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As filed with the U.S. Securities and Exchange Commission on August 4, 2022.

Registration No. 333-266476

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

PRE-EFFECTIVE AMENDMENT NO. 1 TO FORM F-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

QUOIN PHARMACEUTICALS LTD.

(Exact name of Registrant as specified in its charter)

Not Applicable
(Translation of Registrant's name into English)

State of Israel	2834	Not Applicable
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

Azrieli Center, Round Tower, 30th Floor
132 Menachem Begin Blvd
Tel Aviv, 6701101
Tel: +972 58-448-8821

(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Dr. Michael Myers
Chief Executive Officer
Quoin Pharmaceuticals Ltd.
42127 Pleasant Forest Ct
Ashburn, VA 20148
Tel: 703-980-4182

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Yelena M. Barychev Peter I. Tsoflias Peter M. Melampy Blank Rome LLP One Logan Square 130 North 18th Street Philadelphia, PA 19103 Tel: (215) 569-5500	Phillip Waldoks Clifford Davis Amir Assali S. Horowitz & Co. 31 Ahad Ha'am Street Tel Aviv, 6520204 Israel Tel: +972 3 567 0700	Faith L. Charles, Esq. Naveen Pogula, Esq. Thompson Hine LLP 335 Madison Avenue, 12th Floor New York, New York 10017 Tel: (212) 344-5680

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box. ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933.

Emerging growth company ☐

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

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

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the U.S. Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

SUBJECT TO COMPLETION, DATED AUGUST 4, 2022

PRELIMINARY PROSPECTUS

Up to Ordinary Shares Represented by American Depositary Shares
Pre-Funded Warrants to Purchase up to Ordinary Shares Represented by American Depositary Shares
Common Warrants to Purchase up to Ordinary Shares Represented by American Depositary Shares
Up to Ordinary Shares Represented by American Depositary Shares Issuable Upon Exercise of the Pre-Funded Warrants
Up to Ordinary Shares Represented by American Depositary Shares Issuable Upon Exercise of the Common Warrants

We are offering on a "reasonable best efforts" basis up to $14 million of ordinary shares of Quoin Pharmaceuticals Ltd. represented by American Depositary Shares, or "ADSs," at an assumed purchase price of $3.85 per ADS, which was the closing price of our ADSs on The Nasdaq Capital Market on August 1, 2022. Each ADS represents five thousand (5,000) ordinary shares. We are also offering on a "reasonable best efforts" basis pre-funded warrants, or "Pre-Funded Warrants," to purchase up to ordinary shares represented by ADSs. We are offering to certain purchasers whose purchase of ADSs in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding ordinary shares immediately following the consummation of this offering, the opportunity to purchase, if any such purchaser so chooses, Pre-Funded Warrants, in lieu of ADSs that would otherwise result in such purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding ordinary shares. The purchase price of each Pre-Funded Warrant is $3.8499 (which is equal to the assumed public offering price per ADS to be sold in this offering *minus* $0.0001, the exercise price per ADS of each Pre-Funded Warrant). The Pre-Funded Warrants are immediately exercisable and may be exercised at any time until all of the Pre-Funded Warrants are exercised in full. For each Pre-Funded Warrant we sell, the number of ADSs we are offering will be decreased on a one-for-one basis.

Our ordinary shares represented by ADSs and Pre-Funded Warrants are being offered together with warrants, or "Common Warrants," to purchase up to ordinary shares represented by ADSs. Each ADS and Pre-Funded Warrant will be sold together with one Common Warrant. Each Common Warrant has an exercise price of $ per ADS (representing 100% of the assumed public offering price per ADS to be sold in this offering) and will expire on the fifth anniversary of the original issuance date. Because we will issue a Common Warrant for each ADS and for each Pre-Funded Warrant sold in this offering, the number of Common Warrants sold in this offering will not change as a result of a change in the mix of ADSs and Pre-Funded Warrants sold.

Our ordinary shares represented by ADSs, Pre-Funded Warrants and Common Warrants can only be purchased together in this offering but will be issued separately. Ordinary shares represented by ADSs issuable from time to time upon exercise of the Pre-Funded Warrants and the Common Warrants are also being offered by this prospectus. These securities are being sold in this offering to certain purchasers under a securities purchase agreement dated , 2022 between us and the purchasers.

The public offering price for our securities in this offering will be determined at the time of pricing, and may be at a discount to the then current market price. The recent market price used throughout this prospectus may not be indicative of the final offering price. The final public offering price will be determined through negotiation between us and investors based upon a number of factors, including our history and our prospects, the industry in which we operate, our past and present operating results, the previous experience of our executive officers and the general condition of the securities markets at the time of this offering. There is no established public trading market for the Pre-Funded Warrants or the Common Warrants and we do not expect a market to develop. Without an active trading market, the liquidity of the warrants will be limited. In addition, we do not intend to list the Pre-Funded Warrants or the Common Warrants on The Nasdaq Capital Market, any other national securities exchange or any other trading system.

Our ADSs are listed on The Nasdaq Capital Market under the symbol “QNRX.” On August 1, 2022, the last reported sale price of our ADSs on The Nasdaq Capital Market was $3.85 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 10 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.

There is no minimum number of securities or minimum aggregate amount of proceeds for this offering to close. We have engaged A.G.P./ Alliance Global Partners, or the placement agent, as our exclusive placement agent in connection with this offering. The placement agent is not purchasing or selling the securities offered by us, and is not required to arrange for the purchase or sale of any specific number or dollar amount of our securities, but will use its reasonable best efforts to solicit offers to purchase the securities offered by this prospectus. We have agreed to pay the placement agent a cash fee equal to 7% of the aggregate gross proceeds raised in this offering as set forth in the table below. See “Plan of Distribution” beginning on page 120 of this prospectus for more information.

	Per ADS and Accompanying Common Warrant	**Per Pre-Funded Warrant and Accompanying Common Warrant**	**Total**
Public offering price			
Placement agent fees(1)			
Proceeds to us (before expenses)(2)			

(1) We have also agreed to reimburse the placement agent for certain of its offering-related expenses and pay the placement agent a non-accountable expense allowance equal to 1% of the gross proceeds raised in this offering. See “Plan of Distribution” beginning on page 120 of this prospectus for a description of the compensation to be received by the placement agent.

(2) Does not include proceeds from the exercise of the warrants in cash, if any.

Delivery of the securities is expected to be made on or about , 2022.

Sole Placement Agent

A.G.P.

The date of this prospectus is , 2022.

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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. We are offering to sell, and seeking offers to buy, our securities 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 of our securities, nor does this prospectus constitute an offer to sell or the solicitation of an offer to buy our securities 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 a clinical stage, emerging specialty pharmaceutical company dedicated to the development and commercialization of therapeutic products that help treat rare and orphan diseases for which there are currently no approved treatments or cures. 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. Clinical testing of QRX003, under an open Investigational New Drug (IND) application with the Food and Drug Administration, or "FDA," has commenced in the US. 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. Our three other pipeline products in development are also targeting rare skin diseases, including Epidermolysis Bullosa, Netherton Syndrome and Scleroderma.

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 Cellect Biotechnology Ltd. ("Cellect") 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, Cellect 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 Cellect, Quoin Inc. and CellMSC, Inc., a Delaware corporation and wholly-owned subsidiary of Cellect ("Merger Sub"), pursuant to which Merger Sub merged with and into Quoin Inc., with Quoin Inc. surviving as a wholly-owned subsidiary of Cellect (the "Merger"). Immediately after completion of the Merger, Cellect 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. or Quoin Inc., as applicable. 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.

Recent Developments

ADS Ratio Change

On July 12, 2022, our Board of Directors approved the change in the ratio of ADS evidencing ordinary shares from 1 ADS representing four hundred (400) ordinary shares to 1 ADS representing five thousand (5,000) ordinary shares, which will result in a one for 12.5 reverse split of the issued and outstanding ADSs (the "Ratio Change"). The Ratio Change was effective August 1, 2022.

All ADS and related option and warrant information presented in this prospectus, including our financial statements and accompanying footnotes, has been retroactively adjusted to reflect the reduced number of ADSs resulting from the Ratio Change.

Nasdaq Listing

On April 22, 2022, we received a letter from the Listing Qualifications staff of The Nasdaq Stock Market, LLC ("Nasdaq") notifying us that we are no longer in compliance with the minimum stockholders' equity requirement for continued listing on The Nasdaq Capital Market. Nasdaq Rule 5550(b)(1) requires listed companies to maintain stockholders' equity of at least $2.5 million. In addition, as of April 21, 2022, we did not meet the alternative continued listing requirements based on market value of listed securities or net income from continuing operations. In accordance with Nasdaq Rule 5810(c)(2)(A), within 45 calendar days of receiving this notice, we submitted a plan to regain compliance to Nasdaq. This plan was accepted, and Nasdaq has granted us an extension until October 19, 2022 to evidence compliance.

On June 10, 2022, we received a letter from The Nasdaq Listing Qualifications staff notifying us that the closing bid price per ADS was below the required minimum of $1.00 for a period of 30 consecutive business days and that we did not meet the minimum bid price requirements set forth in Nasdaq Rule 5550(a)(2). Pursuant to Nasdaq Rule 5810(c)(3)(A), we have a period of one hundred eighty (180) calendar days, or until December 7, 2022 (the "Compliance Period"), to regain compliance with Nasdaq's minimum bid price requirement. If at any time during the Compliance Period, the closing bid price per ADS is at least $1.00 for a minimum of ten (10) consecutive business days, Nasdaq will provide us a written confirmation of compliance and the matter will be closed. In the event we do not regain compliance by December 7, 2022, we may be eligible for an additional 180 calendar day grace period. To qualify, we will be required to meet the continued listing requirement for market value of publicly held ADSs and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement, and will need to provide written notice of our intention to cure the deficiency during the second compliance period.

Although there is no assurance, we expect that this offering will enable us to regain compliance with Nasdaq's minimum stockholders' equity requirement and the Ratio Change will help us to regain compliance with the minimum bid-price requirement for continued listing on The Nasdaq Capital Market. Although Nasdaq notification letters described above have no immediate effect on our listing on The Nasdaq Capital Market, and we are working on implementing plans to regain compliance with Nasdaq listing standards, there can be no assurance that we will be able to regain compliance with Nasdaq's minimum stockholders' equity requirement or minimum bid-price requirement for continued listing. If our ADSs are delisted from Nasdaq, it will have material negative impacts on the actual and potential liquidity of our securities, as well as material negative impacts on our ability to raise future capital.

Agreements with Altium Growth Fund, LP

On October 28, 2021, Cellect and Quoin Inc. completed the private placement transaction with Altium Growth Fund, LP ("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 $12.0 million in cash from Altium whereby Quoin Inc. issued to Altium (i) common stock of Quoin Inc. immediately prior to the Merger (the "Primary Financing"), pursuant to the Securities Purchase Agreement, entered into as of March 24, 2021, by and among Cellect, Quoin Inc. and Altium, as amended (the "Primary Financing Agreement"), and (ii) warrants to purchase 99,074 ADSs (the "Investor Exchange Warrants") in exchange for warrants issued in connection with the Bridge Financing pursuant to the Securities Purchase Agreement, entered into as of March 31, 2021, by and between Quoin Inc. and Altium, as amended (the "Bridge Agreement" and together with the Primary Financing Agreement, the "Purchase Agreements").

In addition, under the Primary Financing 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 342,100 ADSs (the "Series A Warrant") (ii) Series B Warrant to purchase 342,100 ADSs (the "Series B Warrant") and (iii) Series C Warrant to purchase 191,174 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 $49.75 per ADS. Under the Primary Financing Agreement, upon the exercise of the Series C Warrant in full, Quoin Ltd. was obligated to issue to Altium: (i) an additional Series A Warrant to purchase 191,174 ADSs and (ii) an additional Series B Warrant to purchase 191,174 ADSs ("Additional Investor Warrants" and together with Initial Investor Warrants, the "Investor Warrants"). During the second quarter of 2022, Altium exercised the Series B Warrant in full pursuant to the alternate cashless exercise right of such warrant, under which Altium had an option to receive 1 ADS for each ADS underlying the warrant being exercised in such cashless exercise, resulting in the issuance of a total of 342,100 ADSs to Altium.

On July 14, 2022, we, Quoin Inc. and Altium entered into an agreement, pursuant to which the parties agreed to, among other things, (i) amend certain terms of the Series A Warrant and Investor Exchange Warrants previously issued to Altium to, among other things, reduce the exercise price to $0.00 per ADS with respect to a total of 399,999 ADS, (ii) cancel the Series C Warrant and a portion of the Series A Warrant previously issued to Altium, and (iii) terminate the Purchase Agreements, pursuant to which the warrants were previously issued to Altium. As of August 2, 2022, Altium exercised all of its warrants outstanding and we issued a total of 399,999 ADSs to Altium.

Going Concern Qualification

We expected to receive additional funding through the mandatory exercise provision of the Series C Warrant that was canceled on July 14, 2022, which would have resulted in proceeds of approximately $9.5 million. In the event the requirements of the mandatory exercise provision of such warrant were not met, we expected Altium to act on its written commitment to provide funding equal to the $9.5 million expected upon exercise of the Series C Warrant, at prevailing market rates, and thus we believed that we had sufficient resources to implement our business plan for at least one year from the issuance of our consolidated financial statements as of and for the year ended December 31, 2021, as well as of and for the three months ended March 31, 2022 as of the respective dates of the issuance of these financial statements. Following the cancellation of the Series C Warrant on July 14, 2022, we no longer expect to receive such proceeds from Altium, and we do not have sufficient resources to implement our business plan for at least one year from the date of this prospectus. This raises substantial doubt about our ability to continue as a going concern.

Other than if one or more of our product candidates are accepted into Early Access Programs in certain countries, 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. Additional financing will be required to complete the research and development of our therapeutic targets and our other operating requirements, which may not be available at acceptable terms, if at all. We have filed a registration statement on Form F-1, of which this prospectus forms a part, related to an offering of securities on a “reasonable best efforts” basis, as described in this prospectus. However there is no assurance of the successful consummation of such offering. If we are unable to obtain additional funding when it becomes necessary, the development of our product candidates will be impacted and we would likely be forced to delay, reduce, or terminate some or all of our development programs, all of which could have a material adverse effect on our business, results of operations and financial condition.

Noteholder 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 Primary 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 Primary 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 29,388 ADSs, in the aggregate, at the exercise price of $49.75 per ADS (the “Noteholder Warrants”). The Noteholder Warrants became exercisable immediately upon issuance and will expire five years from March 13, 2022. Effective as of July 14, 2022, in connection with our agreement with Altium, pursuant to which the exercise price of the Series A Warrant and Investor Exchange Warrants was reduced to $0.00 per ADS, the exercise price of the Noteholder Warrants was also reduced to $0.00 per ADS in accordance with the adjustment provisions of such warrants.

License and Distribution Agreements, Supply Agreements and Research Agreements

On June 14, 2022, Quoin Inc. entered into a License and Distribution Agreement with WinHealth Investment (HK) Limited (“WinHealth”). Under the terms of the License Agreement, WinHealth has the exclusive rights to commercialize, upon the receipt of applicable regulatory approvals, pharmaceutical products QRX003 and QRX004 (in finished dosage form for human use) in Greater China, including Hong Kong, Macau and Taiwan.

On July 14, 2022, Quoin Inc. entered into (i) a License and Distribution Agreement with Endo Ventures Limited (“Endo”), and (ii) a Supply Agreement with Endo. Under the terms of the License Agreement, Endo has the exclusive rights to commercialize, upon the receipt of applicable regulatory approvals, pharmaceutical product QRX003 (in finished dosage form for human use) in Canada. Under the terms of the Supply Agreement, Quoin agreed to manufacture and supply (or have manufactured and supplied) to Endo the foregoing pharmaceutical product QRX003 for sale in Canada.

Effective as of May 20, 2022, Quoin Inc. entered into a Research Agreement with Queensland University of Technology, Australia, to collaborate on the project related to the selection of a lead VLA-4 inhibitor for entry into a Scleroderma clinical development program.

Clinical Development

Quoin's lead asset, QRX003, is currently in clinical development in the United States under an open IND application with the FDA. The ongoing study is a randomized, double blinded assessment of two different doses of QRX003 versus a placebo vehicle in Netherton patients. The test materials will be applied once daily, over a twelve-week period, to pre-selected areas of the patient's body. Based on discussions with the FDA, a number of different clinical endpoints are being assessed in the study, including but not limited to, an Investigators Global Assessment (IGA), Patient's Global Assessment (PaGA) and Pruritis. The trial will be conducted in up to six clinical sites in the US. The first clinical site was open in July 2022 and the opening of additional sites is in process, as is patient recruitment into the study.

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 this offering, 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" on page 10 of this prospectus for a more thorough description of these and other risks.

Risks Related to This Offering

- Resales of our ADSs in the public market by our shareholders as a result of this offering may cause the market price of our ADSs to fall.
- This offering may cause the trading price of our ADSs to decrease.

- You will experience immediate and substantial dilution in the net tangible book value per share of the ADSs you purchase.
- You may experience future dilution as a result of future equity offerings.
- Our management will have broad discretion over the use of the net proceeds from this offering, you may not agree with how we use the proceeds, and the proceeds may not be invested successfully.
- This is a reasonable best efforts offering, in which no minimum number or dollar amount of securities is required to be sold, and we may not raise the amount of capital we believe is required for our business plans.
- We will need to raise additional funding to fund our working capital needs or consummate potential future acquisitions.
- Additional financing may not be available on acceptable terms, or at all. Failure to obtain additional capital may force us to limit or terminate our operations.
- There is no public market for the Pre-Funded Warrants or the Common Warrants being offered in this offering.
- Holders of our Pre-Funded Warrants or the Common Warrants will have no rights as holders of ordinary shares represented by ADSs until such warrants are exercised.
- The Pre-Funded Warrants are speculative in nature.
- The Common Warrants may not have any value.
- Provisions of the Common Warrants offered by this prospectus could discourage an acquisition of us by a third party.

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 our ability to continue as a going concern is dependent upon obtaining additional capital and financing, including funds to be raised in this offering.
- 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.

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 for the supply of our preclinical product, clinical product candidates and commercial supplies of any approved product candidates.

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.

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.

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

- Our ADSs may be delisted from The Nasdaq Capital Market.

- The market price for our ADSs is highly volatile.

- 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.

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

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

The Offering

Ordinary shares represented by ADS outstanding prior to this offering	ordinary shares represented by ADSs.
Securities offered by us	Up to ordinary shares represented by ADSs or Pre-Funded Warrants to purchase up to ordinary shares represented by ADSs and Common Warrants to purchase up to ordinary shares represented by ADSs. Each ADS represents 5,000 ordinary shares. Each ADS and Pre-Funded Warrant will be sold together with one Common Warrant.
Per ADS offering price	$ per ADS.
Ordinary shares represented by ADS to be outstanding after this offering	Up to ordinary shares represented by ADSs, assuming no sales of Pre-Funded Warrants, which, if sold, would reduce the number of ADSs that we are offering on a one-for-one basis.
Pre-Funded Warrants	We are offering to certain purchasers whose purchase of ordinary shares represented by ADSs in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% of our outstanding ordinary shares immediately following the closing of this offering, the opportunity to purchase, if such purchasers so choose, Pre-Funded Warrants, in lieu of ordinary shares represented by ADSs that would otherwise result in any such purchaser's beneficial ownership, together with its affiliates and certain related parties, exceeding 4.99% (or, at the election of such purchaser, 9.99%) of our outstanding ordinary shares immediately following the consummation of this offering. The purchase price of each Pre-Funded Warrant is equal to the purchase price of the ADS in this offering minus $0.0001, the exercise price of each Pre-Funded Warrant. Each Pre-Funded Warrant is immediately exercisable and may be exercised at any time until it has been exercised in full. For each Pre-Funded Warrant we sell, the number of ADSs we are offering will be decreased on a one-for-one basis. This offering also relates to the ordinary shares represented by ADSs issuable upon exercise of any Pre-Funded Warrants sold in this offering.
Common Warrants	Each ADS and each Pre-Funded Warrant will be sold together with one Common Warrant. Each Common Warrant has an exercise price per ADS equal to the public offering price of ADS in this offering and expires on the fifth anniversary of the original issuance date. Because we will issue a Common Warrant for each ADS and for each Pre-Funded Warrant sold in this offering, the number of Common Warrants sold in this offering will not change as a result of a change in the mix of ADSs and Pre-Funded Warrants sold. This offering also relates to the ordinary shares represented by ADSs issuable upon exercise of any Common Warrants sold in this offering.
Reasonable Best Efforts	We have agreed to issue and sell the securities offered hereby to the purchasers through the placement agent. The placement agent is not required to buy or sell any specific number or dollar amount of the securities offered hereby, but it will use its reasonable best efforts to solicit offers to purchase the securities offered by this prospectus. See "Plan of Distribution" on page 120 of this prospectus.
Use of proceeds	We intend to use the net proceeds from the sale of the securities under this prospectus for general corporate purposes, which may include operating expenses, research and development, including clinical and pre-clinical testing of our product candidates, working capital, future acquisitions and general capital expenditures. See "Use of Proceeds" on page 42 of this prospectus.

Depositary	The Bank of New York Mellon
Transfer Agent and Registrar	Computershare Trust Company, N.A.
Risk factors	See "Risk Factors" beginning on page 10 of this prospectus for a discussion of factors you should carefully consider before deciding to invest in our securities.
Listing	Our ADSs are listed on The Nasdaq Capital Market under the symbol "QNRX." We do not intend to apply for a listing of the Pre-Funded Warrants or the Common Warrants on any national securities exchange or other nationally recognized trading system.

The information above is based on 7,180,349,799 ordinary shares 99.99% of which were represented by 1,436,067 ADSs outstanding as of August 2, 2022, and excludes the following:

- 9,862,087 ordinary shares represented by 1,972 ADSs issuable upon the exercise of stock options outstanding at a weighted-average exercise price of $339.80 per ADS;
- 1,535,714,000 ordinary shares represented by 307,142 ADSs issuable upon the exercise of stock options outstanding at a weighted-average exercise price of $49.75 per ADS;
- 31,740,000 ordinary shares represented by 6,348 ADSs issuable upon the exercise of outstanding warrants at a weighted-average exercise price of $0.00 per ADS; and
- 40,102,000 ordinary shares represented by 8,820 ADSs issuable upon the exercise of outstanding warrants issued by Cellect at a weighted-average exercise price of $137.50 per ADS.

Unless otherwise indicated, all information in this prospectus assumes no exercise of the outstanding options or warrants described above after August 2, 2022, including, for the avoidance of doubt, any Pre-Funded Warrants or Common Warrants.

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 This Offering

Resales of our ADSs in the public market by our shareholders as a result of this offering may cause the market price of our ADSs to fall.

We are registering up to ordinary shares represented by ADSs, as well as up to ordinary shares represented by ADSs, in the aggregate, issuable upon the exercise of the Pre-Funded Warrants and Common Warrants offered under this prospectus. Sales of substantial amounts of our ADSs in the public market, or the perception that such sales might occur, could adversely affect the market price of our ADSs. The issuance of new ADSs could result in resales of our ADSs by our current shareholders concerned about the potential ownership dilution of their holdings. Furthermore, in the future, we may issue additional ADSs or other equity or debt securities exercisable or convertible into ADSs. Any such issuance could result in substantial dilution to our existing shareholders and could cause our stock price to decline.

This offering may cause the trading price of our ADSs to decrease.

The price per ADS, together with the number of ADSs we propose to issue and ultimately will issue if this offering is completed, may result in an immediate decrease in the market price of our ADSs. This decrease may continue after the completion of this offering.

You will experience immediate and substantial dilution in the net tangible book value per share of the ADSs you purchase.

Because the price per ADS being offered is substantially higher than the net tangible book value per share of our ADSs, you will suffer substantial dilution in the net tangible book value of the ADSs you purchase in this offering. Assuming a public offering price of $ per ADS, which is the last reported sales price of our ADSs on Nasdaq on August 1, 2022, if you purchase ADSs in this offering, you will suffer immediate and substantial dilution of approximately $ per ADS in the net tangible book value of the ADSs. In addition, if previously issued options or warrants to acquire ADSs are exercised at prices below the offering price, you will experience further dilution. See “Dilution” for a more detailed discussion of the dilution you may incur in connection with this offering.

You may experience future dilution as a result of future equity offerings.

In order to raise additional capital, we may in the future offer additional ADSs or other securities convertible into or exchangeable for our ADSs that could result in further dilution to investors purchasing our ordinary shares represented by ADSs in this offering or result in downward pressure on the price of our ADSs. We may sell ADSs or other securities in any other offering at prices that are higher or lower than the prices paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing shareholders.

Our management will have broad discretion over the use of the net proceeds from this offering, you may not agree with how we use the proceeds, and the proceeds may not be invested successfully.

We have not designated any portion of the net proceeds from this offering to be used for any particular purpose. Accordingly, our management will have broad discretion as to the use of the net proceeds from this offering and could use them for purposes other than those contemplated at the time of commencement of this offering. Accordingly, you will be relying on the judgment of our management with regard to the use of these net proceeds, and you will not have the opportunity, as part of your investment decision, to assess whether the proceeds are being used appropriately. It is possible that, pending their use, we may invest the net proceeds in a way that does not yield a favorable, or any, return for our company. Our management’s judgment may not result in positive returns on your investment and you will not have the opportunity to evaluate the economic, financial or other information upon which our management bases its decisions.

This is a reasonable best efforts offering, in which no minimum number or dollar amount of securities is required to be sold, and we may not raise the amount of capital we believe is required for our business plans.

The placement agent has agreed to use its reasonable best efforts to solicit offers to purchase the securities in this offering. The placement agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. There is no required minimum number of securities that must be sold as a condition to completion of this offering, and there can be no assurance that the offering contemplated hereby will ultimately be consummated. Even if we sell securities offered hereby, because there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount is not presently determinable and may be substantially less than the maximum amount set forth above. We may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us. Thus, we may not raise the amount of capital we believe is required for our operations in the short-term and may need to raise additional funds, which may not be available or available on terms acceptable to us.

We will need to raise additional funding to fund our working capital needs or consummate potential future acquisitions. Additional financing may not be available on acceptable terms, or at all. Failure to obtain additional capital may force us to limit or terminate our operations.

Even if we sell all securities offered hereby, the expected net proceeds of this offering may not be sufficient for us to fund the working capital needs of our business or potential strategic acquisitions we may pursue in the future. We may continue to seek funds through equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Additional funding may not be available to us on acceptable terms, or at all. Any failure to raise capital as and when needed could have a negative impact on our financial condition and on our ability to pursue our business plans and strategies.

There is no public market for the Pre-Funded Warrants or the Common Warrants being offered in this offering.

There is no established public trading market for the Pre-Funded Warrants or the Common Warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the Pre-Funded Warrants or the Common Warrants on any securities exchange or nationally recognized trading system. Without an active market, the liquidity of the Pre-Funded Warrants or the Common Warrants will be limited.

Holders of our Pre-Funded Warrants or the Common Warrants will have no rights as holders of ordinary shares represented by ADSs until such warrants are exercised.

Until you acquire ordinary shares represented by ADSs upon exercise of your Pre-Funded Warrants or Common Warrants, you will have no rights with respect to ADSs issuable upon exercise of your Pre-Funded Warrants or Common Warrants. Upon exercise of your Pre-Funded Warrants or Common Warrants, you will be entitled to exercise the rights of a holder of ordinary shares represented by ADSs only as to matters for which the record date occurs after the exercise date.

The Pre-Funded Warrants are speculative in nature.

The Pre-Funded Warrants offered hereby do not confer any rights of ownership of our ordinary shares represented by ADSs on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire ordinary shares represented by ADSs at a fixed price. Specifically, commencing on the date of issuance, holders of the Pre-Funded Warrants may acquire ordinary shares represented by ADSs issuable upon exercise of such warrants at an exercise price of $0.0001 per ADS. Moreover, following this offering, the market value of the Pre-Funded Warrants is uncertain, and there can be no assurance that the market value of the Pre-Funded Warrants will equal or exceed their public offering price.

The Common Warrants may not have any value.

Each Common Warrant has an exercise price per ADS equal to the public offering price of ADS in this offering and expires on the fifth anniversary of its original issuance date. In the event the market price per our ADS does not exceed the exercise price of the Common Warrants during the period when the warrants are exercisable, the Common Warrants may not have any value.

Provisions of the Common Warrants offered by this prospectus could discourage an acquisition of us by a third party.

Certain provisions of the Common Warrants offered by this prospectus could make it more difficult or expensive for a third party to acquire us. The Common Warrants prohibit us from engaging in certain transactions constituting “fundamental transactions” unless, among other things, the surviving entity assumes our obligations under the Common Warrants. Further, the Common Warrants provide that, in the event of certain transactions constituting “fundamental transactions,” with some exception, holders of such warrants will have the right, at their option, to require us to redeem such Common Warrants at a price described in such warrants. These and other provisions of the Common Warrants offered by this prospectus could prevent or deter a third party from acquiring us even where the acquisition could be beneficial to you.

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 and clinical studies for our product candidates, as well as 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 with 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 our ability to continue as a going concern is dependent upon obtaining additional capital and financing, including funds to be raised in this offering.

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 and ongoing clinical 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 and clinical programs.

We expected to receive additional funding through the mandatory exercise provision of the Series C Warrant that was canceled on July 14, 2022, which would have resulted in proceeds of approximately $9.5 million. In the event the requirements of the mandatory exercise provision of such warrant were not met, we expected Altium to act on its written commitment to provide funding equal to the $9.5 million expected upon exercise of the Series C Warrant, at prevailing market rates, and thus we believed that we had sufficient resources to implement our business plan for at least one year from the issuance of our consolidated financial statements as of and for the year ended December 31, 2021, as well as of and for the three months ended March 31, 2022 as of the respective dates of the issuance of these financial statements. Following the cancellation of the Series C Warrant on July 14, 2022, we no longer expect to receive such proceeds from Altium, and we do not have sufficient resources to implement our business plan for at least one year from the date of this prospectus. This raises substantial doubt about our ability to continue as a going concern.

Other than if one or more of our product candidates are accepted into Early Access Programs in certain countries, 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. Additional financing will be required to complete the research and development of our therapeutic targets and our other operating requirements, which may not be available at acceptable terms, if at all. We have filed a registration statement on Form F-1, of which this prospectus forms a part, related to an offering of securities on a "reasonable best efforts" basis, as described in this prospectus. However there is no assurance of the successful consummation of such offering. If we are unable to obtain additional funding when it becomes necessary, the development of our product candidates will be impacted and we would likely be forced to delay, reduce, or terminate some or all of our development programs, all of which could have a material adverse effect on our business, results of operations and financial condition.

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.

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 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. 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;
- attracting, hiring and retaining qualified personnel; and
- the acceptance of one or more of our product candidates into Early Access Programs in certain countries.

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 all of our product candidates are either in preclinical or clinical development. In March 2022, we submitted an Investigational New Drug (IND) application to the FDA. On April 25, 2022, we announced that the FDA had permitted our initial study under our IND for QRX003 to proceed. On July 6, 2022, we announced that the first clinical trial site for our study of QRX003 in Netherton patients had been fully opened and that patient recruitment efforts would start shortly thereafter. We also submitted Scientific Advice Briefing Document with the European Medicines Agency (the "EMA"), for QRX003, our investigational product for Netherton Syndrome, a rare and genetic disease and received comprehensive and constructive Scientific Advice from the EMA in July 2022. Clinical development of therapeutic products 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. There is also no assurance that the FDA or EMA will permit future clinical trials to proceed. For example, while we are permitted to conduct our ongoing first-in-human study, there are additional nonclinical toxicology requirements to support further clinical development and NDA submission that will require FDA input and review. 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 will establish the toxicology profile and 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, including selection of dose and clinical outcome assessments and related efficacy endpoints;
- 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, outside of our own study, there are no other 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 for 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 supple 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. There is no assurance that all of the potentially relevant prior art relating to our patents has been found; such prior art can invalidate a patent. 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 may not adequately protect our intellectual property or prevent others from designing around our claims.

