), and the Investor paid the Company approximately \$11,504,000, which was net of \$393,611 in accrued interest on the Bridge Notes. The Company incurred an additional approximate \$1.4 million in costs associated with the Primary Financing, which resulted in the net proceeds of approximately \$10.1 million. The Company issued 4,276,252 ADSs to the Investor, consisting of 833,773 delivered to the Investor on or after the Merger closing and 3,442,479 initially held in an escrow account for the benefit of the Investor as per the terms of the Securities Purchase Agreement. All such escrow shares were released to the Investor prior to December 31, 2021.

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Quoin Ltd. also was required to issue to the Investor, effective as of March 13, 2022, the 136th day following the consummation of the Merger (i) Series A Warrant to purchase 4,276,252 ADSs (the “Series A Warrant”) (ii) Series B Warrant to purchase 4,276,252 ADSs (the “Series B Warrant”) and (iii) Series C Warrant to purchase 2,389,670 ADSs (“Series C Warrant” and, together with the Series A Warrant and Series B Warrant, the “Investor Warrants”). The exercise price for the Investor Warrants is \$3.98 per ADS, with Series A Warrant having a five-year maturity, and Series B Warrant and Series C Warrant having a two-year maturity. The Company has the right to require the mandatory exercise of the Series C Warrant, subject to an effective registration statement being in place for the resale of the shares underlying such warrants and the satisfaction of equity market conditions, as defined in the Series C Warrant. As of the financial statement filing date, not all of the market related conditions were met. Upon the exercise of the Series C Warrant in full, the Investor would also be granted an additional Series A Warrant to purchase 2,389,670 ADSs and an additional Series B Warrant to purchase 2,389,670 ADSs at an exercise price of \$3.98 per ADS.

NOTE 6 - FAIR VALUE OF FINANCIAL INSTRUMENTS

The Company applies fair value accounting for all assets and liabilities that are recognized or disclosed at fair value in the financial statements on a recurring basis. Fair value is defined as the price that would be received from selling an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. When determining the fair value measurements for assets and liabilities the Company considers the principal or most advantageous market in which it would transact and the market-based risk measurements or assumptions that market participants would use in pricing the asset or liability, such as risks inherent in valuation techniques, transfer restrictions and credit risk. For certain instruments, including cash and cash equivalents, accounts payable, and accrued expenses, it was estimated that the carrying amount approximated fair value because of the short maturities of these instruments.

Fair value is estimated using various valuation models, which utilize certain inputs and assumptions that market participants would use in pricing the asset or liability. The inputs and assumptions used in valuation models are classified in the fair value hierarchy as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Quoted market prices for similar instruments in an active market; quoted prices for identical or similar assets and liabilities in markets that are not active; and model-derived valuations inputs of which are observable and can be corroborated by market data.

Level 3: Unobservable inputs and assumptions that are supported by little or no market activity and that are significant to the fair value of the asset and liability. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining the appropriate hierarchy levels, the Company analyzes the assets and liabilities that are subject to fair value disclosure. Financial assets and liabilities are classified in their entirety based on the lowest level of input that is significant to their fair value measurement.

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The significant estimates used in the determining the fair value of the 2020 Notes warrants (Note 4) were as follows:

	<u>12/31/2021 (1)</u>	<u>12/31/2020</u>
Stock price	\$ 1.82	\$ 3.98
Initial exercise price	\$ 3.98	\$ 3.98
Contractual Term	5.0	5.0
Volatility	89.2 %	98 %
Discount rate	1.26 %	0.81 %

(1) The warrants issued during 2020 were not exchanged for fixed term warrants until 2022, therefore the existing warrants were still considered outstanding at December 31, 2021 and classified as a liability instrument.