We cannot offer any assurances about 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 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 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 licensors, which could be expensive, time consuming and unsuccessful.

Competitors may infringe our patents or the patents of our licensors. 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 licensors 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.

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 were phased 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 or 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

Our ADSs may be delisted from The Nasdaq Capital Market.

On April 22, 2022, we received a letter from the Listing Qualifications staff of The Nasdaq Stock Market, LLC ("Nasdaq") notifying us that we are no longer in compliance with the minimum stockholders' equity requirement for continued listing on The Nasdaq Capital Market. Nasdaq Rule 5550(b)(1) requires listed companies to maintain stockholders' equity of at least $2.5 million. In addition, as of April 21, 2022, we did not meet the alternative continued listing requirements based on market value of listed securities or net income from continuing operations. In accordance with Nasdaq Rule 5810(c)(2)(A), within 45 calendar days of receiving this notice, we submitted a plan to regain compliance to Nasdaq. This plan was accepted, and Nasdaq has granted us an extension until October 19, 2022 to evidence compliance.

On June 10, 2022, we received a letter from The Nasdaq Listing Qualifications staff notifying us that the closing bid price per ADS was below the required minimum of $1.00 for a period of 30 consecutive business days and that we did not meet the minimum bid price requirements set forth in Nasdaq Rule 5550(a)(2). Pursuant to Nasdaq Rule 5810(c)(3)(A), we have a period of one hundred eighty (180) calendar days, or until December 7, 2022 (the "Compliance Period"), to regain compliance with Nasdaq's minimum bid price requirement. If at any time during the Compliance Period, the closing bid price per ADS is at least $1.00 for a minimum of ten (10) consecutive business days, Nasdaq will provide us a written confirmation of compliance and the matter will be closed. In the event we do not regain compliance by December 7, 2022, we may be eligible for an additional 180 calendar day grace period. To qualify, we will be required to meet the continued listing requirement for market value of publicly held ADSs and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement, and will need to provide written notice of our intention to cure the deficiency during the second compliance period.

Although there is no assurance, we expect that this offering will enable us to regain compliance with Nasdaq's minimum stockholders' equity requirement and the Ratio Change will help us to regain compliance with the minimum bid-price requirement for continued listing on The Nasdaq Capital Market. Although Nasdaq notification letters described above have no immediate effect on our listing on The Nasdaq Capital Market, and we are working on implementing plans to regain compliance with Nasdaq listing standards, there can be no assurance that we will be able to regain compliance with Nasdaq's minimum stockholders' equity requirement or minimum bid-price requirement for continued listing. If our ADSs are delisted from Nasdaq, it will have material negative impacts on the actual and potential liquidity of our securities, as well as material negative impacts on our ability to raise future capital.

The market price for our ADSs is highly volatile.

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

- 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 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.

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

As of August 2, 2022, we had 50,000,000,000 authorized ordinary shares, out of which 7,180,349,799 ordinary shares were issued and outstanding (which excludes 2,641,693 shares held in treasury), and 1,621,418,087 ordinary shares reserved for purposes of our Amended and Restated Equity Incentive Plan described below and for the exercise of our outstanding 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 affected.

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.

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.

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.

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 depositary 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 depositary 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 depositary to vote their ADSs. Furthermore, the depositary 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 depositary. However, the depositary 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 depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary 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.

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 comply with the applicable continued listing requirements of Nasdaq;
- 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;
- 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 this offering and future issuances of share capital;
- the requirement for holders of ADSs to act through the depositary 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 estimate that the net proceeds from this offering will be approximately $ million, after deducting the placement agent fee and estimated offering expenses payable by us and excluding the proceeds, if any, from the subsequent exercise of the Pre-Funded Warrants and the Common Warrants. We intend to use the net proceeds from this offering for general corporate purposes, which may include operating expenses, research and development, including clinical and pre-clinical testing of our product candidates, working capital, future acquisitions and general capital expenditures. We have not determined the amount of net proceeds to be used specifically for any of such purposes.

This expected use of net proceeds from this offering and our existing cash and cash equivalents represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering. We have no current agreements, commitments or understandings for any material acquisitions or licenses of any products, businesses or technologies that are definitive or probable to close.

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 March 31, 2022 on:

- an actual basis; and
- an as adjusted basis, to give effect to the sale of ordinary shares represented by ADSs in this offering at the assumed public offering price of $ per ADS (assuming the sale of the maximum offering amount and that no Pre-Funded Warrants are sold in this offering), and after deducting commissions and estimated offering expenses payable by us.

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 March 31, 2022	
	Actual (unaudited)	As Adjusted (unaudited)
Cash	$ 5,189,215	
Liabilities:		
Current liabilities	3,586,950	
Non-current liabilities	3,973,733	
Shareholders' equity (deficit):		
Ordinary shares, no par value, 12,500,000,000 ordinary shares authorized and 3,354,653,999 ordinary shares issued and outstanding (represented by 670,930 ADSs) at March 31, 2022	—	—
Treasury Stock, 2,641,693 ordinary shares	(2,932,000)	
Additional paid in capital	31,955,379	
Accumulated deficit	(29,752,780)	
Total shareholders' equity (deficit)	(729,408)	
Total capitalization	$ (729,408)	

The information above is based on 3,354,653,999 ordinary shares represented by 670,930 ADSs outstanding as of March 31, 2022 and excludes the following:

- 23,276,800 ordinary shares represented by 4,655 ADSs issuable upon the exercise of stock options outstanding at a weighted-average exercise price of $222.19 per ADS;
- 6,930,919,600 ordinary shares represented by 1,386,184 ADSs issuable upon the exercise of outstanding warrants at a weighted-average exercise price of $49.75 per ADS; and
- 44,102,000 ordinary shares represented by 8,820 ADSs issuable upon the exercise of outstanding warrants issued by Cellect, at a weighted-average exercise price of $137.50 per ADS.

DILUTION

If you invest in our ordinary shares represented by ADSs in this offering, your ownership interest will be immediately diluted to the extent of the difference between the public offering price per ADS and our as adjusted net tangible book value per ADS after the completion of this offering. Net tangible book value per ADS is calculated by subtracting our total liabilities from our total tangible assets and dividing this amount by the number of ADSs outstanding. Our net tangible book value as of March 31, 2022 was approximately $(1.51) million, or $(2.25) per ADS.

After giving effect to the sale of ordinary shares represented by ADSs in this offering at the assumed public offering price of $ per ADSs (assuming the sale of the maximum offering amount and that no Pre-Funded Warrants are sold in this offering), and after deducting commissions and other estimated offering expenses payable by us, our as adjusted net tangible book value as of March 31, 2022 would have been approximately $ million, or $ per ADS. This amount represents an immediate dilution in the net tangible book value of $ per ADS to our existing shareholders and an immediate increase in net tangible book value of $ per ADS to new investors purchasing ADSs in this offering.

The following table illustrates this per ADS dilution:

Assumed public offering price per ADS			$	
Net tangible book value per ADS as of March 31, 2022	$	(2.25)		
Net dilution in net tangible book value per ADS attributable to existing shareholders	$			
As adjusted net tangible book value per ADS after this offering			$	
Net increase in net tangible book value per ADS to new investors in this offering			$	

The information above is based on 3,354,653,999 ordinary shares represented by 670,930 ADSs outstanding as of March 31, 2022 and assumes the exercise of the Pre-Funded Warrants, and excludes the following:

- 23,276,800 ordinary shares represented by 4,655 ADSs issuable upon the exercise of stock options outstanding at a weighted-average exercise price of $222.19 per ADS;

- 6,930,919,600 ordinary shares represented by 1,386,184 ADSs issuable upon the exercise of outstanding warrants at a weighted-average exercise price of $49.75 per ADS; and

- 44,102,000ordinary shares represented by 8,820 ADSs issuable upon the exercise of outstanding warrants issued by Cellect, at a weighted-average exercise price of $137.50 per ADS.

This discussion of dilution, and the table quantifying it, assumes no exercise of any outstanding options or warrants after March 31, 2022, including, for the avoidance of doubt, any options issued to our directors and officers, warrants issued to Altium, as well as any Common Warrants. To the extent that these excluded options and warrants have been or will be exercised, investors purchasing securities in this offering will experience further dilution.

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 a clinical stage, emerging specialty pharmaceutical company dedicated to the development and commercialization of therapeutic products that help treat rare and orphan diseases for which there are currently no approved treatments or cures. 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. Clinical testing of QRX003, under an open Investigational New Drug (IND) application with the Food and Drug Administration, or "FDA," has commenced in the US. 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. Our three other pipeline products in development are also targeting rare skin diseases, including Epidermolysis Bullosa, Netherton Syndrome and Scleroderma.

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 those currently established for Canada, Australia/New Zealand, the Middle East, China, Hong Kong, Taiwan, Latin America, Central and Eastern Europe, Turkey; 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.

A novel strain of coronavirus ("COVID-19") created a global pandemic, which commenced in 2020. Our operations, to date, have not been dramatically affected by COVID-19. However, the extent of any future impact on our operational and financial performance will depend on the possibility of a resurgence and resulting severity of COVID-19 impact with respect to our access to API and drugproduct for clinical testing, as well as our ability to safely and efficiently conduct planned clinical trials.

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 continue our operations. See "—Key Recent Events and Developments—Going Concern Qualification."

Key Recent Events and Developments

Merger

On October 28, 2021, Cellect completed the business combination with Quoin Inc. in accordance with the terms of the Merger Agreement, by and among Cellect, Quoin Inc. and Merger Sub, which was a wholly-owned subsidiary of Cellect, pursuant to which Merger Sub merged with and into Quoin Inc., with Quoin Inc. surviving as a wholly-owned subsidiary of Cellect (the "Merger"). Immediately after completion of the Merger, Cellect 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, Cellect sold the entire share capital of its subsidiary, Cellect Biotherapeutics Ltd., which essentially included all of Cellect'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.

Amended and Restated Equity Incentive Plan and Annual Meeting of Shareholders

In March 2022, our board of directors 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 our outstanding ordinary shares on a fully-diluted basis, or 1,826,991,616 ordinary shares, represented by 365,398 ADSs as of March 31, 2022. The board of directors further approved the award of options to our officers and directors to purchase, in the aggregate, 316,571 ADSs under the Amended Plan, and annual discretionary bonuses for officers of $472,500 in aggregate.

We held our Annual General Meeting on April 12, 2022, at which our 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.
- Repayment of amounts due to the two founders at a rate of $25,000 each per month.
- The grant of an option to purchase up to 85,714 ADSs to each of the two founders under the Amended Plan, at an exercise price per ADS of $17.50, to vest over a four-year period.
- The grant of an option to purchase 12,857 ADSs to each of the five non-employee director under the Amended Plan at an exercise price per ADS of $17.50, to vest over a three-year period, and (as an annual grant for 2022) an option to an officer to purchase 71,429 ADSs at an exercise price per ADS of $17.50, to vest over a three-year period.

ADS Ratio Change

On July 12, 2022, our Board of Directors approved the change in the ratio of ADS evidencing ordinary shares from 1 ADS representing four hundred (400) ordinary shares to 1 ADS representing five thousand (5,000) ordinary shares, which will result in a one for 12.5 reverse split of the issued and outstanding ADSs (the "Ratio Change"). The Ratio Change was effective August 1, 2022. All ADS and related option and warrant information presented in this prospectus, including our financial statements and accompanying footnotes, has been retroactively adjusted to reflect the reduced number of ADSs resulting from the Ratio Change.

Nasdaq Listing

On April 22, 2022, we received a letter from the Listing Qualifications staff of The Nasdaq Stock Market, LLC ("Nasdaq") notifying us that we are no longer in compliance with the minimum stockholders' equity requirement for continued listing on The Nasdaq Capital Market. Nasdaq Rule 5550(b)(1) requires listed companies to maintain stockholders' equity of at least $2.5 million. In addition, as of April 21, 2022, we did not meet the alternative continued listing requirements based on market value of listed securities or net income from continuing operations. In accordance with Nasdaq Rule 5810(c)(2)(A), within 45 calendar days of receiving this notice, we submitted a plan to regain compliance to Nasdaq. This plan was accepted, and Nasdaq has granted us an extension until October 19, 2022 to evidence compliance.

On June 10, 2022, we received a letter from The Nasdaq Listing Qualifications staff notifying us that the closing bid price per ADS was below the required minimum of $1.00 for a period of 30 consecutive business days and that we did not meet the minimum bid price requirements set forth in Nasdaq Rule 5550(a)(2). Pursuant to Nasdaq Rule 5810(c)(3)(A), we have a period of one hundred eighty (180) calendar days, or until December 7, 2022 (the "Compliance Period"), to regain compliance with Nasdaq's minimum bid price requirement. If at any time during the Compliance Period, the closing bid price per ADS is at least $1.00 for a minimum of ten (10) consecutive business days, Nasdaq will provide us a written confirmation of compliance and the matter will be closed. In the event we do not regain compliance by December 7, 2022, we may be eligible for an additional 180 calendar day grace period. To qualify, we will be required to meet the continued listing requirement for market value of publicly held ADSs and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement, and will need to provide written notice of our intention to cure the deficiency during the second compliance period.

Although there is no assurance, we expect that this offering will enable us to regain compliance with Nasdaq's minimum stockholders' equity requirement and the Ratio Change will help us to regain compliance with the minimum bid-price requirement for continued listing on The Nasdaq Capital Market. Although Nasdaq notification letters described above have no immediate effect on our listing on The Nasdaq Capital Market, and we are working on implementing plans to regain compliance with Nasdaq listing standards, there can be no assurance that we will be able to regain compliance with Nasdaq's minimum stockholders' equity requirement or minimum bid-price requirement for continued listing. If our ADSs are delisted from Nasdaq, it will have material negative impacts on the actual and potential liquidity of our securities, as well as material negative impacts on our ability to raise future capital.

Agreements with Altium Growth Fund, LP

On October 28, 2021, Cellect and Quoin Inc. completed the private placement transaction with Altium Growth Fund, LP ("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 $12.0 million in cash from Altium whereby Quoin Inc. issued to Altium (i) common stock of Quoin Inc. immediately prior to the Merger (the "Primary Financing"), pursuant to the Securities Purchase Agreement, entered into as of March 24, 2021, by and among Cellect, Quoin Inc. and Altium, as amended (the "Primary Financing Agreement"), and (ii) warrants to purchase 99,074 ADSs (the "Investor Exchange Warrants") in exchange for warrants issued in connection with the Bridge Financing pursuant to the Securities Purchase Agreement, entered into as of March 31, 2021, by and between Quoin Inc. and Altium, as amended (the "Bridge Agreement" and together with the Primary Financing Agreement, the "Purchase Agreements").

In addition, under the Primary Financing 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 342,100 ADSs (the "Series A Warrant") (ii) Series B Warrant to purchase 342,100 ADSs (the "Series B Warrant") and (iii) Series C Warrant to purchase 191,174 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 $49.75 per ADS. Under the Primary Financing Agreement, upon the exercise of the Series C Warrant in full, Quoin Ltd. was obligated to issue to Altium: (i) an additional Series A Warrant to purchase 191,174 ADSs and (ii) an additional Series B Warrant to purchase 191,174 ADSs ("Additional Investor Warrants" and together with Initial Investor Warrants, the "Investor Warrants"). During the second quarter of 2022, Altium exercised the Series B Warrant in full pursuant to the alternate cashless exercise right of such warrant, under which Altium had an option to receive 1 ADS for each ADS underlying the warrant being exercised in such cashless exercise, resulting in the issuance of a total of 342,100 ADSs to Altium.

On July 14, 2022, we, Quoin Inc. and Altium entered into an agreement, pursuant to which the parties agreed to, among other things, (i) amend certain terms of the Series A Warrant and Investor Exchange Warrants previously issued to Altium to, among other things, reduce the exercise price to $0.00 per ADS with respect to a total of 399,999 ADSs, (ii) cancel the Series C Warrant and a portion of the Series A Warrant previously issued to Altium, and (iii) terminate the Purchase Agreements, pursuant to which the warrants were previously issued to Altium. As of August 2. 2022, Altium exercised all of its outstanding warrants and we issued a total of 399,999 ADSs to Altium.

Going Concern Qualification

We expected to receive additional funding through the mandatory exercise provision of the Series C Warrant that was canceled on July 14, 2022, which would have resulted in proceeds of approximately $9.5 million. In the event the requirements of the mandatory exercise provision of such warrant were not met, we expected Altium to act on its written commitment to provide funding equal to the $9.5 million expected upon exercise of the Series C Warrant, at prevailing market rates, and thus we believed that we had sufficient resources to implement our business plan for at least one year from the issuance of our consolidated financial statements as of and for the year ended December 31, 2021, as well as of and for the three months ended March 31, 2022 as of the respective dates of the issuance of these financial statements. Following the cancellation of the Series C Warrant on July 14, 2022, we no longer expect to receive such proceeds from Altium, and we do not have sufficient resources to implement our business plan for at least one year from the date of this prospectus. This raises substantial doubt about our ability to continue as a going concern.

Unless one or more of our product candidates are accepted into Early Access Programs in certain countries, 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. Additional financing will be required to complete the research and development of our therapeutic targets and our other operating requirements, which may not be available at acceptable terms, if at all. We have filed a registration statement on Form F-1, of which this prospectus forms a part, related to an offering of securities on a “reasonable best efforts” basis, as described in this prospectus. However there is no assurance of the successful consummation of such offering. If we are unable to obtain additional funding when it becomes necessary, the development of our product candidates will be impacted and we would likely be forced to delay, reduce, or terminate some or all of our development programs, all of which could have a material adverse effect on our business, results of operations and financial condition.

Noteholder 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 Primary 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 Primary 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 29,388 ADSs, in the aggregate, at the exercise price of $49.75 per ADS (the “Noteholder Warrants”). The Noteholder Warrants became exercisable immediately upon issuance and will expire five years from March 13, 2022. Effective as of July 14, 2022, in connection with our agreement with Altium, pursuant to which the exercise price of the Series A Warrant and Investor Exchange Warrants was reduced to $0.00 per ADS, the exercise price of the Noteholder Warrants was also reduced to $0.00 per ADS in accordance with the adjustment provisions of such warrants. As of August 2, 2022, 23,040 2020 Noteholder Warrants had been exercised.

License and Distribution Agreements, Supply Agreements and Research Agreements

On June 14, 2022, Quoin Inc. entered into a License and Distribution Agreement with WinHealth Investment (HK) Limited (“WinHealth”). Under the terms of the License Agreement, WinHealth has the exclusive rights to commercialize, upon the receipt of applicable regulatory approvals, pharmaceutical products QRX003 and QRX004 (in finished dosage form for human use) in Greater China, including Hong Kong, Macau and Taiwan.

On July 14, 2022, Quoin Inc. entered into (i) a License and Distribution Agreement with Endo Ventures Limited (“Endo”), and (ii) a Supply Agreement with Endo. Under the terms of the License Agreement, Endo has the exclusive rights to commercialize, upon the receipt of applicable regulatory approvals, pharmaceutical product QRX003 (in finished dosage form for human use) in Canada. Under the terms of the Supply Agreement, Quoin agreed to manufacture and supply (or have manufactured and supplied) to Endo the foregoing pharmaceutical product QRX003 for sale in Canada.

Effective as of May 20, 2022, Quoin Inc. entered into a Research Agreement with Queensland University of Technology, Australia, to collaborate on the project related to the selection of a lead VLA-4 inhibitor for entry into a Scleroderma clinical development program.

Clinical Development

Quoin's lead asset, QRX003, is currently in clinical development in the United States under an open IND application with the FDA. The ongoing study is a randomized, double blinded assessment of two different doses of QRX003 versus a placebo vehicle in Netherton patients. The test materials will be applied once daily, over a twelve-week period, to pre-selected areas of the patient's body. Based on discussions with the FDA, a number of different clinical endpoints are being assessed in the study, including but not limited to, an Investigators Global Assessment (IGA), Patient's Global Assessment (PaGA) and Pruritis. The trial will be conducted in up to six clinical sites in the US. The first clinical site was open in July 2022 and the opening of additional sites is in process.

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 our other pipeline products.

The duration, costs and timing of clinical trials of QRX003 and our other pipeline products 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 sets forth our results of operations for the three months ended March 31, 2022, compared to the three months ended March 31, 2021:

	Three months ended March 31,		
	2022	**2021**	**Change**
Operating Expenses			
General and administrative	**$ 1,588,470**	$ 744,973	$ 843,497
Research and development	**587,569**	56,788	530,781
Total operating expenses	**2,176,039**	801,761	1,374,278
Other Expenses			
Settlements of accounts payable	**(416,000)**	—	(416,000)
Fair value adjustments to debt	**—**	500,000	(500,000)
Warrant liability expense (income)	**(77,237)**	2,446,513	(2,523,750)
Financing expense	**—**	90,000	(90,000)
Interest expense	**—**	65,597	(65,597)
Total other expenses (income)	**(493,237)**	3,102,110	(3,595,347)
Net loss	**$ (1,682,802)**	$ (3,903,871)	$ (2,221,069)

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)

Three months ended March 31, 2022 compared to three months ended March 31, 2021

General and Administrative Expenses

General and administrative expenses were approximately $1,600,000 and $700,000, in the three months ended March 31, 2022 and 2021, respectively, representing an increase of $800,000, or 113%. The increase was primarily due to the build up of the company infrastructure post the Merger and the increased costs of becoming a public company.

Research and Development Expenses

Our research and development expenses during the three months ended March 31, 2022 and 2021 were approximately $590,000 and $57,000, respectively, representing an increase of $530,000, or approximately 935%. The increase was primary due to increased expenditures on our development programs following the completion of our financings in October 2021, including work related to the filing of our IND for QRX003 in March 2022. Also, included in the 2022 expenses were approximately $113,000 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 $26,000 in each of the three months ended March 31, 2022 and 2021.

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 $0 and $66,000 in the three months ended March 31, 2022 and 2021 respectively. Interest on the Bridge Notes was paid in October 2021 upon closing of the Primary Financing, and interest on the 2020 Notes did not accrue after October 2021 but remained unpaid and included as a liability on our consolidated balance sheet as of December 31, 2021 a portion of which was paid in the three months ended March 31, 2022. 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 three months ended March 31, 2021 we incurred a fair value adjustment of $500,000 related to the Bridge 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 determined to require liability treatment at fair value, which was remeasured at each reporting period. In the three months ended March 31, 2022, and March 31, 2021 we incurred a fair value gain of ($77,000) related to the warrants associated with the 2020 Notes, and expense of $2,400,000 related to the warrants associated with the 2020 Notes and the Bridge Notes, respectively. The Bridge Note warrants which were exchanged for the Investor Exchange Warrant (as defined below) with a fixed exercise price of $49.75 per share and reclassified as an equity instrument in October 2021 upon closing of the Primary Financing. The 2020 Note warrants were exchanged for warrants on the same terms as the Investor Exchange Warrant and reclassified as an equity instrument in March 2022.

Forgiveness of Trade Payable

In our balance sheet as of December 31, 2021 we had a liability of $584,000 representing amounts due to an investor relations firm for services commencing in 2017. In May 2022 we entered into a settlement with such firm to decrease the liability to $168,000 which resulted in $416,000 of income recognized in the three months ended March 31, 2022.

Net Loss

We recorded a net loss of approximately $1,700,000 in for the three months ended March 31, 2022, as compared to a net loss of $3,900,000 for the three months ended March 31, 2021, representing an decrease of approximately of $2,200,000. The decrease was primarily due to financing related charges aggregating $3,100,000, including warrant expense of $2,400,000, in the three months ended March 31, 2021 compared to other income of $80,000 in the three months ended March 31, 2021, as well as other income recognized in the settlement of accounts payable in the three months ended March 31, 2022, partially offset by increases in research and development expense and general and administrative expense in the three months ended March 31, 2022 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 March 31, 2022. Upon closing of the Merger in October 2021, options held by former Cellect option holders under Cellect Ltd. Employee Shares Incentive Plan (the "2014 Plan") fully vested and expire between January and October 2022. The 2014 Plan was amended and restated and initial grants were made to our Company officers and directors, approved at our Company Annual General Meeting of shareholders held on April 12, 2022.

Income Taxes

For the three months ended March 31, 2022 and 2021, 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, 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 $49.75 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 Cellect option holders under Cellect 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, 2021and 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 three months ended March 31, 2022 and 2021 and 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 estimates used in the determining the fair value of the 2020 Notes warrants were as follows:

	03/13/2022 (1)	12/31/2021(1)
Stock price	$ 18.50	$ 22.75
Initial exercise price	$ 49.75	$ 49.75
Contractual Term	5.0	5.0
Volatility	91.5 %	89.2 %
Discount rate	1.94 %	1.26 %

(1) The warrants issued during 2020 were not exchanged for fixed term warrants until March 13, 2022, therefore the existing warrants were still considered outstanding at December 31, 2021 and classified as a liability instrument up to the exchange date.

The significant estimates used in such calculation of the fair value of the warrants issued in connection with the Bridge Financing were as follows:

	Transaction Date March - May 2021	Merger Date 10/28/2021
Stock price	$ 49.75	$ 145.50
Initial exercise price	$ 49.75	$ 49.75
Contractual Term	5.0	5.0
Volatility	92 %	89.2 %
Discount rate	0.98 %	1.18 %

The following shows the movement of the warrant liability balance during 2021 and the three months ended March 31, 2022.

	Bridge Financing Warrants	2020 Note Warrants
Beginning Balance January 1, 2021	$ —	$ —
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 December 31, 2021	**$ —**	**$ 373,599**
Change in Fair value of warrants	—	(77,237)
Reclassification of warrant liability to an equity instrument	—	(296,362)
Ending Balance March 31, 2022	**$ —**	**$ —**

The Investor Exchange Warrant 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. The Exchange Warrants issued to the 2020 Noteholders effective as of March 13, 2022 were determined to be an equity-classified instrument, and accordingly the warrant liability on such date of $296,262 was reclassified to additional paid in capital on that date.

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 continue to increase substantially throughout 2022 as we advance the clinical development of QRX003 and begin to operate as a publicly traded company.

Future Funding Requirements

We expected to receive additional funding through the mandatory exercise provision of the Series C Warrant that was canceled on July 14, 2022, which would have resulted in proceeds of approximately $9.5 million. In the event the requirements of the mandatory exercise provision of such warrant were not met, we expected Altium to act on its written commitment to provide funding equal to the $9.5 million expected upon exercise of the Series C Warrant, at prevailing market rates, and thus we believed that we had sufficient resources to implement our business plan for at least one year from the issuance of our consolidated financial statements as of and for the year ended December 31, 2021, as well as of and for the three months ended March 31, 2022 as of the respective dates of the issuance of these financial statements. Following the cancellation of the Series C Warrant on July 14, 2022, we no longer expect to receive such proceeds from Altium, and we do not have sufficient resources to implement our business plan for at least one year from the date of this prospectus. This raises substantial doubt about our ability to continue as a going concern.

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. Additional financing will be required to complete the research and development of our therapeutic targets and our other operating requirements, which may not be available at acceptable terms, if at all. We have filed a registration statement on Form F-1, of which this prospectus forms a part, related to an offering of securities on a "reasonable best efforts" basis, as described in this prospectus. However there is no assurance of the successful consummation of such offering. If we are unable to obtain additional funding when it becomes necessary, the development of our product candidates will be impacted and we would likely be forced to delay, reduce, or terminate some or all of our development programs, all of which could have a material adverse effect on our business, results of operations and financial condition.

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 for the Three Months Ended March 31, 2022 and 2021

As of March 31, 2022, we had approximately $5,200,000 in cash.

The table below presents our cash flows for the three months ended March 31, 2022 and 2021:

	Three months ended March 31.	
	2021	2022
Net cash used in operating activities	$ (413,726)	$ (2,093,588)
Net cash used in investing activities	(142,500)	(50,000)
Net cash provided by (used in) financing activities	1,309,977	(150,000)
Net increase (decrease) in cash	$ 753,751	$ (2,293,558)

Operating Activities

Net cash used in operating activities was approximately $2,100,000 and $400,000 for the three months ended March 31, 2022 and 2021, respectively. The increase in 2022 was primarily due to the increase in research and development and general and administrative expenses, including significant expenses incurred in connection with becoming a public company and increased compensation costs, as well as a pay-down of accounts payable from 2021 and partial pay-down of accrued interest on the 2020 Notes.

Investing Activities

Net cash used by investing activities was $50,000 and $143,000 in the three months ended March 31, 2022 and 2021, respectively, each representing payments under the Skinvisible license agreement.

Financing Activities

Net cash (used by) financing activities was $150,000 for the three months ended March 31, 2022 representing repayments of amounts due to officers at the aggregate rate of $50,000 per month. Net cash from financing activities in the three months ended March 31, 2021 was $1,300,000, primarily representing net proceeds received from the Bridge Financing.

Summary Statement of Cash Flows for the Years Ended December 31, 2021, 2020 and 2019

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):

	2019	2020	2021
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	1,299	1,787	13,504
Net increase in cash and cash equivalents	$ —	$ 324	$ 7,159

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 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, the 2020 Notes were mandatorily convertible into 5,180 ADSs in connection with the Primary Financing, subject to adjustment. 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).

After entering into the Merger Agreement in March 2021, the terms of the warrants became measurable and were exercisable for 29,388 ADSs at an initial exercise price of $49.75 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 is included in warrant liability expense in the Company's statement of operations.

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 the same terms as the Investor Exchange Warrants exercisable for 29,388 ADSs, in the aggregate, at the exercise price of $49.75 per ADS.

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 consolidated balance sheet. A total of $312,000 was paid to two of the five 2020 Noteholders during the three months ended March 31, 2022, and the remaining liability of $432,000 is included in Accrued Interest in the Company's consolidated balance sheet as of March 31, 2022.

Interest expense, at the stated interest rate, recognized in the three months ended March 31, 2022 and 2021 was approximately $0 and $66,000, 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 $5,000,000 in exchange for an aggregate purchase price of up to $3,800,000 together with warrants. The Bridge Notes were purchased in three closings: (i) the first purchase of $2,000,000 on March 25, 2021 (Quoin Inc. received proceeds of $1,500,000 less fees of $90,000); (ii) the second purchase of $1,700,000 in April 2021 (Quoin Inc. received proceeds of $1,250,000); and (iii) a third purchase of $1,300,000 in May 2021 (Quoin Inc. received proceeds of $1,000,000 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 100,620 ADSs (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. Interest expense, at the stated interest rate, recognized in the three months ended March 31, 2022 and 2021 was $0 and $4,900, respectively.

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 the Investor Exchange Warrant 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 $17,000,000 (comprised of (x) the set off of approximately $5,000,000 of Bridge Notes, and (y) approximately $12,000,000 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 $1,000,000 in costs associated with the Primary Financing, which resulted in the net proceeds of approximately $10,100,000. The Company issued 342,100 ADSs to the Investor, consisting of 85,525 delivered to the Investor on or after the Merger closing and 256,575 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 99,074 ADSs (the "Investor Exchange Warrant") at an exercise price of $49.75 per ADS, in exchange for Bridge Warrants. The Investor Exchange Warrant and ordinary shares represented by ADSs underlying the Investor Exchange Warrant were registered with the SEC on the Registration Statement on Form F-4. An amendment to the Investor Exchange Warrant 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 342,100 ADSs (the "Series A Warrant") (ii) Series B Warrant to purchase 342,100 ADSs (the "Series B Warrant") and (iii) Series C Warrant to purchase 191,174 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 $49.75 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 had 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, such registration statement on Form F-1was declared effective by the SEC, but not all of the market related conditions were met. Upon the exercise of the Series C Warrant in full, the Investor had the right to be granted an additional

Series A Warrant to purchase 191,174 ADSs and an additional Series B Warrant to purchase 191,174 ADSs at an exercise price of $49.75 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 ($7,500,000) and obtaining US and EU regulatory approval ($15,000,000). The sales milestones required for every licensed product commercialized by Quoin Inc. are $10,000,000 upon achievement of $100,000,000 in sales being achieved in the annual period; $25,000,000 upon achievement of $250,000,000 in sales and $50,000,000 upon the achievement of $400,000,000 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 $21,750,000 upon regulatory approval in the U.S. and EU respectively. No development milestones, sales milestones or royalty payments were due through March 2022.

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. This requirement has been met with the initiation of the clinical study for QRX003 in Netherton Syndrome patients.

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 March 31, 2022, the license acquisition liability due was $200,000 which was paid in full in May 2022.

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. We did not incur any expense for services provided or milestones met in the three months ended March 31, 2022 or 2021, and we have accrued expenses of $193,537 at March 31, 2022.

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 $3,500,000 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. For the three months ended March 31, 2022, and March 31, 2021, the Company incurred a research and development expense under this agreement of approximately $185,000 and $0, respectively.

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 did not incur any expense for the three months ended March 31, 2022.

Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risks in the ordinary course of our business. Market risk represents the risk of loss that may impact our financial position, results of operations or cash flows due to adverse changes in financial market prices and rates, including interest rates and foreign exchange rates, of financial instruments. However, our exposure to market risk for changes in interest rates is not significant as we have no outstanding interest-bearing debt instruments, and we do not hold any interest-generating securities. See “Liquidity and Capital Resources” above.

BUSINESS

Company Overview

We are a clinical stage, emerging specialty pharmaceutical company dedicated to the development and commercialization of therapeutic products that help treat rare and orphan diseases for which there are currently no approved treatments or cures. 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. Clinical testing of QRX003, under an open Investigational New Drug (IND) application with the Food and Drug Administration, or “FDA,” has commenced in the US. 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. Our three other pipeline products in development are also targeting rare skin diseases, including Epidermolysis Bullosa, Netherton Syndrome and Scleroderma.

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 initial 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 be 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 may be 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 which is under clinical development 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 January 30, 2020, we received feedback from the FDA, which we believe 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.. 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. On April 25, 2022, we announced that the FDA had permitted our initial clinical study under our IND for QRX003 to proceed, and on July 6, 2022, we announced that the first clinical site for our Netherton Syndrome study had been fully opened. In its communication allowing our study to proceed, the FDA provided further feedback on our development program. The FDA provided advice on our initial study so that the study could better inform a future Phase 3 study. With regard to nonclinical studies to support further clinical development and an eventual NDA submission, the agency stated that the typical battery of toxicology studies would apply to this product candidate. We also intend to apply for Orphan Drug status as well as Rare Pediatric Disease designation for QRX003 at a later date. In addition, we submitted a briefing document to the EMA seeking guidance regarding the clinical and regulatory development of QRX003 for the EU and announced in July 2022 that we had received comprehensive and constructive Scientific Advice from the EMA in response to this submission.

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, potentially for the duration of a patient's life.

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, Canada, the Middle East, Central and Eastern Europe, Turkey, Greater China including Hong Kong, Taiwan, Macau 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, Scleroderma 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 clinical 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 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 licensed product relating to 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 March 31, 2022, 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.

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 a 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 Depart 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	58	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 and Wellesley Pharmaceuticals 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 and as director of Quoin Ltd. since October 28, 2021. Dr. Langer served as a director of Brooklyn ImmunoTherapeutics, Inc. until June 5, 2022 and as a director of Myriad Genetics, Inc. until June 30, 2022. Dr. Langer currently serves as a director of 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 our directors and executive officers.

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 of our directors and executive officers, 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 85,714 ADSs to Dr. Myers, at an exercise price per ADS of USD $17.50, 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 85,714 ADSs to Ms. Carter, at an exercise price per ADS of USD $17.50, 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 71,429 ADSs to Mr. Dunn, at an exercise price per ADSs of USD $17.50, 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).

The above referenced options were granted on April 12, 2022.

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 9,429 ADS under the Amended and Restated Equity Incentive Plan, at an exercise price per ADS of USD $17.50, 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, each of which was granted on April 12, 2022; and

- as an annual grant for 2022, an option to purchase 3,428 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 The 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 polices; 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 March 31, 2022, 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. Our 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 August 2, 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 7,180,349,799 ordinary shares outstanding as of August 2, 2022. Ordinary shares that may be acquired by a person within 60 days of August 2, 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 5,000 ordinary shares of Quoin Ltd.

Name	Number of Ordinary Shares Beneficially Owned	Percentage Owned
Principal Shareholders:		
Goldman Sachs & Co. LLC(1)	580,219,600	8.08 %
Executive Officers and Directors:		
Michael Myers(2)	560,970,000	7.81 %
Denise Carter(2)	560,970,000	7.81 %
Gordon Dunn	—	*
James Culverwell	19,072,600	*
Joseph Cooper	—	*
Dennis Langer	21,007,400	*
Natalie Leong	—	*
Michael Sember	—	*
All directors and officers as a group (8 persons)	1,162,020,000	16.18 %

* Less than 1%

(1) 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.

(2) Includes ADSs held in escrow.

Bank of New York Mellon, or "BNY," is the holder of record for our ADR program, pursuant to which each ADS represents 5,000 ordinary shares. As of August 2, 2022, BNY held 7,179,987,140 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.

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 March 31, 2022, Quoin Inc. was indebted to each of Dr. Myers and Ms. Carter in the aggregate amount of $ 2,483,700 and $2,090,032, 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.

Exchange Controls

There are currently no Israeli currency control restrictions on payments of dividends or other distributions with respect to our ordinary shares or the proceeds from the sale of the shares, except, under certain circumstances, for shareholders who are subjects of countries that are, or have been, in a state of war with Israel. Israeli residents have an obligation to file reports with the Bank of Israel regarding certain transactions. However, legislation remains in effect pursuant to which currency controls can be imposed by administrative action at any time.

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 five thousand (5,000) ordinary shares (or a right to receive five thousand (5,000) 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 Depository 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 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:	***For*:**
$5.00 (or less) per 5,000 ADSs (or portion of 5,000 ADSs)	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
$0.05 (or less) per ADS	Any cash distribution to ADS holders
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	Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
$0.05 (or less) per ADSs per calendar year	Depositary services
Registration or transfer fees	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
Expenses of the Depositary	Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement); converting foreign currency to U.S. dollars
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	As necessary
Any charges incurred by the Depositary or its agents for servicing the deposited securities	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 depositary agree to indemnify each other under certain circumstances.

Requirements for Depositary Actions

Before the depositary will deliver or register a transfer of ADSs, make a distribution on ADSs, or permit withdrawal of shares, the depositary 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 depositary may refuse to deliver ADSs or register transfers of ADSs when the transfer books of the depositary or our transfer books are closed or at any time if the depositary 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 depositary 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 depositary to deliver ADSs before deposit of the underlying shares. This is called a pre-release of the ADSs. The depositary 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 depositary. The depositary may receive ADSs instead of ordinary shares to close out a pre-release. The depositary 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 depositary 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 depositary considers appropriate; and (3) the depositary must be able to close out the pre-release on not more than five business days' notice. In addition, the depositary will limit the number of ADSs that may be outstanding at any time as a result of pre-release, although the depositary 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 depositary 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 depositary 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 depositary 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 depositary's reliance on and compliance with instructions received by the depositary through the DRS/Profile system and in accordance with the deposit agreement will not constitute negligence or bad faith on the part of the depositary.

Shareholder communications; inspection of register of holders of ADSs

The depositary will make available for your inspection at its office all communications from us that we make generally available to holders of deposited securities. The depositary 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.

DESCRIPTION OF WARRANTS TO BE ISSUED AS PART OF THIS OFFERING

The following summary of certain terms and provisions of Pre-Funded Warrants and Common Warrants that are being offered hereby is not complete and is subject to, and qualified in its entirety by, the provisions of the forms of such warrants, which are filed as an exhibits to the registration statement of which this prospectus is a part. Prospective investors should carefully review the terms and provisions set forth in such forms of warrants for a complete description of the terms and conditions of the Pre-Funded Warrants and Common Warrants. The Pre-Funded Warrants will be issued separately from the accompanying Common Warrants, and may be transferred separately immediately thereafter.

Pre-Funded Warrants Being Offered in this Offering

Duration and Exercise Price

Each Pre-Funded Warrant offered hereby will have an initial exercise price equal to $0.0001 per ADS. The Pre-Funded Warrants will be immediately exercisable and may be exercised at any time until the Pre-Funded Warrants are exercised in full. The exercise price and number of ADSs issuable upon exercise is subject to appropriate proportional adjustment in the event of share dividends, share splits, reorganizations or similar events affecting our ADSs and the exercise price.

Exercisability

The Pre-Funded Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice and, within the earlier of (i) two trading days and (ii) the number of trading days comprising the standard settlement period with respect to the ADSs as in effect on the date of delivery of the notice of exercise thereafter, payment in full for the number of ADSs purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder may not exercise any portion of the Pre-Funded Warrant to the extent that the holder, together with its affiliates and any other persons acting as a group together with any such persons, would own more than 4.99% (or, at the election of the purchaser, 9.99%) of the number of ordinary shares outstanding immediately after exercise (the “Beneficial Ownership Limitation”); provided that a holder with a Beneficial Ownership Limitation of 4.99%, upon notice to us and effective 61 days after the date such notice is delivered to us, may increase the Beneficial Ownership Limitation so long as it in no event exceeds 9.99% of the number of ordinary shares outstanding immediately after exercise.

Cashless Exercise

The Pre-Funded Warrants may also be exercised, in whole or in part, at such time by means of a “cashless exercise” in which the holder shall be entitled to receive upon such exercise (either in whole or in part) the net number of ADSs determined according to a formula set forth in the Pre-Funded Warrants, which generally provides for a number of ADSs equal to (A) (1) the volume weighted average price on (x) the trading day preceding the notice of exercise, if the notice of exercise is executed and delivered on a day that is not a trading day or prior to the opening of “regular trading hours” on a trading day or (y) the trading day of the notice of exercise, if the notice of exercise is executed and delivered after the close of “regular trading hours” on such trading day, or (2) the bid price on the day of the notice of exercise, if the notice of exercise is executed during “regular trading hours” on a trading day and is delivered within two hours thereafter, less (B) the exercise price, multiplied by (C) the number of ADSs the Pre-Funded Warrant was exercisable into, with such product then divided by the number determined under clause (A) in this sentence.

Fractional Shares

No fractional ADSs will be issued upon the exercise of the Pre-Funded Warrants. Rather, we will, at our election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price or round up to the next whole ADS.

Transferability

Subject to applicable laws, a Pre-Funded Warrant may be transferred at the option of the holder upon surrender of the Pre-Funded Warrant to us together with the appropriate instruments of transfer and funds sufficient to pay any transfer taxes payable upon such transfer.

Trading Market

There is no trading market available for the Pre-Funded Warrants on any securities exchange or nationally recognized trading system. We do not intend to list the Pre-Funded Warrants on any securities exchange or nationally recognized trading system. The ADSs issuable upon exercise of the Pre-Funded Warrants are currently listed on The Nasdaq Capital Market under the symbol "QNRX."

Rights as a Shareholder

Except as otherwise provided in the Pre-Funded Warrants or by virtue of such holder's ownership of the underlying ordinary shares represented by ADSs, the holders of the Pre-Funded Warrants do not have the rights or privileges of holders of our ordinary shares represented by ADSs, including any voting rights, until they exercise their Pre-Funded Warrants.

Fundamental Transaction

In the event of a fundamental transaction, as described in the Pre-Funded Warrants and generally including any reorganization, recapitalization or reclassification of our ADSs, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding ADSs, the holders of the Pre-Funded Warrants will be entitled to receive upon exercise of the Pre-Funded Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Pre-Funded Warrants immediately prior to such fundamental transaction.

Common Warrants Being Offered in this Offering

Duration and Exercise Price

Each Common Warrant offered hereby will have an initial exercise price equal to $ per ADS. The Common Warrants will be immediately exercisable and will expire on the fifth anniversary of the original issuance date. The exercise price and number of ADSs issuable upon exercise is subject to appropriate proportional adjustment in the event of share dividends, share splits, reorganizations or similar events affecting our ADSs and the exercise price.

Exercisability

The Common Warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice and, within the earlier of (i) two trading days and (ii) the number of trading days comprising the standard settlement period with respect to the ADSs as in effect on the date of delivery of the notice of exercise thereafter, payment in full for the number of ADSs purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder may not exercise any portion of the Common Warrant to the extent that the holder, together with its affiliates and any other persons acting as a group together with any such persons, would own more than 4.99% (or, at the election of the purchaser, 9.99%) of the number of ordinary shares outstanding immediately after exercise (the "Beneficial Ownership Limitation"); provided that a holder with a Beneficial Ownership Limitation of 4.99%, upon notice to us and effective 61 days after the date such notice is delivered to us, may increase the Beneficial Ownership Limitation so long as it in no event exceeds 9.99% of the number of ordinary shares outstanding immediately after exercise.

Cashless Exercise

If, at the time a holder exercises its Common Warrants, a registration statement registering the issuance of the ADSs underlying the Common Warrants under the Securities Act of 1933, as amended (the "Securities Act") is not then effective or available for the issuance of such shares, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of ADSs determined according to a formula set forth in the Common Warrants, which generally provides for a number of ADSs equal to (A) (1) the volume weighted average price on (x) the trading day preceding the notice of exercise, if the notice of exercise is executed and delivered on a day that is not a trading day or prior to the opening of "regular trading hours" on a trading day or (y) the trading day of the notice of exercise, if the notice of exercise is executed and delivered after the close of "regular trading hours" on such trading day, or (2) the bid price on the day of the notice of exercise, if the notice of exercise is executed during "regular trading hours" on a trading day and is delivered within two hours thereafter, less (B) the exercise price, multiplied by (C) the number of ADSs the Common Warrant was exercisable into, with such product then divided by the number determined under clause (A) in this sentence.

Fractional Shares

No fractional ADSs will be issued upon the exercise of the Common Warrants. Rather, we will, at our election, either pay a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price or round up to the next whole ADS.

Transferability

Subject to applicable laws, a Common Warrant may be transferred at the option of the holder upon surrender of the Common Warrant to us together with the appropriate instruments of transfer and funds sufficient to pay any transfer taxes payable upon such transfer.

Trading Market

There is no trading market available for the Common Warrants on any securities exchange or nationally recognized trading system. We do not intend to list the Common Warrants on any securities exchange or nationally recognized trading system. The ADSs issuable upon exercise of the Common Warrants are currently listed on The Nasdaq Capital Market under the symbol "QNRX."

Rights as a Shareholder

Except as otherwise provided in the Common Warrants or by virtue of such holder's ownership of the underlying ordinary shares represented by ADSs, the holders of the Common Warrants do not have the rights or privileges of holders of our ordinary shares represented by ADSs, including any voting rights, until they exercise their Common Warrants.

Fundamental Transaction

In the event of a fundamental transaction, as described in the Common Warrants and generally including any reorganization, recapitalization or reclassification of our ADSs, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding ADSs, the holders of the Common Warrants will be entitled to receive upon exercise of the Common Warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the Common Warrants immediately prior to such fundamental transaction. Additionally, in the event of a fundamental transaction, we or any successor entity will, at the option of the holder of a Common Warrant exercisable at any time concurrently with or within 30 days after the consummation of the fundamental transaction (or, if later, the date of the public announcement thereof), purchase the Common Warrant from the holder by paying to the holder an amount of consideration equal to the value of the remaining unexercised portion of such Common Warrant on the date of consummation of the fundamental transaction based on the Black-Scholes option pricing model, determined pursuant to a formula set forth in the Common Warrants. The consideration paid to the holder will be the same type or form of consideration that was offered and paid to the holders of ordinary shares in connection with the fundamental transaction; provided that if no such consideration was offered or paid, the holders of ordinary shares will be deemed to have received ordinary shares of the successor entity in such fundamental transaction for purposes of this provision of the Common Warrants.

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 Pre-Funded Warrants

The position of the IRS is that when the holder of an option to purchase property is economically compelled to exercise the option based on all the facts and circumstances, the option holder is treated as the beneficial owner of the underlying property for U.S. federal income tax purposes. Economic compulsion to exercise an option or warrant to acquire stock can result when the exercise price of the option or warrant is nominal in relation to the value of the stock subject to the option or warrant at the time of issuance of such option or warrant.

The purchase price of each Pre-Funded Warrant will comprise substantially all of the value of the ADSs representing our ordinary shares underlying the Pre-Funded Warrant at the time the Pre-Funded Warrants are sold. As a result, the discussion of the U.S. federal income taxation of warrants in this prospectus treats holders of Pre-Funded Warrants as economically compelled to exercise the Pre-Funded Warrants and receive ordinary shares represented by ADSs. Accordingly, references to ordinary shares or ADSs in this section, "Certain Material U.S. Federal Income Tax Considerations", include Pre-Funded Warrants as if the Pre-Funded Warrant holders receive ordinary shares represented by ADSs at the time such Pre-Funded Warrant holders purchase the Pre-Funded Warrants. Additionally, references to warrants in this section, "Certain Material U.S. Federal Income Tax Considerations", means the Common Warrants only and not the Pre-Funded Warrants. There can be no assurance that the IRS or a court will not take a contrary position on the U.S. federal income taxation of the Pre-Funded Warrants. Each prospective investor in Pre-Funded Warrants is urged to consult his or her own tax advisor regarding the U.S. federal income tax consequences of the Pre-Funded Warrants.

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 shareholder upon or after the registration of the Shares on the non-Israeli stock exchange (on July 29, 2016) and (ii) the 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

A.G.P. / Alliance Global Partners, which we refer to herein as the placement agent, located at 590 Madison Ave 28th Floor, New York, NY 10022, has agreed to act as our exclusive placement agent in connection with this offering subject to the terms and conditions of the placement agency agreement dated , 2022. The placement agent is not purchasing or selling any of the securities offered by this prospectus, nor is it required to arrange the purchase or sale of any specific number or dollar amount of securities, but it has agreed to use its reasonable best efforts to arrange for the sale of all of the securities offered hereby. Therefore, we will enter into a securities purchase agreement directly with purchasers in connection with this offering and may not sell the entire amount of securities offered pursuant to this prospectus.

We will deliver the securities being issued to the investors upon receipt of investor funds for the purchase of the securities offered pursuant to this prospectus. We expect to deliver the ADSs, Pre-Funded Warrants and Common Warrants being offered pursuant to this prospectus on or about , 2022.

We have agreed to indemnify the placement agent and specified other persons against specified liabilities, including liabilities under the Securities Act, and to contribute to payments the placement agent may be required to make in respect thereof.

Fees and Expenses

This offering is being conducted on a “reasonable best efforts” basis and the placement agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of securities. We have agreed to pay the placement agent fees set forth in the table below.

	Per ADS and Accompanying Common Warrant	Per Pre-Funded Warrant and Accompanying Common Warrant	Total
Public offering price			
Placement agent fees			
Proceeds to us (before expenses)[(1)]			

(1) Does not include proceeds from the exercise of the warrants in cash, if any.

We have agreed to pay to the placement agent a cash fee equal to 7.0% of the aggregate gross proceeds raised in this offering, provided, that, in the event that proceeds raised in this offering are raised from certain identified investors, the placement agent cash fee will be reduced to 3.5% of such proceeds raised up to $5 million and further reduced to 1.75% of such proceeds raised above $5 million. Because there is no minimum offering amount required as a condition to closing in this offering, the actual aggregate cash placement fee, if any, is not presently determinable and may be substantially less than the maximum amount set forth above.

We estimate the total expenses payable by us for this offering to be approximately $, which amount includes: (i) a placement agent’s fee of $, assuming the purchase of all of the securities we are offering; (ii) a non-accountable expense allowance payable to the placement agent of $ (equal to 1.0% of the aggregate gross proceeds raised in this offering); (iii) reimbursement of the accountable expenses of the placement agent of $125,000 related to the legal fees of the placement agent being paid by us (none of which has been paid in advance); and (iv) other estimated expenses of approximately $ which include our legal, accounting, and printing costs and various fees associated with the registration and listing of our securities.

The placement agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act, and any commissions received by it and any profit realized on the resale of the shares sold by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. As an underwriter, the placement agent would be required to comply with the requirements of the Securities Act and the Exchange Act, including, without limitation, Rule 415(a)(4) under the Securities Act and Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of securities by the placement agent acting as principal. Under these rules and regulations, the placement agent:

- may not engage in any stabilization activity in connection with our securities; and
- may not bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until it has completed its participation in the distribution.

Lock-Up Agreements

Our directors, officers and beneficial owners of 5% or more of our outstanding ordinary shares have entered into lock-up agreements. Under these agreements, these individuals have agreed, subject to specified exceptions, not to sell or transfer any ADSs or securities convertible into, or exchangeable or exercisable for, our ADSs during a period ending 90 days after the date of this prospectus, without first obtaining the written consent of the placement agent, subject to certain exceptions. Specifically, these individuals have agreed, in part, not to:

- offer, pledge, sell, contract to sell or otherwise dispose of Quoin Ltd.'s securities or any securities convertible into or exercisable or exchangeable for ordinary shares;

- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our securities, whether any such transaction is to be settled by delivery of our securities, in cash or otherwise;

- make any demand for or exercise any right with respect to the registration of any of our securities;

- publicly disclose the intention to make any offer, sale, pledge or disposition of, or to enter into any transaction, swap, hedge, or other arrangement relating to any of our securities.

Notwithstanding these limitations, our securities may be transferred under limited circumstances, including, without limitation, by gift, will or intestate succession.

We have agreed with the placement agent to be subject to a lock-up period of 90 days following the date of closing of the offering pursuant to this prospectus. This means that, during the applicable lock-up period, subject to certain limited exceptions, we may not, without the prior written consent of the placement agent: (i) issue, enter into any agreement to issue or announce the issuance or proposed issuance of any ADSs, ordinary shares or ordinary share equivalents, or (ii) file any registration statement or amendment or supplement thereto, other than the preliminary prospectus or the prospectus related to this offering or a registration statement on Form S-8 in connection with any employee benefit plan. In addition, subject to certain exceptions, we have agreed to not issue any securities that are subject to a price reset based on the trading prices of ADSs or upon a specified or contingent event in the future, or enter into any agreement to issue securities at a future determined price for a period of 180 days following the closing date of this offering.

Determination of Offering Price

The public offering price of the securities we are offering was negotiated between us and the investors, in consultation with the placement agent based on the trading of our ADSs prior to the offering, among other things. Other factors considered in determining the public offering price of the securities we are offering include our history and prospects, the industry in which we operate, our past and present operating results, the stage of development of our business, our business plans for the future and the extent to which they have been implemented, the previous experience of our executive officers, general conditions of the securities markets at the time of the offering and such other factors as were deemed relevant.

Listing

Our ADSs are listed on The Nasdaq Capital Market under the trading symbol "QNRX." We do not plan to list the Pre-Funded Warrants or Common Warrants on The Nasdaq Capital Market or any other securities exchange or trading market.

Discretionary Accounts

The placement agent does not intend to confirm sales of the securities offered hereby to any accounts over which it has discretionary authority.

Other Activities and Relationships

The placement agent and certain of its affiliates are full service financial institutions engaged in various activities, which may include securities trading, commercial and investment banking, financial advisory, investment management, investment research, principal investment, hedging, financing and brokerage activities. The placement agent and certain of its affiliates have, from time to time, performed, and may in the future perform, various commercial and investment banking and financial advisory services for us and our affiliates, for which they received or will receive customary fees and expenses.

In the ordinary course of their various business activities, the placement agent and certain of its affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers, and such investment and securities activities may involve securities and/or instruments issued by us and our affiliates. If the placement agent or its affiliates enter into a lending relationship with us, they will routinely hedge their credit exposure to us consistent with their customary risk management policies. The placement agent and its affiliates may hedge such exposure by entering into transactions that consist of either the purchase of credit default swaps or the creation of short positions in our securities or the securities of our affiliates, including potentially the ADSs offered hereby. Any such short positions could adversely affect future trading prices of the ADSs offered hereby. The placement agent and certain of its affiliates may also communicate independent investment recommendations, market color or trading ideas and/or publish or express independent research views in respect of such securities or instruments and may at any time hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

This prospectus in electronic format may be made available on a website maintained by the placement agent, and the placement agent may distribute this prospectus electronically.

The foregoing does not purport to be a complete statement of the terms and conditions of the placement agency agreement or the securities purchase agreement, copies of which are attached to the registration statement of which this prospectus is a part. See “Where You Can Find More Information.”

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	$	1,298
Legal fees and expenses	$	325,000
Accounting fees and expenses	$	58,000
Printing expenses	$	10,000
Miscellaneous expenses	$	2,000
Total	$	396,298

LEGAL MATTERS

Certain legal matters concerning this offering will be passed upon for us by Blank Rome LLP. Certain legal matters with respect to the legality of the issuance of the securities offered by this prospectus will be passed upon for us by S. Horowitz & Co., our Israeli counsel. Certain legal matters related to the offering will be passed upon for the placement agent by Thompson Hine LLP.

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.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

QUOIN PHARMACEUTICALS LTD.

Consolidated Balance Sheets

	March 31, 2022 (unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash	$ 5,189,215	$ 7,482,773
Prepaid expenses	809,466	1,015,474
Total current assets	5,998,681	8,498,247
Intangible assets, net	782,594	808,604
Other assets	50,000	50,000
Total assets	6,831,275	$ 9,356,851
LIABILITIES AND SHAREHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 214,684	$ 923,239
Accrued expenses	2,140,096	1,685,409
Accrued license acquisition	200,000	250,000
Accrued interest	432,170	743,840
Due to officers – short term	600,000	600,000
Warrant liability	—	373,599
Total current liabilities	3,586,950	8,699,819
Due to officers – long term	3,973,733	4,123,732
Total liabilities	7,560,683	8,699,819
Commitments and contingencies		
Shareholders' equity (deficit):		
Ordinary shares, no par value per share, 12,500,000,000 ordinary shares authorized; 3,354,653,999 (670,931 ADSs) ordinary shares issued and outstanding at March 31, 2022 and 3,354,650,799 (670,930 ADSs) at December 31, 2021	$ —	$ —
Treasury Stock, 2,641,693 ordinary shares	(2,932,000)	(2,932,000)
Additional paid in capital	31,955,379	31,659,017
Accumulated deficit	(29,752,787)	(28,069,985)
Total shareholders' equity (deficit)	(729,408)	657,032
Total liabilities and shareholders' equity (deficit)	$ 6,831,275	$ 9,356,851

The accompanying footnotes are an integral part of these statements

QUOIN PHARMACEUTICALS LTD.

Consolidated Statements of Operations (Unaudited)

	Three months ended March 31,	
	2022	**2021**
Operating expenses		
General and administrative	$ 1,588,470	$ 744,973
Research and development	587,569	56,788
Total operating expenses	2,176,039	801,761
Other expenses (income)		
Forgiveness of trade payable	(416,000)	—
Fair value adjustment to convertible notes payable	—	500,000
Change in fair value of warrant liability	(77,237)	2,446,513
Financing expense	—	90,000
Interest expense	—	65,597
Total other expense (income)	(493,237)	3,102,110
Net loss	$ (1,682,802)	$ (3,903,871)
Loss per ADS and ordinary share		
Loss per ADS		
Basic	$ (2.51)	$ (16.25)
Fully-diluted	$ (2.51)	$ (16.25)
Weighted average number of ADSs outstanding		
Basic	670,930	240,292
Fully-diluted	670,930	240,292
Loss per ordinary share		
Basic	$ (0.00)	$ (0.00)
Fully-diluted	$ (0.00)	$ (0.00)
Weighted average number of ordinary shares outstanding		
Basic	3,354,651,784	1,201,460,800
Fully-diluted	3,354,651,784	1,201,460,800

The accompanying footnotes are an integral part of these statements

QUOIN PHARMACEUTICALS LTD.

Consolidated Statements of Shareholders' Deficit (unaudited)

Three months ended March 31, 2022 and 2021

	Ordinary Shares	ADSs	No Par Value	Treasury Stock	Additional Paid in Capital	Accumulated Deficit	Total
Balance at December 31, 2020	1,201,460,800	240,292	—	—	$ 100.00	$ (6,607,397)	$ (6,607,297)
Net loss	—	—	—	—	—	(3,903,871)	(3,903,871)
Balance at March 31, 2021	1,201,460,800	240,292	—	$ —	$ 100	$ (10,511,268)	$ (10,511,168)
Balance at December 31, 2021	3,354,650,799	670,930	—	$ (2,932,000)	$ 31,659,017	$ (28,069,986)	$ 657,032
Net loss	—	—	—	—	—	(1,682,802)	(1,682,802)
Cashless warrant exercise	3,200	1	—	—	—	—	
Reclassification of warrant liability upon issuance of Exchange warrant	—	—		—	296,362	—	296,362
Balance at March 31, 2022	3,354,653,999	670,931	—	$ (2,932,00)	$ 31,955,379	$ (29,752,787)	$ (729,408)

The accompanying footnotes are an integral part of these statements

QUOIN PHARMACEUTICALS LTD.

Consolidated Statements of Cash Flows (unaudited)

	Three months ended March 31, 2022	2021
Cash flows provided by (used in) operating activities		
Net loss	$ (1,682,802)	$ (3,903,871)
Fair value adjustment to convertible notes payable	—	500,000
Change in fair value of warrant liability	(77,237)	2,446,513
Forgiveness of trade payable	(416,000)	—
Financing expense	—	90,000
Amortization of intangibles	26,010	26,011
Changes in assets and liabilities:		
Increase in accounts payable and accrued expenses	162,133	410,533
Decrease in accrued interest	(311,670)	(48,510)
Increase in prepaid expenses	206,008	65,598
Net cash used in operating activities	(2,093,588)	(413,726)
Cash flows used in investing activities		
Payment for license acquisition	(50,000)	(142,500)
Net cash used in investing activities	(50,000)	(142,500)
Cash flows provided by (used in) financing activities:		
Decrease in deferred offering costs	—	(104,309)
Increase in due to officers	—	139,286
Payments of amounts due to officers	(150,000)	(135,000)
Proceeds from issuance of “Bridge Notes”, net	—	1,410,000
Net cash provided by (used in) financing activities	(150,000)	1,309,977
Net change in cash	(2,293,558)	753,751
Cash - beginning of period	7,482,773	323,832
Cash - end of period	$ 5,189,215	$ 1,077,583
Supplemental information:		
Reclassification of warrant liability to equity upon issuance of “Exchange Warrants”	$ 296,362	—

The accompanying footnotes are an integral part of these statements

QUOIN PHARMACEUTICALS LTD.