The significant estimates used in such calculation of the fair value of the warrants issued in connection with the Bridge Financing (Note 5) were as follows:

	<u>Transaction Date</u>	<u>Merger Date</u>
	March - May 2021	10/28/2021
Stock price	\$ 3.98 (post exchange ratio)	\$ 11.64 (post exchange ratio)
Initial exercise price	\$ 3.98 (post exchange ratio)	\$ 3.98 (post exchange ratio)
Contractual Term	5.0	5.0
Volatility	92 %	89.2 %
Discount rate	0.98 %	1.18 %

The following table presents the Company's assets and liabilities that are measured at fair value on a recurring basis by fair value hierarchy at December 31, 2021 and 2020:

December 31, 2021	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
2020 Notes warrants	—	—	\$ 373,599	\$ 373,599
Total Warrant Liability	—	—	\$ 373,599	\$ 373,599
December 31, 2020	<u>Level 1</u>	<u>Level 2</u>	<u>Level 3</u>	<u>Total</u>
2020 Notes payable	\$ —	\$ —	\$ 1,213,333	\$ 1,213,333
Total Liabilities	\$ —	—	\$ 1,213,333	\$ 1,213,333

The fair value of the convertible notes payable issued in 2020 was determined to be \$1,213,333, resulting in a charge to operations of \$378,333 during 2020. The fair value adjustment from December 31, 2020 to their conversion to ADSs at the Merger date was not material. The initial fair value of the Bridge Notes issued in 2021 was determined to be approximately \$5,000,000, resulting in a charge to operations of \$1,250,000 during 2021. The fair value adjustment from the Bridge Notes issuances to their conversion to ADSs upon the Merger date was not significant. The Bridge Notes and 2020 Notes were converted into ADSs at the Merger date. See Notes 4 and 5.

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The following shows the movement of the warrant liability balance during 2021.

	Bridge Financing Warrants	2020 Notes Warrants
Beginning Balance	\$ —	\$ —
Warrant value at issuance (recorded as warrant liability expense)	3,783,079	894,113
Change in Fair value of warrants	8,627,651	(520,514)
Reclassification of warrant liability to an equity instrument	(12,410,730)	—
Ending Balance	<u>\$ —</u>	<u>\$ 373,599</u>

The change in fair value of the Bridge Note warrants are included in other expense in the accompanying consolidated financial statements from the issuance date to the Merger Date. The Exchange warrants issued to the Investor on the Merger date was determined to be an equity-classified instrument, and accordingly the warrant liability on such date of \$12,410,730 was reclassified to additional paid in capital on that date.

NOTE 7 – PREPAID EXPENSES

Prepaid expenses are as follows:

	December 31,	
	2021	2020
Prepaid R&D costs	\$ 329,033	\$ —
Prepaid insurance	684,191	—
Prepaid other expenses	2,250	—
Total	<u>\$ 1,015,474</u>	<u>\$ —</u>

NOTE 8 – ACCRUED EXPENSES

Accrued expenses are as follows:

	December 31,	
	2021	2020
Professional fees	\$ 144,377	\$ 173,095
Investor Relations fees	584,000	528,000
Payroll taxes	199,582	148,899
Payroll	557,937	—
Research contract expenses	193,537	105,052
Other expenses	5,976	5,802
Total	<u>\$ 1,685,409</u>	<u>\$ 960,848</u>

NOTE 9 – ASSET ACQUISITION AND IN-LICENSED TECHNOLOGY

Polytherapeutics

On March 24, 2018, Quoin Inc. entered into a securities purchase agreement (the “Acquisition Agreement”), in which it agreed to acquire all of the equity interests in Polytherapeutics, Inc. (the “Seller” or “Polytherapeutics”) for \$40,833 and future royalties provided Quoin Inc. commercializes products using the technology developed by the Seller. The terms of any royalty payments to the Seller are 4.0% of the net revenue of royalty products, as defined in the Acquisition Agreement,

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received by Quoin Inc. during the ten (10) year period commencing from the date of first sale of a royalty product. If a generic product is introduced by a third party to the market, during the royalty period, the royalty fees shall be reduced from 4% to 2%. If, during the royalty period, two or more generic products are introduced, the royalty fees shall be reduced from 2% to 0%.

The Seller had the option to repurchase the intellectual property for \$100,000 if there were no products in clinical development using such technology. The repurchase option was not exercised and has lapsed.

Quoin Inc. also entered into a research and consulting agreement which commits Quoin Inc. to pay the Seller for additional research and development consulting services (See Notes 12 and 15).