Notes to Consolidated Financial Statements
March 31, 2022 and 2021

NOTE 1 – ORGANIZATION, BUSINESS AND BASIS OF PRESENTATION

Quoin Pharmaceuticals Ltd. ("Quoin Ltd.," the "Company," "we," "us," "our"), formerly known as Cellect Biotechnology Ltd. ("Cellect"), is the holding company for Quoin Pharmaceuticals, Inc., a Delaware corporation ("Quoin Inc."). On October 28, 2021, Cellect 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 Cellect, Quoin Inc. and CellMSC, Inc., a Delaware corporation and wholly-owned subsidiary of Cellect ("Merger Sub"), pursuant to which Merger Sub merged with and into Quoin Inc., with Quoin Inc. surviving as a wholly-owned subsidiary of Cellect (the "Merger"). Immediately after completion of the Merger, Cellect 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. Immediately after the closing of the Merger, there were approximately 8,386,627 American Depositary Shares ("ADSs") issued and outstanding, with one ADS representing 5,000 (as amended – See Note 16) ordinary shares of the Company. 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 Cellect's shareholders immediately prior to the Merger owning approximately 12% of ordinary shares.

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, Cellect sold the entire share capital of its subsidiary, Cellect Biotherapeutics Ltd., which essentially included all of Cellect'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.

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 $30.5 million at March 31, 2022. 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 closing of the Merger. The Company expected to receive additional funding through the mandatory exercise provision of the Series C Warrant issued to the Investor effective as of March 13, 2022 which would have resulted in proceeds of approximately $9.5 million. In the event the requirements of the mandatory exercise provision of such warrant were not met (see Note 5), the Company received 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. However, on July 14, 2022, the Company and Altium entered into an agreement, pursuant to which the parties agreed to, among other things, cancel the Series C Warrant and a portion of the Series A Warrant previously issued to Altium, – See Note 16. Following the cancellation of the Series C Warrant on July 14, 2022, the Company no longer expects to receive such proceeds from Altium, and the

Company does not have sufficient resources to implement its business plan for at least one year from the issuance of these consolidated financial statements. This raises substantial doubt about the Company's ability to continue as a going concern.

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. The Company has filed a registration statement on Form F-1 related to an offering of its securities on a "reasonable best efforts" basis, however there is no assurance of the successful consummation of such offering. The Company is also in the process of discussing 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. 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 unaudited condensed consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") for interim financial information. Accordingly, they do not include all of the information and footnotes required by U.S. GAAP for complete financial statements, reflecting the operations of Quoin Inc. since inception and include the accounts of Quoin Ltd. since the date of the Merger. In the opinion of management, such statements include all adjustments (consisting only of normal recurring items) which are considered necessary for a fair presentation of the unaudited condensed consolidated financial statements of the Company as of March 31, 2022 and for the three months then ended. The results of operations for the three months ended March 31, 2022 are not necessarily indicative of the operating results for the full year ending December 31, 2022 or any other period. These unaudited condensed consolidated financial statements should be read in conjunction with the audited financial statements and related disclosures as of December 31, 2021 and for the year then ended which are included in the Company's Annual Report on Form 20-F for the year ended December 31, 2021. The Company operates in one segment.

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.

Reclassifications:

Certain 2021 amounts were reclassified to conform to the current year presentation. The amount reclassified was $600,000 to separate out short term portion from long term portion for due to officers.

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.

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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 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 product for clinical testing, as well as our ability to safely and efficiently conduct planned clinical trials.

Cash:

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 three months ended March 31, 2022 and 2021, 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.

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 March 31, 2022 and December 31, 2021, 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 and related 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.

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 three months ended March 31, 2022 and 2021, the number of shares excluded from the diluted net earnings (loss) per share included outstanding options and warrants to purchase 1,399,660 ADSs and 63,669 ADSs, respectively. For the three months ended March 31, 2021, the 5,183 ADS's issuable upon the conversion of both the Convertible Notes Payable (as defined below) and the 40,247 ADSs issuable upon conversion of 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.

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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.

Based upon the terms agreed to in March 2021 in the Primary Financing (see Note 5), the 2020 Notes were mandatorily convertible into 5,183 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 and there was no material change in the fair value from issuance until the conversion to equity on the closing of the Merger or the "Merger date". At the closing of the Merger, 5,183 ADSs were issued upon the conversion of the principle of the Convertible Notes Payable.

The noteholders also received 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 terms of the warrants became measurable and were exercisable for 29,388 ADSs at an initial exercise price of $49.75 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.

Effective March 13, 2022, the Company exchanged the noteholders' warrants for on the same terms as the Investor Exchange Warrants, exercisable for 29,388 ADSs, in the aggregate, at the exercise price of $49.75 per ADS. The Exchange Warrants have been determined to have equity classification. The change in the fair value of the warrants through the exchange date was included in other income (expense) in the accompanying statement of operations, and then reclassified from liability to additional paid in capital.

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's estimated amount required to settle these obligations was determined to be approximately $744,000 at December 31, 2021, included in Accrued Interest. A total of $312,000 was paid to two of the five 2020 Noteholders during the three months ended March 31, 2022, and the remaining liability is $432,000 as of March 31, 2022. The Company expects to settle the remaining liability during 2022.

Interest expense, at the stated interest rate, recognized in the three months ended March 31, 2022 and 2021 was approximately $0 and $66,000, respectively.

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 $5,000,000 in exchange for an aggregate purchase price of up to $3,800,000 together with warrants. The Bridge Notes were purchased in three closings: (i) the first purchase of $2,000,000 on March 25, 2021 (Quoin Inc. received proceeds of $1,500,000 less fees of $90,000); (ii) the second purchase of $1,700,000 in April 2021 (Quoin Inc. received proceeds of $1,250,000) ; and (iii) a third purchase of $1,300,000 in May 2021 (Quoin Inc. received proceeds of $1,000,000 less fees of $185,000).

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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 $5,000,000 at the date of issuances. The Bridge Notes were offset against the purchase price under the Securities Purchase Agreement related to the Primary Financing and converted into 100,618 ADSs (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 at the Merger date. Interest expense, at the stated interest rate, recognized in the three months ended March 31, 2022 and 2021 was $0 and $4,900, respectively.

Bridge 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 had a term of five years from the date all of the shares underlying the Bridge Warrants are freely tradable. Quoin Inc. issued a total of 99,074ADSs 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 based 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 on 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 39,630 warrants in connection with the first closing and $2.2 million at the date of issuance of the 59,444 (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 99,074 ADSs at a fixed per share exercise price of $49.75 ("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.

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

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associated with the Primary Financing, which resulted in the net proceeds of approximately $10.1 million. The Company issued 342,100 ADSs to the Investor.

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 342,100 ADSs (the “Series A Warrant”) (ii) Series B Warrant to purchase 342,100 ADSs (the “Series B Warrant”) and (iii) Series C Warrant to purchase 191,174 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 $49,75 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, the registration statement was declared effective by the Securities and Exchange Commission, but 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 191,174 ADSs and an additional Series B Warrant to purchase 191,174 ADSs at an exercise price of $49.75 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.

The significant estimates used in the determining the fair value of the 2020 Notes warrants (Note 4) were as follows:

	03/13/2022	12/31/2021
Stock price	$ 18.50	$ 22.75
Initial exercise price	$ 49.75	$ 49.75
Contractual Term	5.0	5.0
Volatility	91.5 %	89.2 %
Discount rate	1.94 %	1.26 %

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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 (none at March 31, 2022):

December 31, 2021	Level 1	Level 2	Level 3	Total
2020 Notes warrants	—	—	$ 373,599	$ 373,599
Total Warrant Liability	—	—	$ 373,599	$ 373,599

The following shows the movement of the warrant liability balance during 2021 and the three months ended March 31, 2022.

	Bridge Financing Warrants	2020 Note Warrants
Beginning Balance January 1, 2021	$ —	$ —
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 December 31, 2021	**$ —**	**$ 373,599**
Change in Fair value of warrants	—	(77,237)
Reclassification of warrant liability to an equity instrument	—	(296,362)
Ending Balance March 31, 2022	**$ —**	**$ —**

The Investor Exchange Warrant 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. The Exchange Warrants issued to the 2020 Noteholders effective as of March 13, 2022 were determined to be an equity-classified instrument, and accordingly the warrant liability on such date of $296,262 was reclassified to additional paid in capital on that date.

NOTE 7 – PREPAID EXPENSES

Prepaid expenses are as follows:

	March 31, 2022	December 31, 2021
Prepaid R&D costs	$ 329,033	$ 329,033
Prepaid insurance	478,933	684,191
Prepaid other expenses	1,500	2,250
Total	**$ 809,466**	**$ 1,015,474**

NOTE 8 - ACCRUED EXPENSES

Accrued expenses are as follows:

	March 31, 2022	December 31, 2021
Professional fees	$ 467,167	$ 144,377
Investor Relation firm fees (note 12)	168,000	584,000
Payroll taxes (note 11)	168,075	199,582
Payroll (note 11)	776,802	557,937
Research contract expenses (note 12)	486,853	193,537
Other expenses	73,198	5,976
Total	**$ 2,140,095**	**$ 1,685,409**

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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, 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 March 31, 2022.

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 several times to extend the payment due dates. On June 21, 2021, the parties entered into the most recent 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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Notes to Consolidated Financial Statements
March 31, 2022 and 2021

At March 31, 2022 and December 31, 2021, the license acquisition liability due was $200,000 and $250,000, respectively. The $200,000 license acquisition liability was paid in May 2022.

NOTE 10 - INTANGIBLE ASSETS

Intangible assets are as follows:

	March 31, 2022	December 31, 2021
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	(257,839)	(231,829)
Net book value	**$ 782,594**	**$ 808,604**

The Company recorded amortization expense of approximately $26,010 for all three months ended March 31, 2022 and 2021, 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 March 31, 2022 as well as reimbursable travel expenses and other amounts paid by them to third parties on behalf of Quoin Inc. The Company repaid $150,000 and $135,000 of such amounts due to officers/founders in the three months ended March 31, 2022 and 2021, respectively. Since the Merger closing, the Company has been repaying amounts due to officers/founders at a rate of $25,000 each per month.

Amounts due to officers at March 31, 2022 and December 31, 2021 consisted of the following:

	March 31, 2022	December 31, 2021
Salaries and allowances	$ 4,108,500	4,108,500
Invoices paid on behalf of the Company	465,232	615,232
Total	4,573,732	4,723,732
Less: Short-term portion	(600,000)	(600,000)
Long-term portion	$ 3,973,732	$ 4,123,732

For the three months ended March 31, 2022, the Company incurred $12,000 of research and development expense to a related party.

See Note 4 for related party debt and Note 12 for employment agreements.

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Notes to Consolidated Financial Statements
March 31, 2022 and 2021

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 March 31, 2022 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 incurred no research and development expenses, in connection with these agreements, for both of the three months ended March 31, 2022 and 2021, as no services were provided. However, the Company has accrued expenses of $193,537 at both March 31, 2022 and December 31, 2021.

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 three months ended March 31, 2022, and March 31, 2021, the Company incurred a research and development expense under this agreement of approximately $185,000 and $0, respectively.

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. For the three months ended March 31, 2022, the Company did not incur any research and development costs related to this agreement.

Consulting agreement:

Quoin Inc. entered into a consulting agreement with an Investor Relations (IR) firm, which provides for a monthly fee of $14,000. The agreement had an automatic annual renewal clause and has been in effect since November 2017. The Company owed the IR firm $584,000 as of December 31, 2021, which was included in accrued expenses in the accompanying balance sheet. In March 2022, the Company entered into a settlement agreement with the IR firm reducing the liability to $168,000, and recognized $416,000 as other income in the consolidated statement of operations.

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

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Notes to Consolidated Financial Statements
March 31, 2022 and 2021

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.

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 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 16 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 Cellect 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. In connection with the Share Transfer, Cellect 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 Cellect 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 240,292 ADSs in Quoin Ltd., which was subsequently reduced to 224,388 shares in May 2022 following the determination of the number of shares held in escrow allocated to certain former shareholders of Cellect. All share and per share amounts have been adjusted to reflect this recapitalization.

Quoin Ltd.

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.

As of March 31, 2022, Quoin Ltd.'s authorized share capital consisted of 50,000,000,000 ordinary shares from 12,500,000,000, no par value (see Note 16 for subsequent increase in authorized share capital). 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. 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.

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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 depositary, has registered and delivered American Depositary Shares, also referred to as ADSs. Each ADS represents 5,000 (as amended- See Note 16) ordinary shares (or a right to receive 5,000 ordinary shares). Each ADS will also represent any other securities, cash or other property which may be held by the depositary. 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 table summarizes warrant activities (excluding Cellect options, see Note 1 below) during the year ended December 31, 2021 and the three months ended March 31, 2022:

	ADSs Underlying Warrants	Weighted Average Exercise Price
Outstanding at December 31, 2020	—	—
Granted	128,463	$ 49.75
Assumed as part of Merger	13,477	137.50
Exercised	—	—
Forfeited/cancelled	—	—
Outstanding at December 31, 2021	141,940	55.39
Granted	1,257,721	49.75
Exercised – cashless	(1)	—
Forfeited/cancelled	—	—
Outstanding at March 31, 2022	1,399,660	$ 50.30

The following vested stock options and warrants were outstanding at March 31, 2022, exercisable into ADSs:

	ADSs	Exercise Price	Year of maturity
Warrants held by 2020 noteholders	29,388	$ 49.75	2027
Exchange warrant held by Investor	99,074	$ 49.75	2026
Warrants held by former Cellect warrantholders	8,820	$ 137.50	2024
Options held by former Cellect optionholders	4,655	$ 222.19	2022
Series A warrants held by Investor (2)(4)	533,274	$ 49.75	2027
Series B warrants held by Investor (2)(3)(4)	533,274	$ 49.75	2024
Series C warrants held by Investor (2)	191,175	$ 49.75	2024
Total	1,399,660		

1) The options held by former Cellect optionholders fully vested at the closing of the Merger and expire between April 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 Cellect Ltd. Employee Shares Incentive Plan (the “2014 Plan”). During the quarter ended March 31, 2022, 1,088

options expired unexercised. 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 16.

2) Equity-classified warrants issued effective as of March 13, 2022 pursuant to the Primary Financing requirements.

3) The Series B Warrant provides for alternate cashless exercise pursuant to which the Investor has the sole option as elected by the Investor to receive 1.0 ADS for each warrant share being exercised in such cashless exercise (see Note 16).

4) The Company expects to issue additional Series A and Series B Warrants, each to purchase 191,173 ADSs to the Investor upon exercise of the Series C Warrant, which are included in the totals in the table above.

The intrinsic value of outstanding warrants and options at March 31, 2022 was negligible.

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 365,398 ADSs as of March 31, 2022. The board of directors further approved the award of options to Officers and Directors in aggregate to purchase 316,571 ADSs and under the Amended Plan, and an 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 in Note 16

NOTE 14 – 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 15 – 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. During three months ended March 31, 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. No royalty revenues have been received through March 31, 2022 under any of these agreements.

NOTE 16 - SUBSEQUENT EVENTS

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.

- Repayment of amounts due to officers/founders at a rate of $25,000 each per month.

- The grant of an option to purchase up to 85,714 ADSs to each of the two founders under the Amended Plan, at an exercise price per ADS of $17.50, to vest over a four-year period.

- The grant of an option to purchase 12,857 ADSs to each of the five non-employee directors under the Amended Plan at an exercise price per ADS of $17.50, to vest over a three-year period, and (as an annual grant for 2022) an option to an officer to purchase 71,429 ADSs at an exercise price per ADS of $17.50, to vest over a four-year period.

ADS Ratio Change

On July 12, 2022, our Board of Directors approved the change in the ratio of ADS evidencing ordinary shares from 1 ADS representing four hundred (400) ordinary shares to 1 ADS representing five thousand (5,000) ordinary shares, which will result in a one for 12.5 reverse split of the issued and outstanding ADSs (the "Ratio Change"). The Ratio Change was effective August 1, 2022. All ADS and related option and warrant information presented in these financial statements and accompanying footnotes has been retroactively adjusted to reflect the reduced number of ADSs resulting from the Ratio Change.

Nasdaq Listing

On April 22, 2022, we received a letter from the Listing Qualifications staff of The Nasdaq Stock Market, LLC ("Nasdaq") notifying us that we are no longer in compliance with the minimum stockholders' equity requirement for continued listing on The Nasdaq Capital Market. Nasdaq Rule 5550(b)(1) requires listed companies to maintain stockholders' equity of at least $2.5 million. In addition, as of April 21, 2022, we did not meet the alternative continued listing requirements based on market value of listed securities or net income from continuing operations. In accordance with Nasdaq Rule 5810(c)(2)(A), within 45 calendar days of receiving this notice, we submitted a plan to regain compliance to Nasdaq. This plan was accepted, and Nasdaq has granted us an extension until October 19, 2022 to evidence compliance.

On June 10, 2022, we received a letter from The Nasdaq Listing Qualifications staff notifying us that the closing bid price per ADS was below the required minimum of $1.00 for a period of 30 consecutive business days and that we did not meet the minimum bid price requirements set forth in Nasdaq Rule 5550(a)(2). Pursuant to Nasdaq Rule 5810(c)(3)(A), we have a period of one hundred eighty (180) calendar days, or until December 7, 2022 (the "Compliance Period"), to regain compliance with Nasdaq's minimum bid price requirement. If at any time during the Compliance Period, the closing bid price per ADS is at least $1.00 for a minimum of ten (10) consecutive business days, Nasdaq will provide us a written confirmation of compliance and the matter will be closed. In the event we do not regain compliance by December 7, 2022, we may be eligible for an additional 180 calendar day grace period. To qualify, we will be required to meet the continued listing requirement for market value of publicly held ADSs and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement, and will need to provide written notice of our intention to cure the deficiency during the second compliance period.

Although there is no assurance, we expect that the offering that is being registered on the registration statement on Form F-1, which includes these financial statements and accompanying notes, will enable us to regain compliance with Nasdaq's minimum stockholders' equity requirement and the Ratio Change will help us to regain compliance with the minimum bid-price requirement for continued listing on The Nasdaq Capital Market. Although Nasdaq notification letters described above have no immediate effect on our listing on The Nasdaq Capital Market, and we are working on implementing plans to regain compliance with Nasdaq listing standards, there can be no assurance that we will be able to regain compliance with Nasdaq's minimum stockholders' equity requirement or minimum bid-price requirement for continued listing. If our ADSs are delisted from Nasdaq, it will have material negative impacts on the actual and potential liquidity of our securities, as well as material negative impacts on our ability to raise future capital.

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March 31, 2022 and 2021

Agreements with Altium Growth Fund, LP and Altium Warrant Exercises

During the second quarter of 2022, Altium exercised the Series B Warrant in full pursuant to the alternate cashless exercise right of such warrant, under which Altium had an option to receive 1 ADS for each ADS underlying the warrant being exercised in such cashless exercise, resulting in the issuance of a total of 342,100 ADSs to Altium.

On July 14, 2022, we, Quoin Inc. and Altium entered into an agreement (the "Altium Agreement"), pursuant to which the parties agreed to, among other things, (i) amend certain terms of the Series A Warrant and Investor Exchange Warrants previously issued to Altium to, among other things, reduce the exercise price to $0.00 per ADS with respect to a total of 399,999 ADSs, (ii) cancel the Series C Warrant and a portion of the Series A Warrant previously issued to Altium, and (iii) terminate the Purchase Agreements, pursuant to which the warrants were previously issued to Altium. As of August 2, 2022, Altium exercised all of its outstanding warrants and we issued a total of 399,999 ADSs to Altium.

The exercise price of the 2020 noteholder warrants was reduced to $0.00 as of July 14, 2022 as a result of the Altium Agreement described below. As of August 2, 2022, 23,040 2020 Noteholder Warrants had been exercised.

As a result of the Altium and Noteholder warrant exercises and the Altium Agreement, the warrants outstanding as of August 2, 2022 are set out below, exercisable into ADS:

	ADSs	Exercise Price	Year of maturity
Warrants held by 2020 noteholders	6,348	$ 0	2027
Warrants held by former Cellect warrant holders	8,820	$ 137.5	2024
Total	15,168		

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 each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Consideration of the Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has a working capital deficiency, an accumulated deficit, has incurred significant losses and cash outflows from operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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.

Assessment of the measurement of fair value of Warrants (continued):

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

PCAOB ID 711
We have served as the Company's auditor since 2020.
East Hanover, New Jersey
April 13, 2022, except for Notes 2 and 17, as to which the date is August 2, 2022

QUOIN PHARMACEUTICALS LTD.

Consolidated Balance Sheets

	December 31, 2021	December 31, 2020
ASSETS		
Current assets:		
Cash	$ 7,482,773	$ 323,832
Prepaid expenses	1,015,474	—
Deferred offering costs	—	141,338
Total current assets	8,498,247	465,170
Intangible assets, net	808,604	912,648
Other assets	50,000	—
Total assets	$ 9,356,851	$ 1,377,818
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	8,699,819	7,985,115
Commitments and contingencies		
Shareholders' equity (deficit):		
Ordinary shares, no par value, 12,000,000,000 ordinary shares authorized – 3,354,650,799 and 1,201,460,800 (670,930 and 240,292 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	(28,069,985)	(6,607,397)
Total shareholders' equity (deficit)	657,032	(6,607,297)
Total liabilities and shareholders' equity (deficit)	$ 9,356,851	$ 1,377,818

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	$ (67.96)	$ (8.72)	$ (6.49)
Fully-diluted	$ (67.96)	$ (8.72)	$ (6.49)
Weighted average number of ADSs outstanding			
Basic	315,801	240,292	240,292
Fully-diluted	315,801	240,292	240,292
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	1,579,006,444	1,201,460,800	1,201,460,800
Fully-diluted	1,579,006,444	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	$ —	240,292		$ 100	$ (2,951,632)	$ (2,951,532)
Net loss						(1,560,401)	(1,560,401)
Balance at December 31, 2019	1,201,460,800	—	240,292		100	(4,512,033)	(4,511,933)
Net loss		—	—		—	(2,095,364)	(2,095,364)
Balance at December 31, 2020	1,201,460,800	—	240,292		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		5,183		1,213,313		1,213,313
Sale of equity securities, including conversion of "Bridge Notes"	1,710,500,800		342,100		17,000,000		17,000,000
Costs associated with sale of equity securities					(1,897,126)		(1,897,126)
Merger recapitalization of Cellect	416,775,599		83,355	(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	3,354,650,799	$ —	670,930	(2,932,000)	$ 31,659,017	$ (28,069,985)	$ 657,032

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	$ 7,482,773	$ 323,832	$ —
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”or”we,” “us,” “our”), formerly known as Cellect Biotechnology Ltd. (“Cellect”), is the holding company for Quoin Pharmaceuticals, Inc., a Delaware corporation (“Quoin Inc.”). On October 28, 2021, Cellect 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 Cellect, Quoin Inc. and CellMSC, Inc., a Delaware corporation and wholly-owned subsidiary of Cellect (“Merger Sub”), pursuant to which Merger Sub merged with and into Quoin Inc., with Quoin Inc. surviving as a wholly-owned subsidiary of Cellect (the “Merger”). Immediately after completion of the Merger, Cellect 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 5,000 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, Cellect sold the entire share capital of its subsidiary, Cellect Biotherapeutics Ltd., which essentially included all of Cellect’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 670,930 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 Cellect’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 closing of the Merger. The Company expected to receive additional funding through the mandatory exercise provision of the Series C Warrant issued to the Investor in March 2022 which would have resulted in proceeds of approximately $9.5 million. In the event the requirements of the mandatory exercise provision of such warrant were not met (see Note 5), the Company received 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. However, on July 14, 2022, the Company and Altium entered into an agreement, pursuant to which the parties agreed to, among other things, cancel the Series C Warrant and a portion of the Series A Warrant previously issued to Altium (see Note 17). Following the cancellation of the Series C Warrant on July 14, 2022, the Company no longer expects to receive such proceeds from Altium, and the Company does not have sufficient resources to implement its business plan for at least one year from the issuance of these consolidated financial statements. This raises substantial doubt about the Company's ability to continue as a going concern.

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. The Company has filed a registration statement on Form F-1 related to an offering of its securities on a "reasonable best efforts" basis, however there is no assurance of the successful consummation of such offering. The Company is also in the process of discussing 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. 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 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.

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.

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 143,028 ADS or 715,137,600 Ordinary Shares and warrants to purchase 1,257,722 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.

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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.

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 5,183 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 29,388 ADSs at an initial exercise price of $49.75 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, 5,183 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 29,388 ADSs, in the aggregate, at the exercise price of $49.75 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.

QUOIN PHARMACEUTICALS LTD.
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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 100,618 ADSs (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.

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 99,074 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 39,630 warrants in connection with the first closing and $2.2 million at the date of issuance of the 59,444 (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 99,074 ADSs at a fixed per share exercise price of $49.75 ("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 342,100 ADSs to the Investor, consisting of 66,702 delivered to the Investor on or after the Merger closing and 275,398 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 342,100 ADSs (the "Series A Warrant") (ii) Series B Warrant to purchase 342,100 ADSs (the "Series B Warrant") and (iii) Series C Warrant to purchase 191,174 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 $49.75 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 191,174 ADSs and an additional Series B Warrant to purchase 191,174 ADSs at an exercise price of $49.75 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.

The significant estimates used in the determining the fair value of the 2020 Notes warrants (Note 4) were as follows:

	12/31/2021 (1)	12/31/2020
Stock price	$ 22.75	$ 49.75
Initial exercise price	$ 49.75	$ 49.75
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.

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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:

	Transaction Date March - May 2021	Merger Date 10/28/2021
Stock price	$ 49.75 (post exchange ratio)	$ 11.64 (post exchange ratio)
Initial exercise price	$ 49.75 (post exchange ratio)	$ 49.75 (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	Level 1	Level 2	Level 3	Total
2020 Notes warrants	—	—	$ 373,599	$ 373,599
Total Warrant Liability	—	—	$ 373,599	$ 373,599

December 31, 2020	Level 1	Level 2	Level 3	Total
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.

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	**$ —**	**$ 373,599**

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.

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NOTE 7 – PREPAID EXPENSES

Prepaid expenses are as follows:

	December 31, 2021	December 31, 2020
Prepaid R&D costs	$ 329,033	$ —
Prepaid insurance	684,191	—
Prepaid other expenses	2,250	—
Total	**$ 1,015,474**	**$ —**

NOTE 8 – ACCRUED EXPENSES

Accrued expenses are as follows:

	December 31, 2021	December 31, 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	**$ 1,685,409**	**$ 960,848**

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, 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.

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	December 31, 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

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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	December 31, 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.

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.

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 Cellect 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, Cellect 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 Cellect 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 240,292 ADSs in Quoin Ltd., which was subsequently reduced to 224,388 ADSs in May 2022 following the determination of the

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number of shares held in escrow allocated to certain former shareholders of Cellect. 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 12,000,000,000 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 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 depositary, has registered and delivered American Depositary Shares, also referred to as ADSs. Post August 1, 2022 change in ADS ratio, each ADS represents (5,000) ordinary shares (or a right to receive five thousand (5,000) ordinary shares). Each ADS will also represent any other securities, cash or other property which may be held by the depositary. 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:

	ADSs	Exercise Price	Year of maturity
Warrants held by 2020 noteholders	29,388	$ 49.75	2026
Warrants held by Investor	99,074	$ 49.75	2026
Options held by former Cellect optionholders	5,746	636.75	2022
Warrants held by former Cellect warrantholders	8,820	$ 137.50	2022-2024
Total	143,028		

1) The options held by former Cellect 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 Cellect 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.

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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.

	ADSs	Exercise Price
Series A warrants (1)	533,274	$ 49.75
Series B warrants (1)	533,274	$ 49.75
Series C warrants (1)	191,174	$ 49.75
Total	1,257,722	

(1) The Company expects to issue each of 191,174 additional Series A and Series B Warrants to the Investor upon exercise of the Series C Warrant, which are assumed to be exercised and, therefore, are included in the totals of the Series A and B warrants 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	December 31, 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 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 29,388 ADSs, in the aggregate, at the exercise price of $49.75 per ADS. The exercise price was reduced to $0.00 as of July 14, 2022 as a result of the Altium Agreement described below.

- Issued Series A Warrant, Series B Warrant and Series C Warrant to purchase 342,100 ADSs, 342,100 ADSs and 191,174 ADSs, respectively, at the exercise price of $49.75 per ADS, based on the terms of the Primary Financing. These warrants were amended as of July 14, 2022 under the Altium Agreement described below.

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.

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Amended and Restated Equity Incentive Plan and Annual Meeting of Shareholders

In March 2022, our board of directors 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 our outstanding ordinary shares on a fully-diluted basis, or 1,826,991,616 ordinary shares, represented by 365,398 ADSs as of March 31, 2022. The board of directors further approved the award of options to our officers and directors to purchase, in the aggregate, 316,571 ADSs under the Amended Plan, and annual discretionary bonuses for officers of $472,500 in aggregate.

We held our Annual General Meeting on April 12, 2022, at which our 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.
- Repayment of amounts due to the two founders at a rate of $25,000 each per month.
- The grant of an option to purchase up to 85,714 ADSs to each of the two founders under the Amended Plan, at an exercise price per ADS of $17.50, to vest over a four-year period.
- The grant of an option to purchase 12,857 ADSs to each of the five non-employee director under the Amended Plan at an exercise price per ADS of $17.50, to vest over a three-year period, and (as an annual grant for 2022) an option to an officer to purchase 71,429 ADSs at an exercise price per ADS of $17.50, to vest over a four-year period.

ADS Ratio Change

On July 12, 2022, our Board of Directors approved the change in the ratio of ADS evidencing ordinary shares from 1 ADS representing four hundred (400) ordinary shares to 1 ADS representing five thousand (5,000) ordinary shares, which will result in a one for 12.5 reverse split of the issued and outstanding ADSs (the "Ratio Change"). The Ratio Change was effective August 1, 2022. All ADS and related option and warrant information presented in these financial statements and accompanying footnotes has been retroactively adjusted to reflect the reduced number of ADSs resulting from the Ratio Change.

Nasdaq Listing

On April 22, 2022, we received a letter from the Listing Qualifications staff of The Nasdaq Stock Market, LLC ("Nasdaq") notifying us that we are no longer in compliance with the minimum stockholders' equity requirement for continued listing on The Nasdaq Capital Market. Nasdaq Rule 5550(b)(1) requires listed companies to maintain stockholders' equity of at least $2.5 million. In addition, as of April 21, 2022, we did not meet the alternative continued listing requirements based on market value of listed securities or net income from continuing operations. In accordance with Nasdaq Rule 5810(c)(2)(A), within 45 calendar days of receiving this notice, we submitted a plan to regain compliance to Nasdaq. This plan was accepted, and Nasdaq has granted us an extension until October 19, 2022 to evidence compliance.

On June 10, 2022, we received a letter from The Nasdaq Listing Qualifications staff notifying us that the closing bid price per ADS was below the required minimum of $1.00 for a period of 30 consecutive business days and that we did not meet the minimum bid price requirements set forth in Nasdaq Rule 5550(a)(2). Pursuant to Nasdaq Rule 5810(c)(3)(A), we have a period of one hundred eighty (180) calendar days, or until December 7, 2022 (the "Compliance Period"), to regain compliance with Nasdaq's minimum bid price requirement. If at any time during the Compliance Period, the closing bid price per ADS is at least $1.00 for a minimum of ten (10) consecutive business days, Nasdaq will provide us a written confirmation of compliance and the matter will be closed. In the event we do not regain compliance by December 7, 2022, we may be eligible for an additional 180 calendar day grace period. To qualify, we will be required to meet the continued listing requirement for market value of publicly held ADSs and all other initial listing standards for The Nasdaq Capital Market, with the exception of the bid price requirement, and will need to provide written notice of our intention to cure the deficiency during the second compliance period.