Skinvisible

On October 17, 2019, Quoin Inc. entered into an exclusive license agreement with Skinvisible Inc. (“Skinvisible”), pursuant to which Skinvisible granted a license to use certain patented technology for the development of products for commercial sale in the orphan rare skin disease field, and for the use of a proprietary polymer deliver system technology. This technology is currently being used in the development of QRX003. In exchange for the license, Quoin Inc. agreed to pay Skinvisible \$1,000,000, as well as development and sales milestone payments and a single digit royalty on all net sales, as defined.

The development milestones originally required payments upon achieving development milestones for the first Rare Skin Disease drug product developed using the licensed technology and the first two Ketamine products, as defined. Payments were originally due upon successful completions of certain clinical milestones (\$7.5 million) and obtaining US and EU regulatory approval (\$15 million). The sales milestones required for every licensed product commercialized by Quoin Inc. are \$10 million upon achievement of \$100 million in sales being achieved in the annual period; \$25 million upon achievement of \$250 million in sales and \$50 million upon the achievement of \$400 million in sales in an annual period. On January 27, 2021, Quoin Inc. and Skinvisible entered into an amendment which modified the clinical milestone payment requirements such that \$750,000 would be payable to Skinvisible upon achievement of specified clinical milestones, and \$21.75 million upon regulatory approval in the U.S. and EU respectively. No development milestones, sales milestones or royalty payments were due through in 2019, 2020 or 2021.

The agreement has a termination clause that is triggered if no product has commenced clinical testing 12 months after the date of the agreement or the latest subsequent amendment. On April 19, 2021, Quoin Inc. and Skinvisible entered into another amendment which established the development deadline as December 31, 2022. Should the Company not commence clinical testing as defined by the development deadline, the license agreement will terminate immediately except in certain circumstances as specified in the agreement.

The license fee was originally due in two equal installments of \$500,000 payable no later than December 31, 2019 and June 30, 2020, which were not paid. The agreement was subsequently amended for payment due on July 31, 2020. On July 31, 2020, the agreement was amended to further extend the payment until September 30, 2020. On September 30, 2020, the agreement was again amended, requiring payment of the license fee only when outside financing is received, as defined in the agreement. On June 21, 2021, the parties entered into an additional amendment which modified the payment terms and required a payment of \$107,500 on June 26, 2021, a payment of \$250,000 within 10 days of the Primary Financing, and the remaining \$250,000 upon the earlier of approval of an Investigatory New Drug application by the FDA or December 31, 2021. This amendment also eliminated the \$750,000 clinical milestone payments described above and reduced the milestone payment upon regulatory approval of the product containing the Skinvisible technology in either the U.S. or E.U., whichever happens first to a total of \$5,000,000.

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At December 31, 2021 and December 31, 2020, the license acquisition liability due was \$250,000 and \$875,000 respectively. In March 2022, the Company paid \$50,000 against this liability. The remaining license acquisition liability has not been paid in accordance with the terms but has not impaired the Company's rights to the technology as the Company is in the process of renegotiating this payment with Skinvisible.

NOTE 10 - INTANGIBLE ASSETS

Intangible assets are as follows:

	December 31,	
	2021	2020
Acquired technology – Polytherapeutics	\$ 40,433	\$ 40,433
Technology license – Skinvisible	1,000,000	1,000,000
Total cost	1,040,433	1,040,433
Accumulated amortization	(231,829)	(127,785)
Net book value	\$ 808,604	\$ 912,648

The Company recorded amortization expense of approximately \$104,000, \$104,000, and \$21,000 in the years ended December 31, 2021, 2020 and 2019, respectively. Amortization expense for each of the next 5 years is expected to be approximately \$104,000, and then approximately \$288,000 thereafter.

NOTE 11 – RELATED PARTY TRANSACTIONS

Employment Agreements and Due to Officers/Founders

In March 2018, Quoin Inc. executed employment agreements with both of its officers who are also co-founders of Quoin Inc. The employment agreements for both officers/founders allow for a onetime expense that covers the salaries they would have otherwise been paid for efforts they undertook in the periods since inception. The salaries and benefits allowances provided for under the employment agreements began to accrue as the services were being provided by the officers/founders and are included in Due to Officers on the accompanying balance sheet.

Amounts due to the officers/founders consist of amounts specified in the employment agreements since inception through December 31, 2021 as well as reimbursable travel expenses and other amounts paid by them to third parties on behalf of Quoin Inc. The Company repaid \$304,466, \$50,000, and \$0 of such amounts due to officers/founders in the year ended December 31, 2021, 2020 and 2019, respectively. Since the Merger closing, the Company has been repaying amounts due to officers/founders at a rate of \$25,000 each per month (See Note 17).

Amounts due to officers at December 31, 2021 and 2020 consisted of the following:

	December 31,	
	2021	2020
Salaries and allowances	\$ 4,108,500	\$ 3,984,000
Invoices paid on behalf of the Company	615,232	904,913
Total	\$ 4,723,732	\$ 4,888,913

During 2021, the Company incurred \$108,000 of consulting expense from related parties, primarily from a related party company controlled by a member of the Board of Directors.

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See Note 4 for related party debt and Note 12 for employment agreements.

NOTE 12 – RESEARCH, CONSULTING AGREEMENTS AND COMMITMENTS

Research and consulting agreement

Quoin Inc. entered into a research and consulting agreement (the “Research Agreement”) which commits it to pay the former owner of Polytherapeutics (the “Consultant” or “Seller”) to transfer the technical know-how of Polytherapeutics with respect to (i) good manufacturing practices (“GMP”), clinical and commercial manufacturing of the Company’s PolyDur polymer and (ii) formulation development of products utilizing the Company’s PharmaDur polymer (See Note 9). The agreement required monthly consulting payments of \$20,833 beginning on July 31, 2018 and ending February 28, 2021 (the “Post-Closing Period”) for a total of \$666,667 over the consulting period. Pursuant to an amendment, the Post-Closing Period was revised to terminate on December 31, 2020.

Through December 31, 2021 and the financial statement issuance date, the Company has not made any payments, the Consultant has not performed any services and the Company has not incurred or accrued for any expenses. See Note 15 for Consultant’s notification of breach of contract.

Other research consulting agreements

Quoin Inc. entered into three consulting agreements with Axella Research LLC (“Axella”) to provide regulatory and pre-clinical/clinical services to the Company with respect to QRX003 and QRX004. The combined fees of the three agreements are approximately \$270,000, payable as milestones under the three agreements are met. Quoin Inc. has also engaged Axella for additional services pursuant to separate work orders. Further, Quoin Inc. has two options to pay the milestones due 1) one half in equity of Quoin Inc. (at a pre-negotiated valuation) and one-half in cash or 2) entirely in cash, in which case a discount of approximately 20% would be applicable. The Company recognized research and development expenses for services provided and milestones met of approximately \$247,000, \$50,000 and \$25,000 for the years ended December 31, 2021, 2020 and 2019, respectively and has accrued expenses of \$193,537, \$105,052 and \$24,940 at December 31, 2021, 2020 and 2019, respectively.

In November 2020, Quoin Inc. entered into a Master Service Agreement for an initial term of three years with Therapeutics Inc. for managing preclinical and clinical development for new products in the field of dermatology. The agreement required the execution of individual work orders. Quoin Inc. may terminate any work order for any reason with 90 days written notice subject to costs incurred through termination and a defined termination fee, unless there is a material breach by Therapeutics Inc. The first work order was entered into in late 2020 for a clinical study at an expected estimated cost of approximately \$3.5 million and expected timing through the first quarter of 2023. For the year ended December 31, 2021, the Company incurred approximately \$340,000 of research and development costs related to this agreement.

In November 2021, the Company entered into a commitment for research related services associated with Netherton Syndrome of approximately \$250,000 for an expected period of eighteen months, of which an initial \$25,000 expense was incurred in 2021.

Employment agreements

The employment agreements entered into by Quoin Inc. with its two founders/officers provide for a combined base salary, including monthly allowances, of \$996,000 per annum, a discretionary bonus and certain allowances and benefits. In the event of termination of the two founders/officers for reason other than cause, as defined in the employment agreements, the founders shall be entitled to two years of based salary and bonus.

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In November 2021, the Company appointed and entered into an employment agreement with its Chief Financial Officer which provides for a base salary of \$360,000 per annum, a discretionary bonus and certain allowances and benefits.

In November 2021, the Board of Directors of the Company approved amendments to the employment agreements increasing base level compensation by 10% for the two founders and increasing the annual target discretionary bonus to not less than 45% of base salary for the two founders and the Chief Financial Officer. Further a transaction bonus related to the closing of the Merger and private placements aggregating approximately \$324,000 was paid to the two founders in November 2021. See Note 17 describing subsequent shareholder approval of the employment agreements of the two founders/officers.