QUOIN PHARMACEUTICALS LTD.
Notes to Consolidated Financial Statements
December 31, 2021, 2020 and 2019

Although there is no assurance, we expect that the offering that is being registered on the registration statement on Form F-1, which includes these financial statements and accompanying notes, will enable us to regain compliance with Nasdaq's minimum stockholders' equity requirement and the Ratio Change will help us to regain compliance with the minimum bid-price requirement for continued listing on The Nasdaq Capital Market. Although Nasdaq notification letters described above have no immediate effect on our listing on The Nasdaq Capital Market, and we are working on implementing plans to regain compliance with Nasdaq listing standards, there can be no assurance that we will be able to regain compliance with Nasdaq's minimum stockholders' equity requirement or minimum bid-price requirement for continued listing. If our ADSs are delisted from Nasdaq, it will have material negative impacts on the actual and potential liquidity of our securities, as well as material negative impacts on our ability to raise future capital.

Agreements with Altium Growth Fund, LP and Altium Warrant Exercises

During the second quarter of 2022, Altium exercised the Series B Warrant in full pursuant to the alternate cashless exercise right of such warrant, under which Altium had an option to receive 1 ADS for each ADS underlying the warrant being exercised in such cashless exercise, resulting in the issuance of a total of 342,100 ADSs to Altium.

On July 14, 2022, we, Quoin Inc. and Altium entered into an agreement (the "Altium Agreement"), pursuant to which the parties agreed to, among other things, (i) amend certain terms of the Series A Warrant and Investor Exchange Warrants previously issued to Altium to, among other things, reduce the exercise price to $0.00 per ADS with respect to a total of 399,999 ADSs, (ii) cancel the Series C Warrant and a portion of the Series A Warrant previously issued to Altium, and (iii) terminate the Purchase Agreements, pursuant to which the warrants were previously issued to Altium. As of August 2, 2022, Altium exercised all of its warrants outstanding and we issued a total of 399,999 ADSs to Altium.

The exercise price of the 2020 noteholder warrants was reduced to $0.00 as of July 14, 2022 as a result of the Altium Agreement described below. As of August 2, 2022, 23,040 noteholder warrants had been exercised.

As a result of the Altium and noteholder warrant exercises and the Altium Agreement, the warrants outstanding as of August 2, 2022 are set out below, exercisable into ADS:

	ADSs	Exercise Price	Year of maturity
Warrants held by 2020 noteholders	6,348	$ 0	2027
Warrants held by former Cellect warrant holders	8,820	$ 137.5	2024
Total	15,168		

Up to Ordinary Shares Represented by American Depositary Shares

Pre-Funded Warrants to Purchase up to Ordinary Shares Represented by American Depositary Shares

Common Warrants to Purchase up to Ordinary Shares Represented by American Depositary Shares

Up to Ordinary Shares Represented by American Depositary Shares Issuable Upon Exercise of the Pre-Funded Warrants

Up to Ordinary Shares Represented by American Depositary Shares Issuable Upon Exercise of the Common Warrants

PROSPECTUS

Sole Placement Agent

A.G.P.

, 2022

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 6. 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

- a 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 agreements 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.

In the opinion of the SEC, indemnification of directors and other Office Holders 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.

Item 7. Recent Sales of Unregistered Securities.

Please see the disclosure under the headings "—2020 Notes," "—Bridge Financing" and "—Primary Financing" in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" above for a description of transactions during the preceding three fiscal years involving sales of our securities that were not registered under the Securities Act. We believe that each of such issuances was exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act or Rule 506 of Regulation D promulgated under the Securities Act. No underwriter or underwriting discount or commission was involved in any such transaction.

Item 8. Exhibits and Financial Statement Schedules.

(a) The following exhibits are filed with this registration statement or are incorporated herein by reference.

Exhibit No.	Exhibit Description
1.1*	Form of Placement Agency Agreement.
2.1	Agreement and Plan of Merger and Reorganization, dated as of March 24, 2021, by and among Cellect Biotechnology Ltd., CellMSC, Inc. and Quoin Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 of the Form 6-K filed with the Securities and Exchange Commission on March 24, 2021).
2.2	Amendment made as of September 24, 2021, to the Agreement and Plan of Merger and Reorganization, dated as of March 24, 2021, by and among Cellect Biotechnology Ltd., CellMSC, Inc., and Quoin Pharmaceuticals, Inc. (incorporated by reference to Exhibit 99.2 to Form 6-K filed with the SEC on September 27, 2021).
2.3	Amended and Restated Share Transfer Agreement, dated May 27, 2021 by and between Cellect Biotechnology Ltd. and EnCellX Inc. (incorporated by reference to Exhibit 2.2 to Registration Statement on Form F-4 filed with the Securities and Exchange Commission on June 16, 2021).
2.4	Amendment made as of September 26, 2021, to the Amended and Restated Share Transfer Agreement dated as of May 27, 2021, by and between EnCellX, Inc. and Cellect Biotechnology Ltd. (incorporated by reference to Exhibit 99.3 to Form 6-K filed with the SEC on September 27, 2021).
2.5	Securities Purchase Agreement, dated as of March 24, 2021, by and among Cellect Biotechnology Ltd., Quoin Pharmaceuticals, Inc. and the investors named on the Schedule of Buyers attached thereto (incorporated by reference to Exhibit 10.4 of the Form 6-K filed with the Securities and Exchange Commission on March 24, 2021).
2.6	Securities Purchase Agreement, dated as of March 24, 2021, by and among Quoin Pharmaceuticals, Inc. and the investors listed on the Schedule of Buyers attached thereto (incorporated by reference to Exhibit 10.6 of the Form 6-K filed with the Securities and Exchange Commission on March 24, 2021).
2.7	Amendment Agreement, dated as of September 17, 2021, by and among Quoin Pharmaceuticals, Inc., Cellect Biotechnology, Ltd., and Altium Growth Fund, L.P. (incorporated by reference to Exhibit 99.1 of the Form 6-K filed with the Securities and Exchange Commission on September 17, 2021).
2.8	Letter Agreement, dated September 17, 2021, between Quoin Pharmaceuticals, Inc. and Cellect Biotechnology, Ltd. (incorporated by reference to Exhibit 99.2 of the Form 6-K filed with the Securities and Exchange Commission on September 17, 2021).
2.9	Second Amendment Agreement, dated as of March 13, 2022, by and among Quoin Pharmaceuticals, Inc., Quoin Pharmaceuticals Ltd., and Altium Growth Fund, L.P. (incorporated by reference to Exhibit 4.1 to Form 6-K filed with the SEC on March 28, 2022).
2.10	Waiver Agreement, dated June 6, 2022, by and among Quoin Pharmaceuticals Ltd., Quoin Pharmaceuticals, Inc. and Altium Growth Fund, LP (incorporated by reference to Exhibit 10.2 to Form 6-K filed with the SEC on June 6, 2022).
2.11	Agreement, dated July 14, 2022, by and among Quoin Pharmaceuticals, Inc., Quoin Pharmaceuticals Ltd. and Altium Growth Fund, LP (incorporated by reference to Exhibit 10.1 to Form 6-K filed with the SEC on July 15, 2022).

2.12	Letter of Agreement among Cellect Biotechnology Ltd, Dr. Shai Yarkoni and EnCellX, Inc. (incorporated by reference to Exhibit 2.5 to Registration Statement on Form F-4 filed with the Securities and Exchange Commission on July 16, 2021).
2.13	Form of Representative Agreement among Cellect Biotechnology Ltd, Eyal Leibovitz, as Representative, and EnCellX, Inc. (incorporated by reference to Exhibit 2.6 to Registration Statement on Form F-4 filed with the Securities and Exchange Commission on August 6, 2021).
3.1	Amended and Restated Articles of Association of Quoin Pharmaceuticals Ltd., adopted on February 28, 2022 (incorporated by reference to Annex A included in Exhibit 99.1 to Form 6-K filed with the SEC on February 8, 2022).
3.2	Amendment to the Amended and Restated Articles of Association of Quoin Pharmaceuticals Ltd., adopted on April 12, 2022 (incorporated by reference to Annex A included in Exhibit 99.1 to Form 6-K filed with the SEC on March 8, 2022).
4.1	Form of Deposit Agreement between Cellect Biotechnology Ltd. (n/k/a Quoin Pharmaceuticals Ltd.), The Bank of New York Mellon as Depositary, and owners and holders from time to time of ADSs issued thereunder (incorporated by reference to Exhibit 4.1 to Registration Statement on Form F-1/A as filed with the SEC on July 26, 2016).
4.2	Specimen American Depositary Receipt (included in Exhibit 2.1).
4.3	Form of Contingent Value Rights Agreement, by and among Cellect Biotechnology, Ltd., Eyal Leibovitz in the capacity of Representative and Computershare, Inc. in the capacity of Rights Agent (incorporated by reference to Exhibit 4.14 to Registration Statement on Form F-4 filed with the SEC on August 6, 2021).
4.4	Registration Rights Agreement, dated as of March 24, 2021, by and between Cellect Biotechnology Ltd. and the investors listed on the Schedule of Buyers attached thereto (incorporated by reference to Exhibit 10.5 of the Form 6-K filed with the Securities and Exchange Commission on March 24, 2021).
4.5	Form of Primary Warrants for the Purchase Agreement (incorporated by reference to Exhibit B to Exhibit 10.4 to Form 6-K filed with the SEC on March 24, 2021).
4.6	Form of Exchange Warrant (incorporated by reference to Exhibit 99.1 to Form 6-K filed with the SEC on September 17, 2021).
4.7	Form of Series A Warrant (incorporated by reference to Exhibit 2.5 to Form 20-F filed with the SEC on April 13, 2022).
4.8	Form of Series B Warrant (incorporated by reference to Exhibit 2.6 to Form 20-F filed with the SEC on April 13, 2022).
4.9	Form of Series C Warrant (incorporated by reference to Exhibit 2.7 to Form 20-F filed with the SEC on April 13, 2022).
4.10	Form of Warrant Agent Agreement between Cellect Biotechnology Ltd. and Computershare Inc., as warrant agent, including the form of Warrant (incorporated by reference to Exhibit 4.6 of the Registration Statement on Form F-1 filed with the SEC on February 7, 2019).
4.11*	Form of Securities Purchase Agreement.
4.12**	Form of Pre-Funded Warrant.

4.13**	Form of Common Warrant.
5.1*	Legal Opinion of S. Horowitz & Co., Israeli legal counsel to Quoin Pharmaceuticals Ltd.
5.2*	Legal Opinion of Blank Rome LLP, US legal counsel to Quoin Pharmaceuticals Ltd.
10.1	Compensation Policy for Executives and Directors of Quoin Pharmaceuticals Ltd., adopted on April 12, 2022 (incorporated by reference to Annex B included in Exhibit 99.1 to Form 6-K filed with the SEC on March 8, 2022).
10.2	Amended and Restated Equity Incentive Plan of Quoin Pharmaceuticals Ltd., effective as of April 12, 2022 (incorporated by reference to Annex C included in Exhibit 99.1 to Form 6-K filed with the SEC on March 8, 2022).
10.3	Form of Indemnification and Release Agreement, entered into by and between Quoin Pharmaceuticals Ltd. and each of the officers and directors of Quoin Pharmaceuticals Ltd. as of April 12, 2022 (incorporated by reference to Annex D included in Exhibit 99.1 to Form 6-K filed with the SEC on March 8, 2022).
10.4	Executive Employment Agreement, dated March 9, 2018, by and between Quoin Pharmaceuticals, Inc. and Dr. Michael Myers (incorporated by reference to Exhibit 10.1 to Form 6-K filed with the SEC on October 29, 2021).
10.5	Executive Employment Agreement, dated March 9, 2018, by and between Quoin Pharmaceuticals, Inc. and Denise Carter (incorporated by reference to Exhibit 10.2 to Form 6-K filed with the SEC on October 29, 2021).
10.6	Service Agreement, dated November 1, 2021, by and between Quoin Pharmaceuticals, Inc. and Gordon Dunn (incorporated by reference to Exhibit 10.1 to Form 6-K filed with the SEC on November 23, 2021).
10.7	Research Agreement, dated November 1, 2021, by and between Quoin Pharmaceuticals, Inc. and Queensland University of Technology (incorporated by reference to Exhibit 10.2 to Form 6-K filed with the SEC on November 23, 2021).
10.8	License and Distribution Agreement, dated November 5, 2021, by and between Quoin Pharmaceuticals, Inc. and AFT Pharmaceuticals Ltd. (incorporated by reference to Exhibit 10.3 to Form 6-K filed with the SEC on November 23, 2021).
10.9	Supply Agreement, dated September 15, 2021, by and between Quoin Pharmaceuticals, Inc. and AFT Pharmaceuticals Ltd. (incorporated by reference to Exhibit 10.4 to Form 6-K filed with the SEC on November 23, 2021).
10.10	License and Distribution Agreement, dated November 7, 2021, by and between Quoin Pharmaceuticals, Inc. and GenPharm Services FZ LLC (incorporated by reference to Exhibit 10.5 to Form 6-K filed with the SEC on November 23, 2021).
10.11	Supply Agreement, dated November 7, 2021, by and between Quoin Pharmaceuticals, Inc. and GenPharm Services FZ LLC (incorporated by reference to Exhibit 10.6 to Form 6-K filed with the SEC on November 23, 2021).
10.12	Distribution Agreement, dated December 15, 2021, by and between Quoin Pharmaceuticals, Inc. and Orpharm LLC (certain provisions of this exhibit have been omitted pursuant to Instruction No. 4 to Exhibits in Form 20-F) (incorporated by reference to Exhibit 10.1 to Form 6-K filed with the SEC on December 20, 2021).
10.13	License and Distribution Agreement, dated as of January 24, 2022 between the Company and E-Log Logistica LTDA (certain provisions of this exhibit have been omitted pursuant to Instruction No. 4 to Exhibits in Form 20-F) (incorporated by reference to Exhibit 10.1 to Form 6-K filed with the SEC on January 31, 2022).

10.14	License and Distribution Agreement, dated as of February 1, 2022, by and between Quoin Pharmaceuticals Ltd. and Er-Kim İlaç Sanayi ve Ticaret A.Ş, and the First Amendment to the License and Distribution Agreement, dated as of February 17, 2022, by and between Quoin Pharmaceuticals, Inc. and Er-Kim İlaç Sanayi ve Ticaret A.Ş (certain provisions of this exhibit have been omitted pursuant to Instruction No. 4 to Exhibits in Form 20-F) (incorporated by reference to Exhibit 10.4 to Form 6-K filed with the SEC on March 8, 2022).
10.15	License and Distribution Agreement, dated as of February 11, 2022, by and between Quoin Pharmaceuticals Ltd. and Neopharm (Israel) 1996 Ltd. (certain provisions of this exhibit have been omitted pursuant to Instruction No. 4 to Exhibits in Form 20-F) (incorporated by reference to Exhibit 10.5 to Form 6-K filed with the SEC on March 8, 2022).
10.16	Supply Agreement, dated as of February 11, 2022, by and between Quoin Pharmaceuticals Ltd. and Neopharm (Israel) 1996 Ltd. (incorporated by reference to Exhibit 10.6 to Form 6-K filed with the SEC on March 8, 2022).
10.17	License Agreement, dated June 14, 2022, by and between Quoin Pharmaceuticals, Inc. and WinHealth Investment (HK) Limited (certain provisions of this exhibit have been omitted pursuant to Instruction No. 4 to Exhibits in Form 20-F) (incorporated by reference to Exhibit 10.1 to Form 6-K filed with the SEC on June 17, 2022).
10.18	License and Distribution Agreement, dated July 14, 2022, by and between Quoin Pharmaceuticals, Inc. and Endo Ventures Limited (certain provisions of this exhibit have been omitted pursuant to Instruction No. 4 to Exhibits in Form 20-F) (incorporated by reference to Exhibit 10.2 to Form 6-K filed with the SEC on July 15, 2022).
10.19	Supply Agreement, dated July 14, 2022, by and between Quoin Pharmaceuticals, Inc. and Endo Ventures Limited (certain provisions of this exhibit have been omitted pursuant to Instruction No. 4 to Exhibits in Form 20-F) (incorporated by reference to Exhibit 10.3 to Form 6-K filed with the SEC on July 15, 2022).
10.20	Research Agreement, dated May 20, 2022, by and between Quoin Pharmaceuticals, Inc. and Queensland University of Technology, Australia (certain provisions of this exhibit have been omitted pursuant to Instruction No. 4 to Exhibits in Form 20-F) (incorporated by reference to Exhibit 10.1 to Form 6-K filed with the SEC on June 6, 2022).
10.21	Exclusive License Agreement, dated October 17, 2019, by and between Quoin Pharmaceuticals, Inc. and Skinvisible Inc. (incorporated by reference to Exhibit 4.30 to Form 20-F filed with the SEC on April 13, 2022).
10.22	Exclusive License Agreement Renewal, dated May 8, 2020, by and between Quoin Pharmaceuticals, Inc. and Skinvisible Inc. (incorporated by reference to Exhibit 4.31 to Form 20-F filed with the SEC on April 13, 2022).
10.23	First Amendment to the Exclusive License Agreement, dated July 31, 2020, by and between Quoin Pharmaceuticals, Inc. and Skinvisible Inc. (incorporated by reference to Exhibit 4.32 to Form 20-F filed with the SEC on April 13, 2022).
10.24	Second Amendment to the Exclusive License Agreement, dated September 30, 2020, by and between Quoin Pharmaceuticals, Inc. and Skinvisible Inc. (incorporated by reference to Exhibit 4.33 to Form 20-F filed with the SEC on April 13, 2022).
10.25	Third Amendment to the Exclusive License Agreement, dated January 27, 2021, by and between Quoin Pharmaceuticals, Inc. and Skinvisible Inc. (incorporated by reference to Exhibit 4.34 to Form 20-F filed with the SEC on April 13, 2022).
10.26	Fourth Amendment to the Exclusive License Agreement, dated April 19, 2021, by and between Quoin Pharmaceuticals, Inc. and Skinvisible Inc. (incorporated by reference to Exhibit 4.35 to Form 20-F filed with the SEC on April 13, 2022).

10.27	Fifth Amendment to the Exclusive License Agreement, dated June 14, 2021, by and between Quoin Pharmaceuticals, Inc. and Skinvisible Inc. (incorporated by reference to Exhibit 4.36 to Form 20-F filed with the SEC on April 13, 2022).
10.28	Quotation – Tech Transfer and Clinical Manufacture for QRX003 Topical Lotion, dated April 8, 2021, by Ferndale Contract Manufacturing to Quoin Pharmaceuticals, Inc. (incorporated by reference to Exhibit 4.37 to Form 20-F filed with the SEC on April 13, 2022).
10.29	Development and Supply Agreement, dated January 13, 2021, by and between TopChem Pharmaceuticals Limited and Quoin Pharmaceuticals Limited (incorporated by reference to Exhibit 4.38 to Form 20-F filed with the SEC on April 13, 2022).
10.30	Master Services Agreement, dated November 2, 2020, by and between Therapeutics, Inc. and Quoin Pharmaceuticals, Inc. (incorporated by reference to Exhibit 4.39 to Form 20-F filed with the SEC on April 13, 2022).
10.31	Term Sheet for Agreement, dated October 29, 2019, by and between Axella Research, LLC and Quoin Pharmaceuticals, Inc. (incorporated by reference to Exhibit 4.40 to Form 20-F filed with the SEC on April 13, 2022).
10.32	Term Sheet for Agreement, dated January 11, 2020, by and between Axella Research, LLC and Quoin Pharmaceuticals, Inc. (re: QRX003) (incorporated by reference to Exhibit 4.41 to Form 20-F filed with the SEC on April 13, 2022).
10.33	Term Sheet for Agreement, dated January 11, 2020, by and between Axella Research, LLC and Quoin Pharmaceuticals, Inc. (re: QRX004) (incorporated by reference to Exhibit 4.42 to Form 20-F filed with the SEC on April 13, 2022).
10.34**	Form of Non-Qualified Stock Option Award Agreement for directors
10.35**	Form of Non-Qualified Stock Option Award Agreement for officers
21.1	Subsidiaries of Registrant (incorporated by reference to Exhibit 8.1 to Form 20-F filed with the SEC on April 13, 2022).
23.1*	Consent of Friedman LLP, Certified Public Accountants
23.2*	Consent of S. Horowitz & Co. (included in Exhibit 5.1)
23.3*	Consent of Blank Rome LLP (included in Exhibit 5.2)
24.1**	Power of Attorney (included in original signature page)
101*	Information formatted in Extensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Shareholders' Equity, (iv) Consolidated Statements of Cash Flows, and (v) Notes to Consolidated Financial Statements.
107*	Filing Fee Table

* Filed herewith

** Previously filed

(b) Financial Statement Schedules

All schedules have been omitted because either they are not required, are not applicable or the information is otherwise set forth in the consolidated financial statements and related notes thereto.

Item 9. Undertakings.

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) To file a post-effective amendment to the registration statement to include any financial statements required by Item 8.A of Form 20-F at the start of any delayed offering or throughout a continuous offering. Financial statements and information otherwise required by Section 10(a)(3) of the Securities Act of 1933 need not be furnished, provided, that the Registrant includes in the prospectus, by means of a post-effective amendment, financial statements required pursuant to this paragraph (a)(4) and other information necessary to ensure that all other information in the prospectus is at least as current as the date of those financial statements. Notwithstanding the foregoing, with respect to registration statements on Form F-3, a post-effective amendment need not be filed to include financial statements and information required by Section 10(a)(3) of the Securities Act of 1933, or Item 8.A of Form 20-F if such financial statements and information are contained in periodic reports filed with or furnished to the Commission by the Registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the Form F-3.

(5) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(6) That for purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b) (1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(7) That for the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a

form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(8) That insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form F-1 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Ashburn, Virginia on August 4, 2022.

Quoin Pharmaceuticals Ltd.

By: /s/ Dr. Michael Myers

Name: Dr. Michael Myers

Title: Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, as amended, this Registration Statement on Form F-1 has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Dr. Michael Myers Dr. Michael Myers	Chairman and Chief Executive Officer (Principal Executive Officer)	August 4, 2022
/s/ Gordon Dunn Gordon Dunn	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	August 4, 2022
/s/ Denise Carter Denise Carter	Director and Chief Operating Officer	August 4, 2022
* Joseph Cooper	Director	August 4, 2022
* Dennis Langer	Director	August 4, 2022
* Natalie Leong	Director	August 4, 2022
* Mike Sember	Director	August 4, 2022
* James Culverwell	Director	August 4, 2022

*By: /s/ Dr. Michael Myers
Dr. Michael Myers
Attorney-in- Fact

SIGNATURE OF AUTHORIZED U.S. REPRESENTATIVE

Pursuant to the Securities Act of 1933, as amended, the undersigned, the duly authorized representative in the United States of Quoin Pharmaceuticals Ltd., has signed this registration statement on Form F-1 in Ashburn, Virginia on August 4, 2022.

Authorized U.S. Representative
Dr. Michael Myers

By:	/s/ Dr. Michael Myers
Name:	Dr. Michael Myers
Title:	Chief Executive Officer

Exhibit 1.1

August [·], 2022

Quoin Pharmaceuticals Ltd.
Attention: Gordon Dunn
Azrieli Center, Round Tower, 30th Floor
132 Menachem Begin Blvd
Tel Aviv, 6701101

Dear Mr. Gordon Dunn:

Subject to the terms and conditions of this letter agreement (the "**Agreement**") between A.G.P./Alliance Global Partners, as the sole placement agent ("**A.G.P.**") (A.G.P. is also referred to herein as the "**Placement Agent**"), and Quoin Pharmaceuticals Ltd., a company organized under the laws of Israel (the "**Company**"), the parties hereby agree that the Placement Agent shall serve as the placement agent for the Company, on a "reasonable best efforts" basis, in connection with the proposed placement (the "**Placement**") of no less than $12 million of registered securities of the Company, consisting of: (i) ordinary shares, no par value (the "**Ordinary Shares**") represented by American Depositary Shares (the "**ADSs**"), with each ADS representing five thousand (5,000) Ordinary Shares, (ii) pre-funded warrants to purchase Ordinary Shares represented by ADSs (the "**Pre-Funded Warrants**"), and (iii) warrants to purchase ADSs (the "**Common Warrants**" and collectively with the Pre-Funded Warrants, the "**Warrants**"). The ADSs and Warrants actually placed by the Placement Agent are referred to herein as the "**Placement Agent Securities**." The Placement Agent Securities and Ordinary Shares Represented by ADSs issuable upon the exercise of the Warrants shall be offered and sold under the Company's registration statement on Form F-1, as amended (File No. 333-266476), which was declared effective by the Securities and Exchange Commission (the "**Commission**") on August [·], 2022. The documents executed and delivered by the Company and the Purchasers (as defined below) in connection with the Placement, including, without limitation, a securities purchase agreement (the "**Purchase Agreement**"), shall be collectively referred to herein as the "**Transaction Documents**."

The terms of the Placement shall be mutually agreed upon by the Company and the purchasers listed in the Purchase Agreement (each, a "**Purchaser**" and collectively, the "**Purchasers**"), and nothing herein constitutes that the Placement Agent would have the power or authority to bind the Company or any Purchaser, or an obligation for the Company to issue any Placement Agent Securities or complete the Placement. The Company expressly acknowledges and agrees that the Placement Agent's obligations hereunder are on a reasonable best efforts basis only and that the execution of this Agreement does not constitute a commitment by the Placement Agent to purchase the Placement Agent Securities and does not ensure the successful placement of the Placement Agent Securities or any portion thereof or the success of the Placement Agent with respect to securing any other financing on behalf of the Company. The Placement Agent may retain other brokers or dealers to act as sub-agents or selected-dealers on its behalf in connection with the Placement. Certain affiliates of the Placement Agent may participate in the Placement by purchasing some of the Placement Agent Securities. The sale of Placement Agent Securities to any Purchaser will be evidenced by the Purchase Agreement between the Company and such Purchaser, in a form reasonably acceptable to the Company and the Purchaser. Capitalized terms that are not otherwise defined herein have the meanings given to such terms in the Purchase Agreement. Prior to the signing of any Purchase Agreement, officers of the Company will be available to answer inquiries from prospective Purchasers.

SECTION 1. REPRESENTATIONS AND WARRANTIES OF THE COMPANY; COVENANTS OF THE COMPANY.

A. Representations of the Company. With respect to the Placement Agent Securities, each of the representations and warranties (together with any related disclosure schedules thereto) and covenants made by the Company to the Purchasers in the Purchase Agreement in connection with the Placement, is hereby incorporated herein by reference into this Agreement (as though fully restated herein) and is, as of the date of this Agreement and as of the Closing Date, hereby made to, and in favor of, the Placement Agent. In addition to the foregoing, the Company represents and warrants that there are no affiliations with any Financial Industry

Regulatory Authority ("**FINRA**") member firm participating in the Placement among the Company's officers, directors or, to the knowledge of the Company, any five percent (5.0%) or greater stockholder of the Company.

B. Covenants of the Company. The Company covenants and agrees to continue to retain (i) a firm of Public Company Accounting Oversight Board independent registered public accountants for a period of at least two (2) years after the Closing Date and (ii) a reputable depositary with respect to the ADSs for a period of two (2) years after the Closing Date, provided the Company is then subject to the reporting requirement of the Exchange Act (as defined below). Furthermore, for ninety (90) days after the Closing Date, the Company shall not, without the prior written consent of the Placement Agent, (i) issue, enter into any agreement to issue or announce the issuance or proposed issuance of any ADSs, Ordinary Shares or Ordinary Share Equivalents or (ii) file any registration statement or amendment or supplement thereto, other than the Preliminary Prospectus, the Prospectus or a registration statement on Form S-8 in connection with any employee benefit plan; provided, however, such restrictions shall not apply with respect to an Exempt Issuance. In addition, for one-hundred eighty (180) days after the Closing Date, the Company shall not effect or enter into an agreement to effect any issuance of Placement Agent Securities or Ordinary Share Equivalents involving an at-the-market offering or Variable Rate Transaction (as defined in the Purchase Agreement), except such restriction shall not apply with respect to an Exempt Issuance.

SECTION 2. REPRESENTATIONS OF THE PLACEMENT AGENT. The Placement Agent represents and warrants that it (i) is a member in good standing of the FINRA, (ii) is registered as a broker/dealer under the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), (iii) is licensed as a broker/dealer under the laws of the United States of America, applicable to the offers and sales of the Placement Agent Securities by the Placement Agent, (iv) is and will be a corporate body validly existing under the laws of its place of incorporation, and (v) has full power and authority to enter into and perform its obligations under this Agreement. The Placement Agent will immediately notify the Company in writing of any change in its status with respect to subsections (i) through (v) above. The Placement Agent covenants that it will use its reasonable best efforts to conduct the Placement hereunder in compliance with the provisions of this Agreement and the requirements of applicable law.

SECTION 3. COMPENSATION. In consideration of the services to be provided for hereunder, the Company shall pay to the Placement Agent and/or its respective designees a cash fee of 7.0% of the aggregate purchase price paid by Purchasers at the Closing (the "**Cash Fee**"); provided, however, that with respect to the purchase price paid by Altium Growth Fund, LP at the Closing, the Cash Fee shall be reduced to 3.5% for the first $5 million and to 1.75%, for the purchase price paid in excess of $5 million.

SECTION 4. EXPENSES. The Company agrees to pay all costs, fees and expenses incurred by the Company in connection with the performance of its obligations hereunder and in connection with the transactions contemplated hereby, including, without limitation: (i) all expenses incident to the issuance, delivery and qualification of the Placement Agent Securities (including all printing and engraving costs); (ii) all fees and expenses of the depositary of the ADSs; (iii) all necessary issue, transfer and other stamp taxes in connection with the issuance and sale of the Placement Agent Securities; (iv) all fees and expenses of the Company's counsel, independent public or certified public accountants and other advisors; (v) all costs and expenses incurred in connection with the preparation, printing, filing, shipping and distribution of the Registration Statement (including financial statements, exhibits, schedules, consents and certificates of experts), the Preliminary Prospectus and the Prospectus, and all amendments and supplements thereto, and this Agreement; (vi) all filing fees, reasonable attorneys' fees and expenses incurred by the Company in connection with qualifying or registering (or obtaining exemptions from the qualification or registration of) all or any part of the Placement Agent Securities for offer and sale under the state securities or blue sky laws or the securities laws of any other country; (vii) the fees and expenses associated with including the Placement Agent Securities on the Trading Market; (viii) up to $125,000 for accountable expenses related to legal fees of counsel to the Placement Agent; and (ix) non-accountable expenses, including IPREO software related expenses, background check expenses, tombstones and marketing related expenses, including road show expenses, and any other non-accountable expenses incurred by the Placement Agent in connection with the Placement, provided, however, that such reimbursement for non-accountable expenses shall not exceed 1.0% of the gross proceeds raised in the Placement.

SECTION 5. INDEMNIFICATION.

A. To the extent permitted by law, with respect to the Placement Agent Securities, the Company shall indemnify and hold harmless the Placement Agent and its affiliates, agents, stockholders, directors, officers, employees, members and controlling persons (within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act) (each such entity or person, an "**Indemnified Person**") from and against all claims, actions, suits, proceedings (including those of stockholders), damages, costs and liabilities (collectively, "**Claims**"), and shall reimburse each Indemnified Person for all reasonable fees and expenses (including the reasonable fees and expenses of counsel) (collectively, the "**Expenses**") as they are incurred by an Indemnified Person in investigating, preparing, pursuing or defending any Claim, whether or not an Indemnified Person is a party thereto, that is caused by, arises out of, or is based upon (i) any untrue statements made or any statements omitted to be made in the Registration Statement, the Preliminary Prospectus or the Prospectus, or by any omission or alleged omission to state therein a material fact necessary to make the statements therein, in light of the circumstances under which they were made, not misleading (other than untrue statements or alleged untrue statements in, or omissions or alleged omissions from, information relating to an Indemnified Person furnished in writing by or on behalf of such Indemnified Person expressly for use in the Registration Statement, Preliminary Prospectus or any Prospectus) or (ii) any other actions taken or omitted to be taken by the Company or any Indemnified Person in connection with this Agreement; provided, however, the Company will not be responsible for any Claims or Expenses of any Indemnified Person that are judicially determined to have resulted primarily from such Indemnified Person's (x) willful misconduct, violation of law or gross negligence in connection with any of the action, inaction or the services described herein, or (y) use of any offering materials or information concerning the Company in connection with the offer or sale of the Placement Agent's Securities in the Placement, which were not authorized for such use by the Company and which use constitutes gross negligence, violation of law or willful misconduct.