Performance milestones and Royalties

See Note 9 for asset and in-licensed technology commitments.

Merger agreement commitment

In consideration for the Share Transfer disclosed in Note 1, the pre-closing Collect shareholders received a contingent value right (“CVR”) entitling the holders to earnouts during the Payment Period (as such term is defined in the Share Transfer Agreement), comprised mainly of payments upon sale, milestone payments, license fees and exit fees realized by EnCellX. In order to secure such right, shares constituting 40% of EnCellX share capital are held in escrow by Altshuler Shaham Trusts Ltd.

In connection with the Share Transfer, Collect entered into a CVR Agreement with Mr. Eyal Leibovitz, in the capacity of Representative for the holders of CVRs, and Computershare Trust Company, N.A., a federally chartered trust company (the “Rights Agent”). Under the terms of the CVR Agreement, the holders of the Collect ADSs immediately prior to the Merger had the right to receive, through their ownership of CVRs, their pro-rata share of the net Share Transfer consideration, making such holders of CVRs the indirect beneficiaries of the net payments under the Share Transfer. CVRs were recorded in a register administered by the Rights Agent but were not certificated.

Since the Company will not receive any net proceeds from the CVR’s, there is no asset or liability recorded in the consolidated financial statements.

NOTE 13 – SHAREHOLDERS’ EQUITY AND SHARE OWNERSHIP AND RIGHTS

Quoin Inc.

Quoin Inc.’s authorized capital stock consisted of 10,000 shares of common stock. On March 5, 2018, in connection with the incorporation as a Delaware corporation, Quoin Inc. issued 100 shares for a consideration of \$100 split equally between the two founders and officers of Quoin Inc. In connection with the Merger transaction, the two founders exchanged their shares in Quoin Inc. for 3,003,652 ADSs in Quoin Ltd. All share and per share amounts have been adjusted to reflect this recapitalization.

Quoin Ltd.

As of December 31, 2021, Quoin Ltd.’s authorized share capital consisted of 12,500,000,000 ordinary shares, no par value. These ordinary shares are not redeemable and do not have any preemptive rights. However, the Investor has certain approval rights in connection with the issuance of additional shares. Holders of our ordinary shares have one vote for each ordinary share held on all matters submitted to a vote of shareholders at a shareholders meeting. Shareholders may vote at

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shareholders meetings either in person, by proxy or by written ballot. Israeli law does not allow public companies to adopt shareholder resolutions by means of written consent in lieu of a shareholders meeting. The board of directors shall determine and provide a record date for each shareholders meeting and all shareholders at such record date may vote. Unless stipulated differently in the Companies Law or in the articles of association, all shareholders' resolutions shall be approved by a simple majority vote.

Under Israeli law, the Company may declare and pay dividends only if, upon the determination of our board of directors, there is no reasonable concern that the distribution will prevent us from being able to meet the terms of our existing and foreseeable obligations as they become due. Under the Companies Law, the distribution amount is further limited to the greater of retained earnings or earnings generated over the two most recent years legally available for distribution according to our then last reviewed or audited financial statements, provided that the date of the financial statements is not more than six months prior to the date of distribution. In the event that the Company does not have retained earnings or earnings generated over the two most recent years legally available for distribution, the Company may seek the approval of the court in order to distribute a dividend. The court may approve our request if it determines that there is no reasonable concern that the payment of a dividend will prevent the Company from satisfying our existing and foreseeable obligations as they become due.

The Bank of New York Mellon, as depository, has registered and delivered American Depositary Shares, also referred to as ADSs. Each ADS represents four hundred (400) ordinary shares (or a right to receive four hundred (400) ordinary shares). Each ADS will also represent any other securities, cash or other property which may be held by the depository. ADSs may be held either (a) directly (1) by having an American Depositary Receipt, also referred to as an ADR, which is a certificate evidencing a specific number of ADSs or (2) by having uncertificated ADSs, or (b) indirectly by holding a security entitlement in ADSs through a broker or other financial institution that is a direct or indirect participant in The Depository Trust Company, also called DTC.