B. Promptly after receipt by the Placement Agent of notice of any claim or the commencement of any action or proceeding with respect to which any Indemnified Person is entitled to indemnity hereunder, the Placement Agent will notify the Company in writing of such claim or of the commencement of such action or proceeding, but failure to so notify the Company shall not relieve the Company from any obligation it may have hereunder, except and only to the extent such failure results in the forfeiture by the Company of substantial rights and defenses. If the Company so elects or is requested by the Placement Agent, the Company will assume the defense of such action or proceeding and will employ counsel reasonably satisfactory to the Placement Agent and will pay the fees and expenses of such counsel. Notwithstanding the preceding sentence, the Placement Agent will be entitled to employ its own counsel separate from counsel for the Company and from any other party in such action if counsel for the Placement Agent reasonably determines that it would be inappropriate under the applicable rules of professional responsibility for the same counsel to represent both the Company and the Placement Agent. In such event, the reasonable fees and disbursements of no more than one such separate counsel will be paid by the Company, in addition to fees of local counsel.

C. The Company may not settle, compromise or consent to the entry of any judgment in any pending or threatened Claim, in which indemnification may be sought hereunder (whether or not any Indemnified Person is an actual or potential party thereto), without the prior written consent of the Placement Agent (which will not be unreasonably delayed or withheld) unless such settlement, compromise or consent provides for an unconditional and irrevocable release of each Indemnified Person from any and all liability arising out of such Claim.

D. The Company agrees to notify the Placement Agent promptly of the assertion against it or any other person of any Claim or the commencement of any action or proceeding relating to a transaction contemplated by this Agreement.

E. If for any reason the foregoing indemnity is unavailable to the Placement Agent or insufficient to hold the Placement Agent harmless, then the Company shall contribute to the amount paid or payable by the Placement Agent as a result of such Claim or Expenses in such proportion as is appropriate to reflect (a) the relative benefits to the Company on the one hand, and the Placement Agent on the other hand, in connection with the Placement, (b) the relative fault of the parties, and (c) other equitable considerations; provided, however, that in no event shall the amount to be contributed by the Placement Agent exceed the fees actually received by the Placement Agent under this Agreement. Notwithstanding the immediately preceding sentence, to the extent the exception to indemnification contemplated by Paragraph A of this Section applies with respect to the Placement Agent, the Company shall contribute to the amount paid or payable by the Placement Agent as a result of such Claim or Expenses in such proportion as is appropriate to reflect the relative fault of the Company, on the one hand, and the Placement Agent, on the other hand, in connection with the matters contemplated by the Agreement; provided, however, that in no event shall the amount to be contributed by Placement Agent exceed the fees actually received by Placement Agent under the Agreement. The Company agrees that for the purposes of this paragraph the relative benefits to the Company and the Placement Agent of the contemplated transaction (whether or not such transaction is consummated) shall be deemed to be in the same proportion that the aggregate cash consideration payable (or contemplated to be payable) in such transaction bears to the fees paid or payable to the Placement Agent under the Agreement.

F. These indemnification provisions shall remain in full force and effect whether or not the transaction contemplated by this Agreement is completed, survive the termination of this Agreement, and be in addition to any liability that the Company might otherwise have to any Indemnified Person.

SECTION 6. ENGAGEMENT TERM. The Placement Agent's engagement hereunder will be until the earlier of the Closing Date and December 31, 2022. The date of termination of this Agreement is referred to herein as the "**Termination Date**." In the event, however, in the course of the Placement Agent's performance of due diligence it deems, it necessary to terminate the engagement, the Placement Agent may do so prior to the Termination Date. The Company may elect to terminate the engagement hereunder for any reason prior to the Termination Date but will remain responsible for fees pursuant to Section 3 hereof with respect to the Placement Agent Securities if sold in the Placement. Notwithstanding anything to the contrary contained herein, the provisions concerning the Company's obligation to pay any fees actually earned pursuant to Section 3 hereof and the provisions concerning confidentiality, indemnification and contribution contained herein, as well as provisions in Sections 10 – 14 hereof will survive any expiration or termination of this Agreement. If this Agreement is terminated prior to the completion of the Placement, all fees due to the Placement Agent as set forth in Section 3 and Section 4 shall be paid by the Company to the Placement Agent on or before the Termination Date (in the event such fees are earned or owed as of the Termination Date). The Placement Agent agrees not to use any confidential information concerning the Company provided to the Placement Agent by the Company for any purposes other than those contemplated under this Agreement.

SECTION 7. PLACEMENT AGENT INFORMATION. The Company agrees that any information or advice rendered by the Placement Agent in connection with this engagement is for the confidential use of the Company only in its evaluation of the Placement and, except as otherwise required by law, the Company will not disclose or otherwise refer to the advice or information in any manner without the Placement Agent's prior written consent.

SECTION 8. NO FIDUCIARY RELATIONSHIP. This Agreement does not create, and shall not be construed as creating rights enforceable by any person or entity not a party hereto, except those entitled hereto by virtue of the indemnification provisions hereof. The Company acknowledges and agrees that the Placement Agent is not and shall not be construed as a fiduciary of the Company and shall have no duties or liabilities to the equity holders or the creditors of the Company or any other person by virtue of this Agreement or the retention of the Placement Agent hereunder, all of which are hereby expressly waived.

SECTION 9. CLOSING. The obligations of the Placement Agent, and the closing of the sale of the Placement Agent Securities hereunder are subject to the accuracy, when made and on the Closing Date, of the representations and warranties on the part of the Company contained herein and in the Purchase Agreement, to the performance by the Company of its obligations hereunder, and to each of the following additional terms and conditions, except as otherwise disclosed to and acknowledged and waived by the Placement Agent:

A. All corporate proceedings and other legal matters incident to the authorization, form, execution, delivery and validity of each of this Agreement, the Placement Agent Securities, and all other legal matters relating to this Agreement and the transactions contemplated hereby with respect to the

Placement Agent Securities shall be reasonably satisfactory in all material respects to the Placement Agent.

B. The Placement Agent shall have received from each of the Company's U.S. Counsel, Blank Rome LLP, and Israeli Counsel, S. Horowitz & Co., such counsel's written opinion with respect to the Placement Agent Securities, addressed to the Placement Agent and dated as of the Closing Date, in form and substance reasonably satisfactory to the Placement Agent.

C. The Placement Agent shall have received an executed FINRA questionnaire from each of the Company and the Company's executive officers, directors and 5% or greater securityholders as well as executed Lock-Up Agreements from the Company's executive officers and directors.

D. ADSs sold in the Placement, including ADSs issuable upon the exercise of the Warrants, must be registered under the Exchange Act. The Company shall have taken no action designed to, or likely to have the effect of, terminating the registration of the ADSs under the Exchange Act or delisting or suspending from trading the ADSs from the Trading Market or other applicable U.S. national exchange, nor has the Company received any information suggesting that the Commission or the Trading Market or other U.S. applicable national exchange is contemplating terminating such registration or listing, except as disclosed in the Registration Statement, the Preliminary Prospectus and the Prospectus.

E. No action shall have been taken and no statute, rule, regulation or order shall have been enacted, adopted or issued by any governmental agency or body which would, as of the Closing Date, prevent the issuance or sale of the Placement Agent Securities or materially and adversely affect or potentially and adversely affect the business or operations of the Company; and no injunction, restraining order or order of any other nature by any federal or state court of competent jurisdiction shall have been issued as of the Closing Date which would prevent the issuance or sale of the Placement Agent Securities or materially and adversely affect or potentially and adversely affect the business or operations of the Company.

F. The Company shall have entered into a Purchase Agreement with each of the Purchasers of the Placement Agent Securities and such agreements shall be in full force and effect and shall contain representations, warranties and covenants of the Company as agreed upon between the Company and the Purchasers.

G. FINRA shall have raised no objection to the fairness and reasonableness of the terms and arrangements of this Agreement. In addition, the Company shall, if requested by the Placement Agent, make or authorize Placement Agent's counsel to make on the Company's behalf, any filing with the FINRA Corporate Financing Department pursuant to FINRA Rule 5110 with respect to the Placement and pay all filing fees required in connection therewith.

H. The Placement Agent shall have received from Friedman LLP, or such other independent registered public accounting firm of the Company, letters dated as of the date hereof and the Closing Date, respectively, in each case addressed to the Placement Agent in forms and substance satisfactory in all respects to the Placement Agent and its counsel.

I. The Placement Agent shall have received customary certificates of the Company's executive officers, as to the accuracy of the representations and warranties contained in the Purchase Agreement, and a certificate of the Company's secretary certifying (i) that the Company's charter documents are true and complete, have not been modified and are in full force and effect; (ii) that the resolutions of the Company's Board of Directors relating to the Placement are in full force and effect and have not been modified; and (iii) as to the incumbency of the officers of the Company.

If any of the conditions specified in this Section 9 shall not have been fulfilled when and as required by this Agreement, all obligations of the Placement Agent hereunder may be cancelled by the Placement Agent at, or at any time prior to, the Closing Date. Notice of such cancellation shall be given to the Company in writing or orally. Any such oral notice shall be confirmed promptly thereafter in writing.

SECTION 10. GOVERNING LAW. This Agreement will be governed by, and construed in accordance with, the laws of the State of New York applicable to agreements made and to be performed entirely in such State, without regard to principles of conflicts of law. This Agreement may not be assigned by either party without the prior written consent of the other party. This Agreement shall be binding upon and inure to the benefit of the parties hereto, and their respective successors and permitted assigns. Any right to trial by jury with respect to any dispute arising under this Agreement or any transaction or conduct in connection herewith is waived. Any dispute arising under this Agreement may be brought into the courts of the State of New York or into the Federal Court located in New York, New York and, by execution and delivery of this Agreement, the Company hereby accepts for itself and in respect of its property, generally and unconditionally, the jurisdiction of aforesaid courts. Each party hereto hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by delivering a copy thereof via overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any manner permitted by law. If either party shall commence an action or proceeding to enforce any provisions of this Agreement, then the prevailing party in such action or proceeding shall be reimbursed by the other party for its attorney's fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

SECTION 11. ENTIRE AGREEMENT/MISCELLANEOUS. This Agreement embodies the entire agreement and understanding between the parties hereto, and supersedes all prior agreements and understandings, relating to the subject matter hereof. If any provision of this Agreement is determined to be invalid or unenforceable in any respect, such determination will not affect such provision in any other respect or any other provision of this Agreement, which will remain in full force and effect. This Agreement may not be amended or otherwise modified or waived except by an instrument in writing signed by both the Placement Agent and the Company. The representations, warranties, agreements and covenants contained herein shall survive the Closing Date of the Placement and delivery of the Placement Agent Securities for the applicable statute of limitations. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to the other party, it being understood that both parties need not sign the same counterpart. In the event that any signature is delivered by facsimile transmission or a .pdf format file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or .pdf signature page were an original thereof.

SECTION 12. NOTICES. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be in writing and shall be deemed given and effective on the earliest of (a) the date of transmission, if such notice or communication is sent to the email address specified on the signature pages attached hereto prior to 6:30 p.m. (New York City time) on a business day, (b) the next business day after the date of transmission, if such notice or communication is sent to the email address on the signature pages attached hereto on a day that is not a business day or later than 6:30 p.m. (New York City time) on any business day, (c) the third business day following the date of mailing, if sent by an internationally recognized air courier service, or (d) upon actual receipt by the party to whom such notice is required to be given. The address for such notices and communications shall be as set forth on the signature pages hereto.

SECTION 13. PRESS ANNOUNCEMENTS. The Company agrees that the Placement Agent shall, on and after the Closing Date, have the right to reference the Placement and the Placement Agent’s role in connection therewith in the Placement Agent’s marketing materials and on its website and to place advertisements in financial and other newspapers and journals, in each case at its own expense.

SECTION 14. PAYMENTS. All payments made or deemed to be made by the Company to the Placement Agent, its affiliates, stockholders, directors, officers, employees, members and controlling persons (within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act) (each, a “**Payee**”), if any, will be made without withholding or deduction for or on account of any present or future taxes, duties, assessments or governmental charges of whatever nature (other than taxes on net income or similar taxes) imposed or levied by or on behalf of the State of Israel or any political subdivision or any taxing authority thereof or therein unless the Company is or becomes required by law to withhold or deduct such taxes, duties, assessments or other governmental charges. In such event, the Company will pay such additional amounts as will result, after such withholding or deduction, in the receipt by the Payee of the amounts that would otherwise have been receivable in respect thereof. For the avoidance of doubt, all sums payable, paid or deemed payable under this Agreement shall be considered exclusive of value added tax, sales tax or other similar taxes which shall be borne by, paid, collected and remitted by the Company in accordance with applicable law.

Please confirm that the foregoing correctly sets forth our agreement by signing and returning to the Placement Agent the enclosed copy of this Agreement.

[*The remainder of this page has been intentionally left blank.*]

The foregoing Agreement is hereby accepted and agreed to as of the date first written above.

A.G.P./ALLIANCE GLOBAL PARTNERS

By: ________________________________
Name: Thomas Higgins
Title: Managing Director

Address for Notice:
590 Madison Avenue 28th Floor
New York, New York 10022
Attn: Thomas J. Higgins
Email: thiggins@allianceg.com

[*Signature Page to Placement Agency Agreement*]

Accepted and Agreed to as of the date first written above:

QUOIN PHARMACEUTICALS LTD.

By: ______________________________________
Name:
Title:

Address for Notice:
Axrieli Center, Round Tower, 30th Floor
132 Menachem Begin Blvd
Attn:
Email:

[*Signature Page to Placement Agency Agreement*]

SECURITIES PURCHASE AGREEMENT

This Securities Purchase Agreement (this "Agreement") is dated as of August [·], 2022, between Quoin Pharmaceuticals Ltd., a company organized under the laws of Israel (the "Company"), and each purchaser identified on the signature pages hereto (each, including its successors and assigns, a "Purchaser" and collectively the "Purchasers").

WHEREAS, subject to the terms and conditions set forth in this Agreement and pursuant to an effective registration statement under the Securities Act (as defined below), the Company desires to issue and sell to each Purchaser, and each Purchaser, severally and not jointly, desires to purchase from the Company, securities of the Company as more fully described in this Agreement.

NOW, THEREFORE, IN CONSIDERATION of the mutual covenants contained in this Agreement, and for other good and valuable consideration the receipt and adequacy of which are hereby acknowledged, the Company and each Purchaser agree as follows:

ARTICLE I.
DEFINITIONS

1.1 Definitions. In addition to the terms defined elsewhere in this Agreement, for all purposes of this Agreement, the following terms have the meanings set forth in this Section 1.1:

"Acquiring Person" shall have the meaning ascribed to such term in Section 4.5.

"Action" shall have the meaning ascribed to such term in Section 3.1(j).

"ADS(s)" means American Depositary Shares issued pursuant to the Deposit Agreement (as defined below), each representing five thousand (5,000) Ordinary Shares.

"Affiliate" means any Person that, directly or indirectly through one or more intermediaries, controls or is controlled by or is under common control with a Person as such terms are used in and construed under Rule 405 under the Securities Act.

"Board of Directors" means the board of directors of the Company.

"Business Day" means any day other than Saturday, Sunday, or other day on which banking institutions in the State of New York are authorized or required by law to remain closed.

"Closing" means the closing of the purchase and sale of the Securities pursuant to Section 2.1.

"Closing Date" means the Trading Day on which all of the Transaction Documents have been executed and delivered by the applicable parties thereto, and all conditions precedent to (i) the Purchasers' obligations to pay the Subscription Amount at the Closing and (ii) the Company's obligations to deliver the Securities, in each case, at the Closing have been satisfied or waived, but in no event later than the second (2nd) Trading Day following the date hereof.

"Commission" means the United States Securities and Exchange Commission.

"Common Warrants" means, collectively, the warrants delivered to the Purchasers at Closing in accordance with Section 2.2(a) hereof, which Common Warrants shall be exercisable immediately upon issuance of such

Common Warrants and may be exercised during a period of five (5) years commencing from their issuance, in the form of Exhibit A attached hereto.

"Company Israeli Counsel" means S. Horowitz & Co. with offices located at 31 Ahad Ha'am Street, Tel Aviv 6520204, Israel.

"Company U.S. Counsel" means Blank Rome LLP with offices located at One Logan Square, 130 North 18th Street, Philadelphia, PA 19103.

"Deposit Agreement" means the Deposit Agreement dated as of July 28, 2016 among the Company, the Depositary and the owners and holders of ADSs from time to time, as such agreement may be amended or supplemented.

"Depositary" means The Bank of New York Mellon, as depositary under the Deposit Agreement.

"Disclosure Schedules" means the Disclosure Schedules of the Company delivered concurrently herewith.

"Disclosure Time" means, (i) if this Agreement is signed on a day that is not a Trading Day or after 9:00 a.m. (New York City time) and before midnight (New York City time) on any Trading Day, 9:01 a.m. (New York City time) on the Trading Day immediately following the date hereof, unless otherwise instructed as to an earlier time by the Placement Agent, and (ii) if this Agreement is signed between midnight (New York City time) and 9:00 a.m. (New York City time) on any Trading Day, no later than 9:01 a.m. (New York City time) on the date hereof, unless otherwise instructed as to an earlier time by the Placement Agent.

"DWAC" shall have the meaning ascribed to such term in Section 2.2(v).

"Evaluation Date" shall have the meaning ascribed to such term in Section 3.1(r).

"Exchange Act" means the Securities Exchange Act of 1934, as amended, and the rules and regulations promulgated thereunder.

"Exempt Issuance" means the issuance of (a) ADSs, Ordinary Shares, restricted share units or options to employees, consultants, officers, or directors of the Company pursuant to any share or option plan in existence as of the date hereof, (b) ADSs or Ordinary Shares upon the exercise or exchange of or conversion of securities exercisable or exchangeable for or convertible into ADSs or Ordinary Shares issued and outstanding on the date of this Agreement, provided that such securities have not been amended since the date of this Agreement to increase the number of such securities or to decrease the exercise price, exchange price or conversion price of such securities or to extend the term of such securities, (c) securities issued pursuant to acquisitions or strategic transactions approved by a majority of the disinterested directors of the Company, provided that such securities are issued as "restricted securities" (as defined in Rule 144) and carry no registration rights that require or permit the filing of any registration statement in connection therewith during the prohibition period in Section 4.10(a) herein, and provided that any such issuance shall only be to a Person (or to the equityholders of a Person) which is, itself or through its subsidiaries, an operating company or an owner of an asset in a business synergistic with the business of the Company and shall provide to the Company additional benefits in addition to the investment of funds, but shall not include a transaction in which the Company is issuing securities primarily for the purpose of raising capital or to an entity whose primary business is investing in securities (for avoidance of doubt, securities issued to a venture arm of a strategic investor shall be deemed an "Exempt Issuance"), (d) issuances of ADSs or Ordinary Shares to consultants or vendors of the Company, provided that such securities are issued as "restricted securities" (as defined in Rule 144) and carry no registration rights; and (e) issuances of ADSs or Ordinary Shares to existing holders of the Company's securities in compliance with the terms of agreements entered into with, or instruments issued to, such holders, provided that such securities are issued as "restricted securities" (as defined in Rule 144) and carry no registration rights (other than Ordinary Shares represented by ADSs issuable to holders of the Company's outstanding warrants upon the exercise of such warrants, as registered under the Registration Statement on Form F-1 (File No. 333-264305).

"FCPA" means the Foreign Corrupt Practices Act of 1977, as amended.

"GAAP" means generally accepted accounting principles in the United States.

"Indebtedness" shall have the meaning ascribed to such term in Section 3.1(z).

"Intellectual Property Rights" shall have the meaning ascribed to such term in Section 3.1(o).

"Liens" means a lien, charge, pledge, security interest, encumbrance, right of first refusal, preemptive right or other restriction.

"Lock-Up Agreement" means the Lock-Up Agreement, dated as of the date hereof, by and among the Company and the directors and officers of the Company, in the form of Exhibit C attached hereto.

"Material Adverse Effect" shall have the meaning assigned to such term in Section 3.1(b).

"Material Permits" shall have the meaning ascribed to such term in Section 3.1(m).

"Ordinary Share(s)" means the ordinary shares of the Company, no par value per share, and any other class of securities into which such securities may hereafter be reclassified or changed.

"Ordinary Share Equivalents" means any securities of the Company or the Subsidiaries which would entitle the holder thereof to acquire at any time Ordinary Shares or ADSs, including, without limitation, any debt, preferred share, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Ordinary Shares or ADSs.

"Per ADS Purchase Price" equals $[·], subject to adjustment for reverse and forward share splits, share dividends, share combinations and other similar transactions of ADSs and/or the Ordinary Shares that occur between the date hereof and the Closing Date.

"Per Pre-Funded Warrant Purchase Price" equals $[·], subject to adjustment for reverse and forward share splits, share dividends, share combinations and other similar transactions of ADSs and/or the Ordinary Shares that occur after the date of this Agreement.

"Person" means an individual or corporation, partnership, trust, incorporated or unincorporated association, joint venture, limited liability company, joint stock company, government (or an agency or subdivision thereof) or other entity of any kind.

"Placement Agent" means A.G.P./Alliance Global Partners.

"Pre-Funded Warrants" means, collectively, the warrants delivered to the Purchasers at Closing in accordance with Section 2.2(a) hereof, which Pre-Funded Warrants shall be exercisable immediately upon issuance and shall expire in accordance with the terms thereof, in the form of Exhibit B attached hereto.

"Preliminary Prospectus" means any preliminary prospectus included in the Registration Statement, as originally filed or as part of any amendment thereto, or filed with the Commission pursuant to Rule 424(a) of the rules and regulations of the Commission under the Securities Act.

"Proceeding" means an action, claim, suit, investigation or proceeding (including, without limitation, an informal investigation or partial proceeding, such as a deposition), whether commenced or threatened.

"Prospectus" means the final prospectus filed pursuant to the Registration Statement.

"Purchaser Party" shall have the meaning ascribed to such term in Section 4.8.

"Registration Statement" means the effective registration statement with the Commission on Form F-1 (File No. 333-266476), as amended, which registers the sale of the Securities and includes any Rule 462(b) Registration Statement.

"Required Approvals" shall have the meaning ascribed to such term in Section 3.1(e).

"Rule 144" means Rule 144 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.

"Rule 424" means Rule 424 promulgated by the Commission pursuant to the Securities Act, as such Rule may be amended or interpreted from time to time, or any similar rule or regulation hereafter adopted by the Commission having substantially the same purpose and effect as such Rule.

"Rule 462(b) Registration Statement" means any registration statement prepared by the Company registering additional Securities, which was filed with the Commission on or prior to the date hereof and became automatically effective pursuant to Rule 462(b) promulgated by the Commission pursuant to the Securities Act.

"SEC Reports" shall have the meaning ascribed to such term in Section 3.1(h).

"Securities" means the Shares, the Warrants, the Warrant ADSs, the Warrant Shares and ADSs.

"Securities Act" means the Securities Act of 1933, as amended, and the rules and regulations promulgated thereunder.

"Securities Law" means the Israeli Securities Law, 5728-1968, as amended, and the rules and regulations promulgated thereunder.

"Shares" means the Ordinary Shares, as represented by ADSs issued pursuant to the Deposit Agreement, each ADS representing five thousand (5,000) Ordinary Shares issued and issuable to each Purchaser pursuant to this Agreement.

"Short Sales" means all "short sales" as defined in Rule 200 of Regulation SHO under the Exchange Act (but shall not be deemed to include locating and/or borrowing shares of Ordinary Shares and/or ADSs).

"Subscription Amount" means, as to each Purchaser, the aggregate amount to be paid for ADSs, each ADS representing five thousand (5,000) Ordinary Shares, and Pre-Funded Warrants, purchased hereunder as specified below such Purchaser's name on the signature page of this Agreement and next to the heading "Subscription Amount," in United States dollars and in immediately available funds.

"Subsidiary" means any subsidiary of the Company as set forth in the SEC Reports and shall, where applicable, also include any direct or indirect subsidiary of the Company formed or acquired after the date hereof.

"Trading Day" means a day on which the principal Trading Market is open for trading.

"Trading Market" means any of the following markets or exchanges on which ADSs and/or the Ordinary Shares are listed or quoted for trading on the date in question: the NYSE American, the Nasdaq Capital Market, the Nasdaq Global Market, the Nasdaq Global Select Market, or the New York Stock Exchange (or any successors to any of the foregoing).

"Transaction Documents" means this Agreement the Warrants, the Lock-Up Agreements and all exhibits and schedules thereto and hereto and any other documents or agreements executed in connection with the transactions contemplated hereunder.

"Variable Rate Transaction" shall have the meaning ascribed to such term in Section 4.10(b).

"Warrants" means the Common Warrants and the Pre-Funded Warrants.

"Warrant ADSs" means ADSs representing Warrant Shares.

"Warrant Shares" means the Ordinary Shares issuable upon exercise of the Warrants.

ARTICLE II.
PURCHASE AND SALE

2.1 Closing. On the Closing Date, upon the terms and subject to the conditions set forth herein, substantially concurrent with the execution and delivery of this Agreement by the parties hereto, the Company agrees to sell, and the Purchasers, severally and not jointly, agree to purchase, (i) the number of Ordinary Shares represented by ADSs set forth under the heading "Subscription Amount" on the Purchaser's signature page hereto, at the Per ADS Purchase Price, and (ii) Common Warrants exercisable for ADSs as calculated pursuant to 2.2(a); provided, however, that, to the extent that a Purchaser determines, in its sole discretion, that such Purchaser (together with such Purchaser's Affiliates, and any Person acting as a group together with such purchaser or any of such Holder's Affiliates) would beneficially own in excess of the Beneficial Ownership Limitation, or as such Purchaser may otherwise choose, in lieu of purchasing ADSs, such Purchaser may elect to purchase Pre-Funded Warrants in lieu of ADSs in such manner to result in the full Subscription Amount being paid by such Purchaser to the Company. The "Beneficial Ownership Limitation" shall be 4.99% (or, at the election of the Purchaser, 9.99%) of the number of Ordinary Shares, in each case, outstanding immediately after giving effect to the issuance of the Securities on the Closing Date.

Each Purchaser's Subscription Amount as set forth on the signature page hereto executed by such Purchaser shall be made available for Delivery Versus Payment ("DVP") settlement with the Company or its designees. The Company shall deliver to each Purchaser its respective Shares and Warrants as determined pursuant to Section 2.2(a), and the Company and each Purchaser shall deliver the other items set forth in Section 2.2 at the Closing. Upon satisfaction of the covenants and conditions set forth in Sections 2.2 and 2.3, the Closing shall occur at the offices of the Placement Agent or such other location as the parties shall mutually agree. Unless otherwise directed by the Placement Agent, settlement of the Shares shall occur via DVP (i.e., on the Closing Date, the Company shall issue the Shares registered in the Purchasers' names and addresses and released by the Depositary directly to the account(s) at the Placement Agent identified by each Purchaser; upon receipt of such Shares, the Placement Agent shall promptly electronically deliver such Shares to the applicable Purchaser, and payment therefor shall be made by the Placement Agent (or its clearing firm) by wire transfer to the Company). Notwithstanding anything herein to the contrary, if at any time on or after the time of execution of this Agreement by the Company and an applicable Purchaser through the Closing (the "Pre-Settlement Period"), such Purchaser sells to any Person all, or any portion, of any Shares to be issued hereunder to such Purchaser at the Closing (collectively, the "Pre-Settlement Shares"), such Person shall, automatically hereunder (without any additional required actions by such

Purchaser or the Company), be deemed to be a Purchaser under this Agreement unconditionally bound to purchase, and the Company shall be deemed unconditionally bound to sell, such Pre-Settlement Shares to such Person at the Closing; provided, that the Company shall not be required to deliver any Pre-Settlement Shares to such Purchaser prior to the Company's receipt of the Subscription Amount for such Pre-Settlement Shares hereunder; provided, further, that the Company hereby acknowledges and agrees that the forgoing shall not constitute a representation or covenant by such Purchaser as to whether or not such Purchaser will elect to sell any Pre-Settlement Shares during the Pre-Settlement Period. The decision to sell any Shares will be made in the sole discretion of such Purchaser from time to time, including during the Pre-Settlement Period.

2.2 Deliveries.

(a) On or prior to the Closing Date, the Company shall deliver or cause to be delivered to each Purchaser the following:

(i) this Agreement duly executed by the Company;

(ii) the Company's wire instructions, on Company letterhead and executed by the Company's Chief Executive Officer or Chief Financial Officer;

(iii) subject to the last sentence in Section 2.1, a copy of the irrevocable instructions to the Depositary instructing the Depositary to deliver on an expedited basis via The Depository Trust Company Deposit or Withdrawal at Custodian system ("DWAC") ADSs equal to the portion of such Purchaser's Subscription Amount applicable to ADSs divided by the Per ADS Purchase Price, registered in the name of such Purchaser;

(iv) for each Purchaser of Pre-Funded Warrants pursuant to Section 2.1, a Pre-Funded Warrant registered in the name of such Purchaser to purchase up to a number of Ordinary Shares represented by ADSs equal to the portion of such Purchaser's Subscription Amount applicable to Pre-Funded Warrants divided by the sum of the Per Pre-Funded Warrant Purchase Price and an exercise price equal to $0.0001, subject to adjustment therein;

(v) the Preliminary Prospectus and the Prospectus (which may be delivered in accordance with Rule 172 under the Securities Act);

(vi) a Common Warrant registered in the name of such Purchaser to purchase up to a number of Ordinary Shares represented by ADSs equal to 100% of such Purchaser's Ordinary Shares represented by ADSs or Pre-Funded Warrants, as applicable, with an exercise price per ADS equal to $[·], subject to adjustment therein;

(vii) the duly executed Lock-Up Agreements;

(viii) a legal opinion of Company U.S. Counsel, in form reasonably acceptable to the Placement Agent and the Purchasers; and

(ix) a legal opinion of Company Israeli Counsel, in form reasonably acceptable to the Placement Agent and the Purchasers.

(b) On or prior to the Closing Date, each Purchaser shall deliver or cause to be delivered to the Company, the following:

(i) this Agreement duly executed by such Purchaser; and

(ii) such Purchaser's Subscription Amount with respect to the Securities purchased by such Purchaser, which shall be made available for DVP settlement with the Company or its designees.

2.3 Closing Conditions.

(a) The obligations of the Company hereunder in connection with the Closing are subject to the following conditions being met:

(i) the accuracy in all material respects (or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects) when made and on the Closing Date of the representations and warranties of the Purchasers contained herein (unless as of a specific date therein in which case they shall be accurate as of such date);

(ii) all obligations, covenants and agreements of each Purchaser required to be performed at or prior to the Closing Date shall have been performed; and

(iii) the delivery by each Purchaser of the items set forth in Section 2.2(b) of this Agreement.

(b) The respective obligations of the Purchasers hereunder in connection with the Closing are subject to the following conditions being met:

(i) the accuracy in all material respects (or, to the extent representations or warranties are qualified by materiality or Material Adverse Effect, in all respects) when made and on the Closing Date of the representations and warranties of the Company contained herein (unless as of a specific date therein in which case they shall be accurate as of such date);

(ii) all obligations, covenants and agreements of the Company required to be performed at or prior to the Closing Date shall have been performed;

(iii) the delivery by the Company of the items set forth in Section 2.2(a) of this Agreement;

(iv) there shall have been no Material Adverse Effect with respect to the Company since the date hereof; and

(v) from the date hereof to the Closing Date, trading in the ADSs and Company's securities shall not have been suspended by the Commission or any Trading Market, and, at any time prior to the Closing Date, trading in securities generally as reported by Bloomberg L.P. shall not have been suspended or limited, or minimum prices shall not have been established on securities whose trades are reported by such service, or on any Trading Market, nor shall a banking moratorium have been declared either by the United States or New York State nor shall there have occurred after the date of this Agreement any material outbreak or escalation of hostilities or other national or international calamity of such magnitude in its effect on, or any material adverse change in, any financial market which, in each case, in the reasonable judgment of such Purchaser, makes it impracticable or inadvisable to purchase the Securities at the Closing.

ARTICLE III.
REPRESENTATIONS AND WARRANTIES

3.1 Representations and Warranties of the Company. Except as set forth in the Disclosure Schedules, which Disclosure Schedules shall be deemed a part hereof and shall qualify any representation made herein, or as disclosed in the Registration Statement or the Preliminary Prospectus, the Company hereby makes the following representations and warranties to each Purchaser:

(a) Subsidiaries. The Company owns, directly or indirectly, all of the capital shares or other equity interests of each Subsidiary, free and clear of any Liens, except as set forth in the SEC Reports, and all of the issued and outstanding shares of capital shares of each Subsidiary are validly issued and are fully paid, non-assessable and free of preemptive and similar rights to subscribe for or purchase securities. If the Company has no subsidiaries, all other references to the Subsidiaries or any of them in the Transaction Documents shall be disregarded.

(b) Organization and Qualification. The Company and each of the Subsidiaries is an entity duly incorporated or otherwise organized, validly existing, and, if applicable under the laws of the jurisdiction in which they are formed, in good standing under the laws of the jurisdiction of its incorporation or organization, with the requisite power and authority to own and use its properties and assets and to carry on its business as currently conducted. No proceedings have been instituted in the State of Israel for the dissolution of the Company or any of its Israeli Subsidiaries. The Company is not currently designated as a “breaching company” (within the meaning of the Israeli Companies Law, 5759-1999) by the Registrar of Companies of the State of Israel, nor has a proceeding been instituted by the Registrar of Companies in Israel for the dissolution of the Company or Subsidiaries. Neither the Company nor any Subsidiary is in violation nor default of any of the provisions of its respective memorandum of association, articles of association, certificate or articles of incorporation, bylaws or other organizational or charter documents. Each of the Company and the Subsidiaries is duly qualified to conduct business and is in good standing as a foreign corporation or other entity in each jurisdiction in which the nature of the business conducted or property owned by it makes such qualification necessary, except where the failure to be so qualified or in good standing, as the case may be, could not have or reasonably be expected to result in: (i) a material adverse effect on the legality, validity or enforceability of any Transaction Document, (ii) a material adverse effect on the results of operations, assets, business, prospects or condition (financial or otherwise) of the Company and the Subsidiaries, taken as a whole, or (iii) a material adverse effect on the Company’s ability to perform in any material respect on a timely basis its obligations under any Transaction Document (any of (i), (ii) or (iii), a “Material Adverse Effect”) and no Proceeding has been instituted in any such jurisdiction revoking, limiting or curtailing or seeking to revoke, limit or curtail such power and authority or qualification.

(c) Authorization; Enforcement. The Company has the requisite corporate power and authority to enter into and to consummate the transactions contemplated by this Agreement and each of the other Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of this Agreement and each of the other Transaction Documents by the Company and the consummation by it of the transactions contemplated hereby and thereby have been duly authorized by all necessary action on the part of the Company and no further action is required by the Company, the Board of Directors, a committee of the Board of Directors or the Company’s shareholders in connection herewith or therewith other than in connection with the Required Approvals. This Agreement and each other Transaction Document to which it is a party has been (or upon delivery will have been) duly executed by the Company and, when delivered in accordance with the terms hereof and thereof, will constitute the valid and binding obligation of the Company enforceable against the Company in accordance with its terms, except (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors’ rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(d) No Conflicts. Except as set forth in Schedule 3.1(d), the execution, delivery and performance by the Company of this Agreement and the other Transaction Documents to which it is a party, the issuance and sale of the Securities and the consummation by it of the transactions contemplated hereby and thereby do not and will not (i) conflict with or violate any provision of the Company’s or any Subsidiary’s memorandum of association, articles of association, certificate or articles of incorporation, bylaws or other organizational or charter documents, or (ii) conflict with, or constitute a default (or an event that with notice or lapse of time or both would become a default) under, result in the creation of any Lien upon any of the properties or assets of the Company or any Subsidiary, or give to others any rights of termination, amendment, anti-dilution or similar adjustments acceleration or cancellation (with or without notice, lapse of time or both) of, any agreement, credit facility, debt or other instrument (evidencing a Company or Subsidiary debt or otherwise) or other understanding to which the Company or any Subsidiary is a party or by which any property or asset of the Company or any Subsidiary is bound or affected, or (iii) subject to the Required Approvals, conflict with or result in a violation of any law, rule, regulation, order, judgment, injunction, decree or other restriction of any court or governmental authority to which the Company or a Subsidiary is subject (including federal and state securities laws and regulations), or by which any property or asset of the Company or a Subsidiary is bound or affected; except in the case of each of clauses (ii) and (iii), such as could not have or reasonably be expected to result in a Material Adverse Effect.

(e) Filings, Consents and Approvals. The Company is not required to obtain any consent, waiver, authorization or order of, give any notice to, or make any filing or registration with, any court or other federal, state, local or other governmental authority or other Person in connection with the execution, delivery and performance by the Company of the Transaction Documents, other than: (i) the filings required pursuant to Section 4.4 of this Agreement, (ii) the filing with the Commission of the Prospectus, (iii) notices and/or application(s) to and approvals by each applicable Trading Market for the listing of the applicable Securities for trading thereon in the time and manner required thereby, (iv) filings required by the Israeli Registrar of Companies, and (v) such other filings required to be made under applicable state securities laws, the Israeli Securities Authority and the Securities Laws (collectively, the "Required Approvals").

(f) Issuance of the Securities; Registration. The Shares and Warrant Shares are duly authorized and, when issued and paid for in accordance with the applicable Transaction Documents, will be duly and validly issued, fully paid and non-assessable, free and clear of all Liens imposed by the Company. The Warrants are duly authorized and, when issued in accordance with this Agreement, will be duly and validly issued, and free and clear of all Liens imposed by the Company. The Company has reserved from its duly authorized share capital the maximum number of Ordinary Shares issuable pursuant to this Agreement and the Warrants. The Company has prepared and filed the Registration Statement in conformity with the requirements of the Securities Act, which became effective on August [·], 2022, including the Prospectus, and such amendments and supplements thereto as may have been required to the date of this Agreement. The Company and the Depositary have prepared and filed with the Commission a registration statement relating to ADSs on Form F-6 (File No. 333-212698) for registration under the Securities Act (the "ADS Registration Statement"). The Registration Statement and ADS Registration Statement are effective under the Securities Act and no stop order preventing or suspending the effectiveness of the Registration Statement or suspending or preventing the use of the Preliminary Prospectus or the Prospectus has been issued by the Commission and no proceedings for that purpose have been instituted or, to the knowledge of the Company, are threatened by the Commission. The Company, if required by the rules and regulations of the Commission, shall file the Preliminary Prospectus or the Prospectus with the Commission pursuant to Rule 424(b). At the time the Registration Statement, ADS Registration Statement and any amendments thereto became effective as determined under the Securities Act, at the date of this Agreement and at the Closing Date, the Registration Statement and any amendments thereto conformed and will conform in all material respects to the requirements of the Securities Act and did not and will not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein not misleading; and the Prospectus and any amendments or supplements thereto, at the time the Preliminary Prospectus, the Prospectus or any amendment or supplement thereto was issued and at the Closing Date, conformed and will conform in all material respects to the requirements of the Securities Act and did not and will not contain an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

(g) Capitalization. The capitalization of the Company as of the date hereof is as set forth on Schedule 3.1(g). The Company has not issued any shares since its most recently filed periodic report under the Exchange Act. No Person has any right of first refusal, preemptive right, right of participation, or any similar right to participate in the transactions contemplated by the Transaction Documents. Except as set forth on Schedule 3.1(g) and as a result of the purchase and sale of the Securities, there are no outstanding options, warrants, scrip rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any Person any right to subscribe for or acquire, any ADSs, Ordinary Shares, or contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to issue additional ADSs, Ordinary Shares or Ordinary Share Equivalents. The issuance and sale of the Securities will not obligate the Company to issue ADSs or Ordinary Shares or other securities to any Person (other than the Purchasers) and will not result in a right of any holder of Company securities to adjust the exercise, conversion, exchange or reset price under any of such securities. There are no outstanding securities or instruments of the Company or any Subsidiary that contain any redemption or similar provisions, and there are no contracts, commitments, understandings or arrangements by which the Company or any Subsidiary is or may become bound to redeem a security of the Company or such Subsidiary. The Company does not have any share appreciation rights or "phantom share" plans or agreements or any similar plan or agreement. All of the outstanding shares of the Company are duly authorized, validly issued, fully paid and non-assessable, have been issued in compliance with all federal and state securities laws where applicable, and none of such outstanding shares was issued in violation of any preemptive rights or similar rights to subscribe for or purchase securities. Except for the Required Approvals, no further approval or authorization of any shareholder, the Board of Directors or others is required for the issuance and sale of the Securities. There are no shareholders agreements, voting agreements or other similar agreements with respect to the Company's share capital to which the Company is a party or, to the knowledge of the Company, between or among any of the Company's shareholders.

(h) SEC Reports; Financial Statements. The Company has filed all reports, schedules, forms, statements and other documents required to be filed by the Company under the Securities Act and the Exchange Act, including pursuant to Section 13(a) or 15(d) thereof, for the one year preceding the date hereof (or such shorter period as the Company was required by law or regulation to file such materials) (the foregoing materials, including the exhibits thereto and documents incorporated by reference therein, together with the Preliminary Prospectus and the Prospectus, being collectively referred to herein as the "SEC Reports") on a timely basis or has received a valid extension of such time of filing and has filed any such SEC Reports prior to the expiration of any such extension. As of their respective dates, the SEC Reports complied in all material respects with the requirements of the Securities Act and the Exchange Act, as applicable, and none of the SEC Reports, when filed, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. The financial statements of the Company included in the SEC Reports comply in all material respects with applicable accounting requirements and the rules and regulations of the Commission with respect thereto as in effect at the time of filing. Such financial statements have been prepared in accordance with GAAP, except as may be otherwise specified in such financial statements or the notes thereto and except that unaudited financial statements may not contain all footnotes required by GAAP, and fairly present in all material respects the financial position of the Company and its consolidated Subsidiaries as of and for the dates thereof and the results of operations and cash flows for the periods then ended, subject, in the case of unaudited statements, to normal, immaterial, year-end audit adjustments.

(i) Material Changes; Undisclosed Events, Liabilities or Developments. Since the date of the latest audited financial statements included within the SEC Reports, except as disclosed in a subsequent SEC Report filed prior to the date hereof, (i) there has been no event, occurrence or development that has had or that could reasonably be expected to result in a Material Adverse Effect, (ii) the Company has not incurred any liabilities (contingent or otherwise) other than (A) trade payables and accrued expenses incurred in the ordinary course of business consistent with past practice and strategic acquisitions and (B) liabilities not required to be reflected in the Company's financial statements pursuant to GAAP or disclosed in filings made with the Commission, (iii) the Company has not altered its method of accounting, (iv) the Company has not declared or made any dividend or distribution of cash or other property to its shareholders or purchased, redeemed or made any agreements to purchase or redeem any of its shares and (v) the Company has not issued any equity securities to any officer, director or Affiliate, except pursuant to existing Company share option plans. The Company does not have pending before the Commission any request for confidential treatment of information. Except for the issuance of the Securities contemplated by this Agreement or as set forth on Schedule 3.1(i), no event, liability, fact, circumstance, occurrence or development has occurred or exists or is reasonably expected to occur or exist with respect to the Company or its Subsidiaries or their respective businesses, prospects, properties, operations, assets or financial condition that would be required to be disclosed by the Company under applicable securities laws at the time this representation is made or deemed made that has not been publicly disclosed at least one (1) Trading Day prior to the date that this representation is made.

(j) Litigation. Except as set forth on Schedule 3.1(j), there is no action, suit, inquiry, notice of violation, proceeding or investigation pending or, to the knowledge of the Company, threatened against or affecting the Company, any Subsidiary or any of their respective properties before or by any court, arbitrator, governmental or administrative agency or regulatory authority (federal, state, county, local or foreign) (collectively, an "Action") which (i) adversely affects or challenges the legality, validity or enforceability of any of the Transaction Documents, the Shares or the Warrant Shares (ii) could, if there were an unfavorable decision, have or reasonably be expected to result in a Material Adverse Effect. Except as set forth on Schedule 3.1(j), neither the Company nor any Subsidiary, nor any director or officer thereof, is or has been the subject of any Action involving a claim of violation of or liability under federal or state securities laws or a claim of breach of fiduciary duty, which could result in a Material Adverse Effect. There has not been, and to the knowledge of the Company, there is not pending or contemplated, any investigation by the Israel Securities Authority or the Commission involving the Company or any current or former director or officer of the Company. The Commission has not issued any stop order or other order suspending the effectiveness of any registration statement filed by the Company or any Subsidiary under the Exchange Act or the Securities Act.

(k) Labor Relations. No labor dispute exists or, to the knowledge of the Company, is imminent with respect to any of the employees of the Company, which could reasonably be expected to result in a Material Adverse Effect. None of the Company's or its Subsidiaries' employees is a member of a union that relates to such employee's relationship with the Company or such Subsidiary, and neither the Company nor any of its Subsidiaries is a party to a collective bargaining agreement, and the Company and its Subsidiaries believe that their relationships with their employees are good. To the knowledge of the Company, no executive officer of the Company or any Subsidiary, is, or is now expected to be, in violation of any material term of any employment contract, confidentiality, disclosure or proprietary information agreement or non-competition agreement, or any other contract or agreement or any restrictive covenant in favor of any third party, and the continued employment of each such executive officer does not subject the Company or any of its Subsidiaries to any liability with respect to any of the foregoing matters. The Company and its Subsidiaries are in compliance with all applicable U.S. federal, state, local and foreign (including Israeli) laws and regulations relating to employment and employment practices, terms and conditions of employment and wages and hours, except where the failure to be in compliance could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(l) Compliance. Neither the Company nor any Subsidiary: (i) is in default under or in violation of (and no event has occurred that has not been waived that, with notice or lapse of time or both, would result in a default by the Company or any Subsidiary under), nor has the Company or any Subsidiary received notice of a claim that it is in default under or that it is in violation of, any indenture, loan or credit agreement or any other agreement or instrument to which it is a party or by which it or any of its properties is bound (whether or not such default or violation has been waived), (ii) is in violation of any judgment, decree or order of any court, arbitrator or other governmental authority or (iii) is or has been in violation of any statute, rule, ordinance or regulation of any governmental authority, including without limitation all foreign, federal, state and local laws relating to taxes, environmental protection, occupational health and safety, product quality and safety and employment and labor matters, except in each case of (i), (ii) and (iii) as could not have or reasonably be expected to result in a Material Adverse Effect.

(m) Regulatory Permits. The Company and the Subsidiaries possess all certificates, authorizations and permits issued by the appropriate federal, state, local or foreign regulatory authorities necessary to conduct their respective businesses as described in the SEC Reports, except where the failure to possess such certificates, authorizations or permits could not reasonably be expected to result in a Material Adverse Effect ("Material Permits"), and neither the Company nor any Subsidiary has received any notice of proceedings relating to the revocation or modification of any Material Permit.

(n) Title to Assets. The Company and the Subsidiaries have good and marketable title in fee simple to all real property owned by them and good and marketable title in all personal property owned by them that is material to the business of the Company and the Subsidiaries, in each case free and clear of all Liens, except for (i) Liens as do not materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company and the Subsidiaries and (ii) Liens for the payment of Israeli, federal, state or other taxes, for which appropriate reserves have been made therefor in accordance with GAAP and, the payment of which is neither delinquent nor subject to penalties. Any real property and facilities held under lease by the Company and the Subsidiaries are held by them under valid, subsisting and enforceable leases with which the Company and the Subsidiaries are in compliance in all material respects.

(o) Intellectual Property. The Company and the Subsidiaries have, or have rights to use, all patents, patent applications, trademarks, trademark applications, service marks, trade names, trade secrets, inventions, copyrights, licenses and other intellectual property rights and similar rights necessary or required for use in connection with their respective businesses as described in the SEC Reports and which the failure to so have could have a Material Adverse Effect (collectively, the "Intellectual Property Rights"). None of, and neither the Company nor any Subsidiary has received a notice (written or otherwise) that any of, the Intellectual Property Rights has expired, terminated or been abandoned, or is expected to expire or terminate or be abandoned, within two (2) years from the date of this Agreement except as would not reasonably be expected to have a Material Adverse Effect. Neither the Company nor any Subsidiary has received, since the date of the latest audited financial statements included within the SEC Reports, a written notice of a claim or otherwise has any knowledge that the Intellectual Property Rights violate or infringe upon the rights of any Person, except as could not have or reasonably be expected to not have a Material Adverse Effect. To the knowledge of the Company, all such Intellectual Property Rights are enforceable and there is no existing infringement by another Person of any of the Intellectual Property Rights. The Company and its Subsidiaries have taken reasonable security measures to protect the secrecy, confidentiality and value of all of their intellectual properties, except where failure to do so could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Effect.

(p) Insurance. The Company and the Subsidiaries are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are prudent and customary in the businesses in which the Company and the Subsidiaries are engaged, including, but not limited to, directors and officers insurance coverage. Neither the Company nor any Subsidiary has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business without a significant increase in cost.

(q) Transactions with Affiliates and Employees. Except as set forth on Schedule 3.1(q), none of the officers or directors of the Company or any Subsidiary and, to the knowledge of the Company, none of the employees of the Company or any Subsidiary is presently a party to any transaction with the Company or any Subsidiary (other than for services as employees, officers and directors), including any contract, agreement or other arrangement providing for the furnishing of services to or by, providing for rental of real or personal property to or from, providing for the borrowing of money from or lending of money to or otherwise requiring payments to or from any officer, director or such employee or, to the knowledge of the Company, any entity in which any officer, director, or any such employee has a substantial interest or is an officer, director, trustee, shareholder, member or partner, in each case in excess of $120,000 other than for (i) payment of salary or consulting fees for services rendered, (ii) reimbursement for expenses incurred on behalf of the Company or a Subsidiary and (iii) other employee benefits, including share option agreements under any share option plan of the Company.

(r) Sarbanes-Oxley; Internal Accounting Controls. The Company and the Subsidiaries are in material compliance with any and all applicable requirements of the Sarbanes-Oxley Act of 2002 that are effective as of the date hereof, and any and all applicable rules and regulations promulgated by the Commission thereunder that are effective as of the date hereof and as of the Closing Date. The Company and the Subsidiaries maintain a system of internal accounting controls sufficient to provide reasonable assurance that: (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization, and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. The Company and the Subsidiaries have established disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and the Subsidiaries and designed such disclosure controls and procedures to ensure that information required to be disclosed by the Company in the reports it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the Commission's rules and forms. The Company's certifying officers have evaluated the effectiveness of the disclosure controls and procedures of the Company and the Subsidiaries as of the end of the period covered by the most recently filed Form 20-F under the Exchange Act (such date, the "Evaluation Date"). The Company presented in its most recently filed Form 20-F under the Exchange Act the conclusions of the certifying officers about the effectiveness of the disclosure controls and procedures based on their evaluations as of the Evaluation Date. Since the Evaluation Date, there have been no changes in the internal control over financial reporting (as such term is defined in the Exchange Act) that have materially affected, or is reasonably likely to materially affect, the internal control over financial reporting of the Company and its Subsidiaries.

(s) Certain Fees. No brokerage or finder's fees or commissions are or will be payable by the Company or any Subsidiary to any broker, financial advisor or consultant, finder, placement agent, investment banker, bank or other Person with respect to the transactions contemplated by the Transaction Documents (for the avoidance of doubt, the foregoing shall not include any fees and/or commissions owed to the Depositary). Other than for Persons engaged by any Purchaser, if any, the Purchasers shall have no obligation with respect to any fees or with respect to any claims made by or on behalf of other Persons for fees of a type contemplated in this Section that may be due in connection with the transactions contemplated by the Transaction Documents.

(t) Investment Company. The Company is not, and is not an Affiliate of, and immediately after receipt of payment for the Securities, will not be or be an Affiliate of, an "investment company" within the meaning of the Investment Company Act of 1940, as amended. The Company shall conduct its business in a manner so that it will not become an "investment company" subject to registration under the Investment Company Act of 1940, as amended.

(u) Registration Rights. No Person has any right to cause the Company to effect the registration under the Securities Act of any securities of the Company or any Subsidiary.

(v) Listing and Maintenance Requirements. The ADSs are registered pursuant to Section 12(b) or 12(g) of the Exchange Act, and the Company has taken no action designed to, or which to its knowledge is likely to have the effect of, terminating the registration of the ADSs under the Exchange Act nor has the Company received any notification that the Commission is contemplating terminating such registration. The ADSs are currently eligible for electronic transfer through The Depository Trust Company or another established clearing corporation and the Company is current in payment of the fees to The Depository Trust Company (or such other established clearing corporation) in connection with such electronic transfer.

(w) Application of Takeover Protections. The Company and the Board of Directors have taken all necessary action, if any, in order to render inapplicable any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or other similar anti-takeover provision under the Company's memorandum of association, articles of association or the laws of its state of incorporation that is or could become applicable to the Purchasers as a result of the Purchasers and the Company fulfilling their obligations or exercising their rights under the Transaction Documents, including without limitation as a result of the Company's issuance of the Securities and the Purchasers' ownership of the Securities.

(x) Disclosure. Except with respect to the material terms and conditions of the transactions contemplated by the Transaction Documents, the Company confirms that neither it nor any other Person acting on its behalf has provided any of the Purchasers or their agents or counsel with any information that it believes constitutes or might constitute material, non-public information which is not otherwise disclosed in the Prospectus. The Company understands and confirms that the Purchasers will rely on the foregoing representation in effecting transactions in securities of the Company. All of the disclosure furnished by or on behalf of the Company to the Purchasers regarding the Company and its Subsidiaries, their respective businesses and the transactions contemplated hereby, including the Disclosure Schedules to this Agreement, is true and correct in all material respects and does not contain any untrue statement of a material fact or omit to state any material fact necessary in order to make the statements made therein, in the light of the circumstances under which they were made, not misleading. The press releases disseminated by the Company during the twelve (12) months preceding the date of this Agreement taken as a whole do not contain any untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in light of the circumstances under which they were made and when made, not misleading. The Company acknowledges and agrees that no Purchaser makes or has made any representations or warranties with respect to the transactions contemplated hereby other than those specifically set forth in Section 3.2 hereof.

(y) No Integrated Offering. Assuming the accuracy of the Purchasers' representations and warranties set forth in Section 3.2, neither the Company, nor any of its Affiliates, nor any Person acting on its or their behalf has, directly or indirectly, made any offers or sales of any security or solicited any offers to buy any security, under circumstances that would cause this offering of the Securities to be integrated with prior offerings by the Company for purposes of any applicable shareholder approval provisions of any Trading Market on which any of the securities of the Company are listed or designated.

(z) Solvency. Based on the consolidated financial condition of the Company as of the Closing Date, after giving effect to the receipt by the Company of the proceeds from the sale of the Securities hereunder, (i) the fair saleable value of the Company's assets exceeds the amount that will be required to be paid on or in respect of the Company's existing debts and other liabilities (including known contingent liabilities) as they mature, (ii) the Company's assets do not constitute unreasonably small capital to carry on its business as now conducted and as proposed to be conducted including its capital needs taking into account the particular capital requirements of the business conducted by the Company, consolidated and projected capital requirements and capital availability thereof, and (iii) the current cash flow of the Company, together with the proceeds the Company would receive, were it to liquidate all of its assets, after taking into account all anticipated uses of the cash, would be sufficient to pay all amounts on or in respect of its liabilities when such amounts are required to be paid. The Company does not intend to incur debts beyond its ability to pay such debts as they mature (taking into account the timing and amounts of cash to be payable on or in respect of its debt). The Company has no knowledge of any facts or circumstances which lead it to believe that it will file for reorganization or liquidation under the bankruptcy or reorganization laws of any jurisdiction within one year from the Closing Date. Schedule 3.1(z) sets forth as of the date hereof all outstanding secured and unsecured Indebtedness of the Company or any Subsidiary, or for which the Company or any Subsidiary has commitments. For the purposes of this Agreement, "Indebtedness" means (x) any liabilities for borrowed money or amounts owed by the Company in excess of $50,000 (other than trade accounts payable incurred in the ordinary course of business), (y) all guaranties, endorsements and other contingent obligations in respect of indebtedness of others to third parties, whether or not the same are or should be reflected in the

Company's consolidated balance sheet (or the notes thereto), except guaranties by endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of business; and (z) the present value of any lease payments in excess of $50,000 due under leases required to be capitalized in accordance with GAAP. Neither the Company nor any Subsidiary is in default with respect to any Indebtedness.

(aa) Tax Compliance. Except for matters that would not, individually or in the aggregate, have or reasonably be expected to result in a Material Adverse Effect, the Company and its Subsidiaries each (i) has made or filed all Israeli and United States federal, state and local income and all foreign income and franchise tax returns, reports and declarations required by any jurisdiction to which it is subject, (ii) has paid all taxes and other governmental assessments and charges, fines or penalties that are material in amount, shown or determined to be due on such returns, reports and declarations and (iii) has set aside on its financial statements provision reasonably adequate for the payment of all material tax liability of which has not been finally determined and all material taxes for periods subsequent to the periods to which such returns, reports or declarations apply. There are no unpaid taxes in any material amount claimed to be due by the taxing authority of any jurisdiction, and the officers of the Company or of any Subsidiary know of no basis for any such claim.

(bb) Foreign Corrupt Practices. Neither the Company nor any Subsidiary, nor to the knowledge of the Company or any Subsidiary, any agent or other person acting on behalf of the Company or any Subsidiary, has (i) directly or indirectly, used any funds for unlawful contributions, gifts, entertainment or other unlawful expenses related to foreign or domestic political activity, (ii) made any unlawful payment to foreign or domestic government officials or employees or to any foreign or domestic political parties or campaigns from corporate funds, (iii) failed to disclose fully any contribution made by the Company or any Subsidiary (or made by any person acting on its behalf of which the Company is aware) which is in violation of law, or (iv) violated in any material respect any provision of FCPA.

(cc) Accountants. The Company's independent registered public accounting firm is as set forth in the Prospectus. To the knowledge and belief of the Company, such accounting firm (i) is a registered public accounting firm as required by the Exchange Act and (ii) shall express its opinion with respect to the financial statements to be included in the Company's Annual Report for the fiscal year ended December 31, 2022.

(dd) Acknowledgment Regarding Purchasers' Purchase of Securities. The Company acknowledges and agrees that each of the Purchasers is acting solely in the capacity of an arm's length purchaser with respect to the Transaction Documents and the transactions contemplated thereby. The Company further acknowledges that no Purchaser is acting as a financial advisor or fiduciary of the Company (or in any similar capacity) with respect to the Transaction Documents and the transactions contemplated thereby and any advice given by any Purchaser or any of their respective representatives or agents in connection with the Transaction Documents and the transactions contemplated thereby is merely incidental to the Purchasers' purchase of the Securities. The Company further represents to each Purchaser that the Company's decision to enter into this Agreement and the other Transaction Documents has been based solely on the independent evaluation of the transactions contemplated hereby by the Company and its representatives.

(ee) Acknowledgment Regarding Purchaser's Trading Activity. Anything in this Agreement or elsewhere herein to the contrary notwithstanding (except for Sections 3.2(f) and 4.12 hereof), it is understood and acknowledged by the Company that: (i) none of the Purchasers has been asked by the Company to agree, nor has any Purchaser agreed, to desist from purchasing or selling, long and/or short, securities of the Company, or "derivative" securities based on securities issued by the Company or to hold the Shares for any specified term; (ii) past or future open market or other transactions by any Purchaser, specifically including, without limitation, Short Sales or "derivative" transactions, before or after the closing of this or future private placement transactions, may negatively impact the market price of the Company's publicly-traded securities; (iii) any Purchaser, and counter-parties in "derivative" transactions to which any such Purchaser is a party, directly or indirectly, presently may have a "short" position in the Ordinary Shares and/or ADSs, and (iv) each Purchaser shall not be deemed to have any affiliation with or control over any arm's length counter-party in any "derivative" transaction. The Company further understands and acknowledges that (y) one or more Purchasers may engage in hedging activities at various times during the period that the ADSs and Shares are outstanding, and (z) such hedging activities (if any) could reduce the value of the existing shareholders' equity interests in the Company at and after the time that the hedging activities are being conducted. The Company acknowledges that such aforementioned hedging activities do not constitute a breach of any of the Transaction Documents.

(ff) Regulation M Compliance. The Company has not, and to its knowledge no one acting on its behalf has, (i) taken, directly or indirectly, any action designed to cause or to result in the stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of any of the ADSs or Shares, (ii) sold, bid for, purchased, or, paid any compensation for soliciting purchases of, any of the ADSs or Shares, or (iii) paid or agreed to pay to any Person any compensation for soliciting another to purchase any other securities of the Company, other than, in the case of clauses (ii) and (iii), compensation paid to the Company's placement agent in connection with the placement of the ADSs and Shares.

(gg) FDA. The Company does not have any pharmaceutical products approved for marketing by the U.S. Food and Drug Administration ("FDA") under the Federal Food, Drug, and Cosmetic Act, as amended, and the regulations thereunder ("FDCA"). The properties, business and operations of the Company have been and are being conducted in all material respects in accordance with the FDCA. The Company has not been informed by the FDA that the FDA will not approve an application for any product proposed to be marketed by the Company in the United States.

(hh) Stock Option Plans. Each stock option granted by the Company under the Company's stock option plan was granted (i) in accordance with the terms of the Company's stock option plan and (ii) with an exercise price at least equal to the fair market value of the Ordinary Share on the date such stock option would be considered granted under GAAP and applicable law. No stock option granted under the Company's stock option plan has been backdated.

(ii) Cybersecurity. Except as would not, individually or in the aggregate, have a Material Adverse Effect, (i) the Company and the Subsidiaries are presently in compliance with all applicable laws or statutes and all judgments, orders, rules and regulations of any court or arbitrator or governmental or regulatory authority, internal policies and contractual obligations relating to the privacy and security of the Company's or any Subsidiary's information technology and computer systems, networks, hardware, software, data (including the data of its respective customers, employees, suppliers, vendors and any third party data maintained by or on behalf of it), equipment or technology (collectively, "IT Systems and Data") and to the protection of such IT Systems and Data from unauthorized use, access, misappropriation or modification; (ii) the Company and the Subsidiaries have implemented and maintained commercially reasonable safeguards to maintain and protect its material confidential information and the integrity, continuous operation, redundancy and security of all IT Systems and Data; and (iii) the Company and the Subsidiaries have implemented backup and disaster recovery technology consistent with commercially reasonable industry standards and practices.