Warrants and Options

The following vested stock options and warrants were outstanding at December 31, 2021, exercisable into ADSs:

	<u>ADSs</u>	<u>Exercise Price</u>	<u>Year of maturity</u>
Warrants held by 2020 noteholders	367,356	\$ 3.98	2026
Warrants held by Investor	1,238,429	\$ 3.98	2026
Warrants held by former Collect warrantholders	110,263	\$ 0.20-\$11.00	2022-2024
Options held by former Collect optionholders(1)	71,796	\$8.60-\$217.00	2022
Total	<u>1,787,844</u>		

- 1) The options held by former Collect optionholders fully vested at the closing of the Merger and expire between January and October 2022. The incremental fair value of the stock options at the closing of the Merger was not significant. The options were issued under the Collect Ltd. Employee Shares Incentive Plan (the "2014 Plan"). The 2014 Plan was amended and restated and initial grants were made to Company officers and directors, approved at the Company Annual General Meeting held on April 12, 2022. See Note 17.

The intrinsic value of the above stock options and warrants at December 31, 2021 was negligible.

Effective as of March 13, 2022, the Company issued warrants to the Investor under the terms of the Primary Financing, exercisable into ADSs in the following aggregate amounts. See Note 17.

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	ADSs	Exercise Price
Series A warrants	6,665,922	\$ 3.98
Series B warrants	6,665,922	\$ 3.98
Series C warrants (1)	2,389,670	\$ 3.98
Total	<u>15,721,514</u>	

(1) The Company expects to issue each of 2,389,670 additional Series A and Series B Warrants to the Investor upon exercise of the Series C Warrant, which are included in the totals in the table above.

NOTE 14 – INCOME TAXES

The Company’s deferred tax assets relate primarily to its net operating loss carryforwards and other balance sheet basis differences. The Company maintains a valuation allowance to fully offset the gross deferred tax asset because it is not more likely than not that the Company will realize future benefits associated with these deferred tax assets at December 31, 2021 and 2020. The valuation allowance increased by approximately \$2,178,000 and \$515,000 for the years ended December 31, 2021 and 2020, respectively.

Significant components of the Company’s deferred tax assets are as follows:

	December 31,	
	2021	2020
Deferred tax assets:		
Net operating losses carryforward	\$ 1,945,000	\$ 355,000
Due to officers	1,411,000	1,467,000
Accrued expenses and other	212,000	44,000
R&D credit carryforward	102,000	—
Debt related attributes	375,000	—
Total deferred tax assets	4,045,000	1,866,000
Valuation allowance	(4,045,000)	(1,866,000)
Deferred tax asset, net of valuation allowance	\$ —	\$ —

At December 31, 2021 and 2020, the Company had U.S. federal and state income tax net operating loss (“NOL”) carryforward of approximately \$6,482,000 and \$1,180,000, respectively, that may be used to offset future taxable income. The Internal Revenue Code (the “IRC”) contains limitations on the use of net operating loss carryforwards after the occurrence of a substantial ownership change as defined by IRC Section 382. The Company has not performed a detailed analysis, however utilization of such net operating loss carryforwards will likely be significantly limited due to the shares issued in the Primary Financing and the Merger. At December 31, 2021, the Company had approximately \$102,000 of federal research and development (“R&D”) tax credit carryforwards. If not utilized, the federal R&D credits will begin to expire in 2038.

The income tax benefit for the years ended December 31, 2021 and 2020 differed from the amounts computed by applying the US federal income tax rate of 21% primarily because of the increase in the valuation allowance and the tax impact of fair value adjustments and other permanent items, which resulted in an effective tax rate of zero for both years.

On March 27, 2020, the United States enacted the Coronavirus Aid, Relief and Economic Security Act (“CARES Act”). The CARES Act is an emergency economic stimulus package that includes spending and tax breaks to strengthen the

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United States economy and fund a nationwide effort to curtail the effect of COVID-19. While the CARES Act provides sweeping tax changes in response to the COVID-19 pandemic, some of the more significant provisions which are expected to impact the Company's financial statements include removal of certain limitations on utilization of net operating losses, increasing the loss carryback period for certain losses to five years, and increasing the ability to deduct interest expense, as well as amending certain provisions of the previously enacted Tax Cuts and Jobs Act. The Company has concluded that the CARES Act did not have a material impact on its financial position, results of operations, or cash flows.

On December 27, 2020, the United States enacted the Consolidated Appropriations Act which extended many of the benefits of the CARES Act that were scheduled to expire. The Company evaluated the impact of the Consolidated Appropriations Act on its consolidated financial statements and related disclosures and concluded that the impact is immaterial.

NOTE 15 - CONTINGENCIES

From time to time, the Company may become involved in various legal matters arising in the ordinary course of business. Management is unaware of any matters requiring accrual for related losses in the financial statements.

In February 2020, the seller of the equity interests in Polytherapeutics and party to the Research Agreement communicated with Quoin Inc. threatening litigation for non-payment and related breach of contract and immediate payment of all monthly payments in the amount of \$666,667. See Notes 9 and 12. The Consultant has not provided any services and has not complied with other technical requirements under the Research Agreement, and therefore is considered to be in breach of contract. The Company and the Consultant have had communications with respect to the duration, commencement date and payment of the consulting services, but a revised agreement has not been reached. No lawsuits have been filed as of the financial statement issuance date. Should a formal claim or lawsuit be filed, the Company believes it has meritorious defenses.

NOTE 16 – LICENSE AGREEMENTS

In November and December 2021, the Company entered into three license and supply agreements, whereby the Company is entitled to a royalty or other proceeds from the specified product revenues in select non-US markets from the licensee, if and when the underlying products are approved and commercialized. No royalty revenues were received in 2021.

NOTE 17 - SUBSEQUENT EVENTS

In March 2022, the Company paid an aggregate of \$311,670 to two out of five 2020 noteholders in settlement of the amounts included in accrued interest payable at the closing of the Merger. See Note 4.

In the first quarter of 2022, the Company entered into four license and supply agreements, whereby the Company will receive a royalty or other proceeds from the specified product revenues in select non-US markets from the licensor, if and when the underlying products are approved and commercialized.

Effective as of March 13, 2022, the Company issued warrants to purchase ADSs as follows:

- Exchanged the existing warrants of 2020 noteholders (Note 4) for warrants on substantially the same terms as the Investor Exchange Warrant (See Note 5), exercisable for 367,356 ADSs, in the aggregate, at the exercise price of \$3.98 per ADS.
- Issued Series A Warrant, Series B Warrant and Series C Warrant to purchase 4,276,252 ADSs, 4,276,252 ADSs and 2,389,670 ADSs, respectively, at the exercise price of \$3.98 per ADS, based on the terms of the Primary

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Financing.

The Company held a Special General Meeting on February 28, 2022, at which the Company's shareholders adopted the Amended and Restated Articles of Association of the Company.

In March 2022, the board of directors of the Company approved the Amended and Restated Equity Incentive Plan (the "Amended Plan") which increased the number of ordinary shares reserved for issuance under such equity incentive plan to 15% of the Company's outstanding ordinary shares on a fully-diluted basis, or 1,826,991,616 ordinary shares, represented by 4,567,479 ADSs. The board of directors further approved the award of options to Officers and Directors in aggregate to acquire 3,957,142 ADSs under the Amended Plan, and annual discretionary bonuses for Officers of \$472,500 in aggregate. The Amended Plan and certain individual option grants and bonuses were subject to shareholder approval at our Annual General Meeting, as described below.

The Company held its Annual General Meeting on April 12, 2022, and which the Company's shareholders approved, among other items, the following:

- The increase in authorized share capital from 12.5 billion to 50 billion ordinary shares.
- Modification of the annual compensation of the two founders to a combined base salary of \$990,000 and to increase the annual discretionary bonus to not less than 45% of the annual base salary.
- The grant of an option to purchase up to 1,071,429 ADSs to each of the two founders under the Amended Plan, at an exercise price per ADS of \$1.40, to vest over a four-year period.
- The grant of an option to purchase 117,857 ADSs to each non-employee director under the Amended Plan at an exercise price per ADS of \$1.40, to vest over a three-year period, and (as an annual grant for 2022) an option to purchase 42,857 ADSs at an exercise price per ADS of \$1.40, to vest over a three-year period.

The terms of repayment of indebtedness to the two founders by providing monthly payments of \$25,000 to each founder.