(jj) Office of Foreign Assets Control. Neither the Company nor any Subsidiary nor, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company or any Subsidiary is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("OFAC").

(kk) U.S. Real Property Holding Corporation. The Company is not and has never been a U.S. real property holding corporation within the meaning of Section 897 of the Internal Revenue Code of 1986, as amended, and the Company shall so certify upon Purchaser's request.

(ll) Bank Holding Company Act. Neither the Company nor any of its Subsidiaries or Affiliates is subject to the Bank Holding Company Act of 1956, as amended (the "BHCA") and to regulation by the Board of Governors of the Federal Reserve System (the "Federal Reserve"). Neither the Company nor any of its Subsidiaries or Affiliates owns or controls, directly or indirectly, five percent (5%) or more of the outstanding shares of any class of voting securities or twenty-five percent (25%) or more of the total equity of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve. Neither the Company nor any of its Subsidiaries or Affiliates exercises a controlling influence over the management or policies of a bank or any entity that is subject to the BHCA and to regulation by the Federal Reserve.

(mm) Money Laundering. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial record-keeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the Israeli Prohibition on Money Laundering Law, 2000, as amended, applicable money laundering statutes and applicable rules and regulations thereunder (collectively, the "Money Laundering Laws"), and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any Subsidiary with respect to the Money Laundering Laws is pending or, to the knowledge of the Company or any Subsidiary, threatened.

3.2 Representations and Warranties of the Purchasers. Each Purchaser, for itself and for no other Purchaser, hereby represents and warrants as of the date hereof and as of the Closing Date to the Company as follows (unless as of a specific date therein, in which case they shall be accurate as of such date):

(a) Organization; Authority. Such Purchaser is either an individual or an entity duly incorporated or formed, validly existing and in good standing under the laws of the jurisdiction of its incorporation or formation with full right, corporate, partnership limited liability company or similar power and authority to enter into and to consummate the transactions contemplated by the Transaction Documents and otherwise to carry out its obligations hereunder and thereunder. The execution and delivery of the Transaction Documents and performance by such Purchaser of the transactions contemplated by the Transaction Documents have been duly authorized by all necessary corporate, partnership, limited liability company or similar action, as applicable, on the part of such Purchaser. Each Transaction Document to which it is a party has been duly executed by such Purchaser, and when delivered by such Purchaser in accordance with the terms hereof, will constitute the valid and legally binding obligation of such Purchaser, enforceable against it in accordance with its terms, except: (i) as limited by general equitable principles and applicable bankruptcy, insolvency, reorganization, moratorium and other laws of general application affecting enforcement of creditors' rights generally, (ii) as limited by laws relating to the availability of specific performance, injunctive relief or other equitable remedies and (iii) insofar as indemnification and contribution provisions may be limited by applicable law.

(b) Understandings or Arrangements. Such Purchaser is acquiring the Securities as principal for its own account and has no direct or indirect arrangement or understandings with any other persons to distribute or regarding the distribution of such Securities (this representation and warranty not limiting such Purchaser's right to sell the Securities pursuant to the Registration Statement or otherwise in compliance with applicable federal and state securities laws).

(c) Purchaser Status. At the time such Purchaser was offered the Securities, it was, and as of the date hereof it is, and on each date on which it exercises any Warrants, it will be either (i) an "accredited investor" as defined in Rule 501(a)(1), (a)(2), (a)(3), (a)(7) or (a)(8) under the Securities Act, or (ii) a "qualified institutional buyer" as defined in Rule 144A(a) under the Securities Act.

(d) Experience of Such Purchaser. Such Purchaser, either alone or together with its representatives, has such knowledge, sophistication and experience in business and financial matters so as to be capable of evaluating the merits and risks of the prospective investment in the Securities, and has so evaluated the merits and risks of such investment. Such Purchaser is able to bear the economic risk of an investment in the Securities and, at the present time, is able to afford a complete loss of such investment.

(e) Access to Information. Such Purchaser acknowledges that it has had the opportunity to review the Transaction Documents (including all exhibits and schedules thereto) and the SEC Reports and has been afforded (i) the opportunity to ask such questions as it has deemed necessary of, and to receive answers from, representatives of the Company concerning the terms and conditions of the offering of the Securities and the merits and risks of investing in the Securities; (ii) access to information about the Company and its financial condition, results of operations, business, properties, management and prospects sufficient to enable it to evaluate its investment; and (iii) the opportunity to obtain such additional information that the Company possesses or can acquire without unreasonable effort or expense that is necessary to make an informed investment decision with respect to the investment. Such Purchaser acknowledges and agrees that neither the Placement Agent nor any Affiliate of the Placement Agent has provided such Purchaser with any information or advice with respect to the Securities nor is such information or advice necessary or desired. Neither the Placement Agent nor any Affiliate has made or makes any representation as to the Company or the quality of the Securities and the Placement Agent and any Affiliate may have acquired non-public information with respect to the Company which such Purchaser agrees need not be provided to it. In connection with the issuance of the Securities to such Purchaser, neither the Placement Agent nor any of its Affiliates has acted as a financial advisor or fiduciary to such Purchaser.

(f) Certain Transactions and Confidentiality. Other than consummating the transactions contemplated hereunder, such Purchaser has not, nor has any Person acting on behalf of or pursuant to any understanding with such Purchaser, directly or indirectly executed any purchases or sales, including Short Sales, of the securities of the Company during the period commencing as of the time that such Purchaser first received a term sheet (written or oral) from the Company or any other Person representing the Company setting forth the material terms of the transactions contemplated hereunder and ending immediately prior to the execution hereof. Notwithstanding the foregoing, in the case of a Purchaser that is a multi-managed investment vehicle whereby separate portfolio managers manage separate portions of such Purchaser's assets and the portfolio managers have no direct knowledge of the investment decisions made by the portfolio managers managing other portions of such Purchaser's assets, the representation set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that made the investment decision to purchase the Securities covered by this Agreement. Other than to other Persons party to this Agreement or to such Purchaser's representatives, including, without limitation, its officers, directors, partners, legal and other advisors, employees, agents and Affiliates, such Purchaser has maintained the confidentiality of all disclosures made to it in connection with this transaction (including the existence and terms of this transaction). Notwithstanding the foregoing, for the avoidance of doubt, nothing contained herein shall constitute a representation or warranty, or preclude any actions, with respect to locating or borrowing shares order to effect Short Sales or similar transactions in the future.

(g) No Voting Agreements. The Purchaser is not a party to any agreement or arrangement, whether written or oral, between the Purchaser and any other Purchaser and any of the Company's shareholders as of the date hereof or a corporation in which the Company's shareholders are an Interested Party (as defined in the Israeli Companies Law, 5759-1999 (the "Companies Law")) as of the date hereof, regulating the management of the Company, the shareholders' rights in the Company, the transfer of shares in the Company, including any voting agreements, shareholder agreements or any other similar agreement even if its title is different or has any other relations or agreements with any of the Company's shareholders, directors or officers.

(h) No Governmental Review. Such Purchaser understands that no Israeli or United States federal or state agency or any other government or governmental agency has passed on or made any recommendation or endorsement of the Securities or the fairness or suitability of the investment in the Securities nor have such authorities passed upon or endorsed the merits of the offering of the Securities.

(i) Brokers. Except as set forth on Schedule 3.2(i) or in the Prospectus, no agent, broker, investment banker, person or firm acting in a similar capacity on behalf of or under the authority of the Purchaser is or will be entitled to any broker's or finder's fee or any other commission or similar fee, directly or indirectly, for which the Company or any of its Affiliates after the Closing could have any liabilities in connection with this Agreement, any of the transactions contemplated by this Agreement, or on account of any action taken by the Purchaser in connection with the transactions contemplated by this Agreement.

(j) Independent Advice. Each Purchaser understands that nothing in this Agreement or any other materials presented by or on behalf of the Company to the Purchaser in connection with the purchase of the Securities constitutes legal, tax or investment advice.

The Company acknowledges and agrees that the representations contained in this Section 3.2 shall not modify, amend or affect such Purchaser's right to rely on the Company's representations and warranties contained in this Agreement or any representations and warranties contained in any other Transaction Document or any other document or instrument executed and/or delivered in connection with this Agreement or the consummation of the transactions contemplated hereby. Notwithstanding the foregoing, for the avoidance of doubt, nothing contained herein shall constitute a representation or warranty, or preclude any actions, with respect to locating or borrowing shares in order to effect Short Sales or similar transactions in the future.

ARTICLE IV.
OTHER AGREEMENTS OF THE PARTIES

4.1 Legends. The Shares, the Warrants, the Warrant ADSs and the Warrant Shares shall be issued free of legends. If at any time following the date hereof the Registration Statement is not effective or is not otherwise available for the sale of the Shares, the Warrants, the Warrant ADSs or the Warrant Shares, the Company shall immediately notify the holders of the Warrants in writing that such registration statement is not then effective and thereafter shall promptly notify such holders when the registration statement is effective again and available for the sale of the Shares, the Warrants, the Warrant ADSs or the Warrant Shares (it being understood and agreed that the foregoing shall not limit the ability of the Company to issue, or any Purchaser to sell, any of the Shares, the Warrants, the Warrant ADSs or the Warrant Shares in compliance with applicable federal and state securities laws). The Company shall use commercially reasonable best efforts to keep a registration statement (including the Registration Statement) registering the issuance of the Warrant Shares effective during the term of the Warrants.

4.2 Furnishing of Information; Public Information. Until the earliest of the time that (i) no Purchaser owns Securities, or (ii) the Common Warrants have expired, the Company covenants to maintain the registration of the ADSs under Section 12(b) or 12(g) of the Exchange Act and to timely file (or obtain extensions in respect thereof and file within the applicable grace period) all reports required to be filed by the Company after the date hereof pursuant to the Exchange Act, even if the Company is not then subject to the reporting requirements of the Exchange Act, except in the event that the Company consummates: (i) any transaction or series of related transactions as a result of which any Person (together with its Affiliates) acquires then outstanding securities of the Company representing more than fifty percent (50%) of the voting control of the Company; (ii) a merger or reorganization of the Company with one or more other entities in which the Company is not the surviving entity; or (iii) a sale of all or substantially all of the assets of the Company, where the consummation of such transaction results in the Company no longer being subject to the reporting requirements of the Exchange Act, provided, however, only in connection with subsections (i) and (iii) of this Section 4.2, that such limitation shall not apply on or after the date as of which the Purchasers may sell all of their Securities without restriction or limitation pursuant to Rule 144.

4.3 Integration. The Company shall not sell, offer for sale or solicit offers to buy or otherwise negotiate in respect of any security (as defined in Section 2 of the Securities Act) that would be integrated with the offer or sale of the Securities for purposes of the rules and regulations of any Trading Market such that it would require shareholder approval prior to the closing of such other transaction unless shareholder approval is obtained before the closing of such subsequent transaction.

4.4 Securities Laws Disclosure; Publicity. The Company shall (a) by the Disclosure Time, issue a press release disclosing the material terms of the transactions contemplated hereby, and (b) file a Report on Form 6-K, including the Transaction Documents as exhibits thereto, with the Commission within the time required by the Exchange Act. From and after the issuance of such press release, the Company represents to the Purchasers that it shall have publicly disclosed all material, non-public information delivered to any of the Purchasers by the Company or any of its Subsidiaries, or any of their respective officers, directors, employees or agents in connection with the transactions contemplated by the Transaction Documents. In addition, effective upon the issuance of such press release, the Company acknowledges and agrees that any and all confidentiality or similar obligations under any agreement, whether written or oral, between the Company, any of its Subsidiaries or any of their respective officers, directors, agents, employees or Affiliates on the one hand, and any of the Purchasers or any of their Affiliates on the other hand, shall terminate. The Company and each Purchaser shall consult with each other in issuing any other press releases with respect to the transactions contemplated hereby, and neither the Company nor any Purchaser shall issue any such press release nor otherwise make any such public statement without the prior consent of the Company, with respect to any press release of any Purchaser, or without the prior consent of each Purchaser, with respect to any press release of the Company, which consent shall not unreasonably be withheld or delayed, except if such disclosure is required by law, in which case the disclosing party shall promptly provide the other party with prior notice of such public statement or communication. Notwithstanding the foregoing, the Company shall not publicly disclose the name of any Purchaser, or include the name of any Purchaser in any filing with the Commission or any regulatory agency or Trading Market, without the prior written consent of such Purchaser, except (a) as required by federal securities law in connection with the filing of final Transaction Documents with the Commission, and (b) to the extent such disclosure is required by law or Trading Market regulations, in which case the Company shall provide the Purchasers with prior notice of such disclosure permitted under this clause (b).

4.5 Shareholder Rights Plan. No claim will be made or enforced by the Company or, with the consent of the Company, any other Person, that any Purchaser is an “Acquiring Person” under any control share acquisition, business combination, poison pill (including any distribution under a rights agreement) or similar anti-takeover plan or arrangement in effect or hereafter adopted by the Company, or that any Purchaser could be deemed to trigger the provisions of any such plan or arrangement, by virtue of receiving Securities under the Transaction Documents or under any other agreement between the Company and the Purchasers.

4.6 Non-Public Information. Except with respect to the material terms and conditions of the transactions contemplated by the Transaction Documents, which shall be disclosed pursuant to Section 4.4, the Company covenants and agrees that neither it, nor any other Person acting on its behalf will provide any Purchaser or its agents or counsel with any information that the Company believes constitutes material non-public information, unless prior thereto such Purchaser shall have entered into a written agreement with the Company regarding the confidentiality and use of such information. The Company understands and confirms that each Purchaser shall be relying on the foregoing covenant in effecting transactions in securities of the Company. To the extent that the Company delivers any material, non-public information to a Purchaser without such Purchaser’s consent, the Company hereby covenants and agrees that such Purchaser shall not have any duty of confidentiality to the Company, any of its Subsidiaries, or any of their respective officers, directors, agents, employees or Affiliates, or a duty to the Company, and of its Subsidiaries or any of their respective officers, directors, agents, employees or Affiliates not to trade on the basis of, such material, non-public information, provided that the Purchaser shall remain subject to applicable law. To the extent that any notice provided pursuant to any Transaction Document constitutes, or contains, material, non-public information regarding the Company or any Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Current Report on Form 6-K. The Company understands and confirms that each Purchaser shall be relying on the foregoing covenant in effecting transactions in securities of the Company.

4.7 Use of Proceeds. The Company shall use the net proceeds from the sale of the Securities hereunder for working capital purposes and shall not use such proceeds: (a) for the satisfaction of any portion of the Company's debt (other than payment of trade payables in the ordinary course of the Company's business or repayment of obligations outstanding as of the date of this Agreement consistent with prior practices), (b) for the redemption of any ADSs, Ordinary Shares or Ordinary Share Equivalents, (c) for the settlement of any outstanding litigation or (d) in violation of FCPA or OFAC regulations or similar applicable regulations.

4.8 Indemnification of Purchasers. Subject to the provisions of this Section 4.8, the Company will indemnify and hold each Purchaser and its directors, officers, shareholders, members, partners, employees and agents (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title), each Person who controls such Purchaser (within the meaning of Section 15 of the Securities Act and Section 20 of the Exchange Act), and the directors, officers, shareholders, agents, members, partners or employees (and any other Persons with a functionally equivalent role of a Person holding such titles notwithstanding a lack of such title or any other title) of such controlling persons (each, a "Purchaser Party") harmless from any and all losses, liabilities, obligations, claims, contingencies, damages, costs and expenses, including all judgments, amounts paid in settlements, court costs and reasonable attorneys' fees and costs of investigation that any such Purchaser Party may suffer or incur as a result of or relating to (a) any breach of any of the representations, warranties, covenants or agreements made by the Company in this Agreement or in the other Transaction Documents or (b) any action instituted against a Purchaser Party in any capacity, or any of them or their respective Affiliates, by any shareholder of the Company who is not an Affiliate of such Purchaser Party, with respect to any of the transactions contemplated by the Transaction Documents (unless such action is based upon a material breach of such Purchaser Party's representations, warranties or covenants under the Transaction Documents or any agreements or understandings such Purchaser Party may have with any such shareholder or any violations by such Purchaser Party of state or federal securities laws or any conduct by such Purchaser Party which is finally judicially determined to constitute fraud, gross negligence or willful misconduct). If any action shall be brought against any Purchaser Party in respect of which indemnity may be sought pursuant to this Agreement, such Purchaser Party shall promptly notify the Company in writing, and the Company shall have the right to assume the defense thereof with counsel of its own choosing reasonably acceptable to the Purchaser Party. Any Purchaser Party shall have the right to employ separate counsel in any such action and participate in the defense thereof, but the fees and expenses of such counsel shall be at the expense of such Purchaser Party except to the extent that (i) the employment thereof has been specifically authorized by the Company in writing, (ii) the Company has failed after a reasonable period of time to assume such defense and to employ counsel or (iii) in such action there is, in the reasonable opinion of counsel, a material conflict on any material issue between the position of the Company and the position of such Purchaser Party, in which case the Company shall be responsible for the reasonable fees and expenses of no more than one such separate counsel. The Company will not be liable to any Purchaser Party under this Agreement (y) for any settlement by a Purchaser Party effected without the Company's prior written consent, which shall not be unreasonably withheld or delayed; or (z) to the extent, but only to the extent that a loss, claim, damage or liability is attributable to any Purchaser Party's breach of any of the representations, warranties, covenants or agreements made by such Purchaser Party in this Agreement or in the other Transaction Documents. The indemnification required by this Section 4.8 shall be made by periodic payments of the amount thereof during the course of the investigation or defense, as and when bills are received or are incurred. The indemnity agreements contained herein shall be in addition to any cause of action or similar right of any Purchaser Party against the Company or others and any liabilities the Company may be subject to pursuant to law.

4.9 Listing of Shares. The Company hereby agrees to use commercially reasonable best efforts to maintain the listing or quotation of the ADSs and Warrant ADSs on each Trading Market on which each is currently listed, and concurrently with the Closing, the Company shall apply to list or quote all of the Warrant ADSs and/or ADSs on such Trading Markets and promptly secure the listing of all of the Warrant ADSs and ADSs on such Trading Markets. The Company further agrees, if the Company applies to have the ADSs traded on any other Trading Market, it will then include in such application all of the ADSs and Warrant ADSs, and will take such other action as is necessary to cause all of the ADSs and Warrant ADSs to be listed or quoted on such other Trading Market as promptly as possible. The Company will then take all action reasonably necessary to continue the listing and trading of its ADSs on a Trading Market and will comply in all material respects with the Company's reporting, filing and other obligations under the bylaws or rules of the Trading Market. The Company agrees to use commercially reasonable efforts to maintain the eligibility of the ADSs for electronic transfer through the Depository Trust Company or another established clearing corporation, including, without limitation, by timely payment of fees to the Depository Trust Company or such other established clearing corporation in connection with such electronic transfer.

4.10 Subsequent Equity Sales.

(a) From the date hereof until ninety (90) days after the Closing Date, neither the Company nor any Subsidiary shall issue, enter into any agreement to issue or announce the issuance or proposed issuance of any ADSs, Ordinary Shares or Ordinary Share Equivalents.

(b) From the date hereof until one-hundred eighty (180) days following the Closing Date, the Company shall be prohibited from effecting or entering into an agreement to effect any issuance by the Company or any of its Subsidiaries of ADSs, Ordinary Shares or Ordinary Share Equivalents (or a combination of units thereof) involving a Variable Rate Transaction. "Variable Rate Transaction" means a transaction in which the Company (i) issues or sells any debt or equity securities that are convertible into, exchangeable or exercisable for, or include the right to receive additional ADSs or Ordinary Shares either (A) at a conversion price, exercise price or exchange rate or other price that is based upon and/or varies with the trading prices of or quotations for the ADSs and Ordinary Shares at any time after the initial issuance of such debt or equity securities, or (B) with a conversion, exercise or exchange price that is subject to being reset at some future date after the initial issuance of such debt or equity security or upon the occurrence of specified or contingent events directly or indirectly related to the business of the Company or the market for ADSs or Ordinary Shares or (ii) enters into, or effects a transaction under, any agreement, including, but not limited to, an equity line of credit, whereby the Company may issue securities at a future determined price. Any Purchaser shall be entitled to obtain injunctive relief against the Company to preclude any such issuance, which remedy shall be in addition to any right to collect damages.

(c) Notwithstanding the foregoing, this Section 4.10 shall not apply in respect of an Exempt Issuance, except that no Variable Rate Transaction shall be an Exempt Issuance.

4.11 Equal Treatment of Purchasers. No consideration (including any modification of the Transaction Documents) shall be offered or paid to any Person to amend or consent to a waiver or modification of any provision of the Transaction Documents unless the same consideration is also offered to all of the parties to the Transaction Documents. For clarification purposes, this provision constitutes a separate right granted to each Purchaser by the Company and negotiated separately by each Purchaser, and is intended for the Company to treat the Purchasers as a class and shall not in any way be construed as the Purchasers acting in concert or as a group with respect to the purchase, disposition or voting of the ADSs, the Shares or otherwise.

4.12 Certain Transactions and Confidentiality. Each Purchaser, severally and not jointly with the other Purchasers, covenants that neither it nor any Affiliate acting on its behalf or pursuant to any understanding with it will execute any purchases or sales, including Short Sales of any of the Company's securities during the period commencing with the execution of this Agreement and ending at such time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial press release as described in Section 4.4. Each Purchaser, severally and not jointly with the other Purchasers, covenants that until such time as the transactions contemplated by this Agreement are publicly disclosed by the Company pursuant to the initial press release as described in Section 4.4, such Purchaser will maintain the confidentiality of the existence and terms of this transaction and the information included in the Disclosure Schedules. Notwithstanding the foregoing, and notwithstanding anything contained in this Agreement to the contrary, the Company expressly acknowledges and agrees that (i) no Purchaser makes any representation, warranty or covenant hereby that it will not engage in effecting transactions in any securities of the Company after the time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial press release as described in Section 4.4, (ii) no Purchaser shall be restricted or prohibited from effecting any transactions in any securities of the Company in accordance with applicable securities laws from and after the time that the transactions contemplated by this Agreement are first publicly announced pursuant to the initial press release as described in Section 4.4 and (iii) no Purchaser shall have any duty of confidentiality or duty not to trade in the securities of the Company to the Company or its Subsidiaries after the issuance of the initial press release as described in Section 4.4. Notwithstanding the foregoing, in the case of a Purchaser that is a multi-managed investment vehicle whereby separate portfolio managers manage separate portions of such Purchaser's assets and the portfolio managers have no direct knowledge of the investment decisions made by the portfolio managers managing other portions of such Purchaser's assets, the covenant set forth above shall only apply with respect to the portion of assets managed by the portfolio manager that made the investment decision to purchase the Securities covered by this Agreement.

4.13 Exercise Procedures. The form of Notice of Exercise included in the Warrants set forth the totality of the procedures required of the Purchasers in order to exercise the Warrants. No additional legal opinion, other information or instructions shall be required of the Purchasers to exercise their Warrants. Without limiting the preceding sentences, no ink-original Notice of Exercise shall be required, nor shall any medallion guarantee (or other type of guarantee or notarization) of any Notice of Exercise form be required in order to exercise the Warrants. The Company shall honor exercises of the Warrants and shall deliver Warrant ADSs and/or Warrant Shares in accordance with the terms, conditions and time periods set forth in the Transaction Documents.

4.14 Reservations of Shares. As of the date hereof, the Company has reserved and the Company shall continue to reserve and keep available at all times, free of preemptive rights, a sufficient number of Ordinary Shares for the purpose of enabling the Company to issue Ordinary Shares pursuant to this Agreement and Warrant Shares pursuant to any exercise of the Warrant ADSs.

4.15. Lock-Up Agreements. The Company shall not amend, modify, waive or terminate any provision of any of the Lock-Up Agreements without the prior written consent of the Placement Agent, except to extend the term of the lock-up period, and shall enforce the provisions of each Lock-Up Agreement in accordance with its terms. If any party to a Lock-Up Agreement breaches any provision of a Lock-Up Agreement, the Company shall promptly use its best efforts to seek specific performance of the terms of such Lock-Up Agreement.

ARTICLE V.
MISCELLANEOUS

5.1 Termination. This Agreement may be terminated by any Purchaser, as to such Purchaser's obligations hereunder only and without any effect whatsoever on the obligations between the Company and the other Purchasers, by written notice to the other parties, if the Closing has not been consummated on or before the fifth (5th) Trading Day following the date hereof; provided, however, that no such termination will affect the right of any party to sue for any breach by any other party (or parties).

5.2 Fees and Expenses. Except as expressly set forth in the Transaction Documents to the contrary, each party shall pay the fees and expenses of its advisers, counsel, accountants and other experts, if any, and all other expenses incurred by such party incident to the negotiation, preparation, execution, delivery and performance of this Agreement. The Company shall pay all Depositary Fees (including, without limitation, any fees required for same-day processing of any instruction letter delivered by the Company and any exercise notice delivered by a Purchaser), stamp taxes and other taxes and duties levied in connection with the delivery of any Securities to the Purchasers.

5.3 Entire Agreement. The Transaction Documents, together with the exhibits and schedules thereto, the Preliminary Prospectus and the Prospectus, contain the entire understanding of the parties with respect to the subject matter hereof and thereof and supersede all prior agreements and understandings, oral or written, with respect to such matters, which the parties acknowledge have been merged into such documents, exhibits and schedules.

5.4 Notices. Any and all notices or other communications or deliveries required or permitted to be provided hereunder shall be in writing and shall be deemed given and effective on the earliest of: (a) the time of transmission, if such notice or communication is delivered via facsimile at the facsimile number or email attachment at the email address as set forth on the signature pages attached hereto at or prior to 5:30 p.m. (New York City time) on a Trading Day, (b) the next Trading Day after the time of transmission, if such notice or communication is delivered via facsimile at the facsimile number or email attachment at the email address as set forth on the signature pages attached hereto on a day that is not a Trading Day or later than 5:30 p.m. (New York City time) on any Trading Day, (c) the second (2nd) Trading Day following the date of mailing, if sent by U.S. nationally recognized overnight courier service or (d) upon actual receipt by the party to whom such notice is required to be given. The address for such notices and communications shall be as set forth on the signature pages attached hereto. To the extent that any notice provided pursuant to any Transaction Document constitutes, or contains, material, non-public information regarding the Company or any Subsidiaries, the Company shall simultaneously file such notice with the Commission pursuant to a Report on Form 6-K.

5.5 Amendments; Waivers. No provision of this Agreement may be waived, modified, supplemented or amended except in a written instrument signed, in the case of an amendment, by the Company and the Purchasers who purchased at least 50.1% in interest of the sum of (i) the Shares and (ii) the Pre-Funded Warrant Shares initially issuable upon exercise of the Pre-Funded Warrants based on the initial Subscription Amounts hereunder, or, in the case of a waiver, by the party against whom enforcement of any such waived provision is sought; provided, that if any amendment, modification or waiver disproportionately and adversely impacts a Purchaser (or group of Purchasers), the consent of at least 50.1% in interest of such disproportionately impacted Purchaser (or group of Purchasers) shall also be required. No waiver of any default with respect to any provision, condition or requirement of this Agreement shall be deemed to be a continuing waiver in the future or a waiver of any subsequent default or a waiver of any other provision, condition or requirement hereof, nor shall any delay or omission of any party to exercise any right hereunder in any manner impair the exercise of any such right. Any proposed amendment or waiver that disproportionately, materially and adversely affects the rights and obligations of any Purchaser relative to the comparable rights and obligations of the other Purchasers shall require the prior written consent of such adversely affected Purchaser. Any amendment effected in accordance with this Section 5.5 shall be binding upon each Purchaser and holder of Securities and the Company.

5.6 Headings. The headings herein are for convenience only, do not constitute a part of this Agreement and shall not be deemed to limit or affect any of the provisions hereof.

5.7 Successors and Assigns. This Agreement shall be binding upon and inure to the benefit of the parties and their successors and permitted assigns. The Company may not assign this Agreement or any rights or obligations hereunder without the prior written consent of each Purchaser (other than by merger). Any Purchaser may assign any or all of its rights under this Agreement to any Person to whom such Purchaser assigns or transfers any Securities, provided that such transferee agrees in writing to be bound, with respect to the transferred Securities, by the provisions of the Transaction Documents that apply to the "Purchasers."

5.8 No Third-Party Beneficiaries. The Placement Agent shall be the third party beneficiary of the representations and warranties of the Company in Section 3.1 and the representations and warranties of the Purchasers in Section 3.2. This Agreement is intended for the benefit of the parties hereto and their respective successors and permitted assigns and is not for the benefit of, nor may any provision hereof be enforced by, any other Person, except as otherwise set forth in Section 4.8 and this Section 5.8.

5.9 Governing Law. All questions concerning the construction, validity, enforcement and interpretation of the Transaction Documents shall be governed by and construed and enforced in accordance with the internal laws of the

State of New York, without regard to the principles of conflicts of law thereof. Each party agrees that all legal proceedings concerning the interpretations, enforcement and defense of the transactions contemplated by this Agreement and any other Transaction Documents (whether brought against a party hereto or its respective affiliates, directors, officers, shareholders, partners, members, employees or agents) shall be commenced exclusively in the state and federal courts sitting in the City of New York. Each party hereby irrevocably submits to the exclusive jurisdiction of the state and federal courts sitting in the City of New York, Borough of Manhattan for the adjudication of any dispute hereunder or in connection herewith or with any transaction contemplated hereby or discussed herein (including with respect to the enforcement of any of the Transaction Documents), and hereby irrevocably waives, and agrees not to assert in any suit, action or proceeding, any claim that it is not personally subject to the jurisdiction of any such court, that such suit, action or proceeding is improper or is an inconvenient venue for such proceeding. Each party hereby irrevocably waives personal service of process and consents to process being served in any such suit, action or proceeding by mailing a copy thereof via registered or certified mail or overnight delivery (with evidence of delivery) to such party at the address in effect for notices to it under this Agreement and agrees that such service shall constitute good and sufficient service of process and notice thereof. Nothing contained herein shall be deemed to limit in any way any right to serve process in any other manner permitted by law. If either party shall commence an action, suit or proceeding to enforce any provisions of the Transaction Documents, then, in addition to the obligations of the Company under Section 4.8, the prevailing party in such action, suit or proceeding shall be reimbursed by the other party for its reasonable attorneys' fees and other costs and expenses incurred with the investigation, preparation and prosecution of such action or proceeding.

5.10 Survival. The representations and warranties contained herein shall survive the Closing and the delivery of the Securities for the applicable statute of limitations.

5.11 Execution. This Agreement may be executed in two or more counterparts, all of which when taken together shall be considered one and the same agreement and shall become effective when counterparts have been signed by each party and delivered to each other party, it being understood that the parties need not sign the same counterpart. In the event that any signature is delivered by facsimile transmission or by e-mail delivery of a ".pdf" format data file, such signature shall create a valid and binding obligation of the party executing (or on whose behalf such signature is executed) with the same force and effect as if such facsimile or ".pdf" signature page were an original thereof.

5.12 Severability. If any term, provision, covenant or restriction of this Agreement is held by a court of competent jurisdiction to be invalid, illegal, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions set forth herein shall remain in full force and effect and shall in no way be affected, impaired or invalidated, and the parties hereto shall use their commercially reasonable efforts to find and employ an alternative means to achieve the same or substantially the same result as that contemplated by such term, provision, covenant or restriction. It is hereby stipulated and declared to be the intention of the parties that they would have executed the remaining terms, provisions, covenants and restrictions without including any of such that may be hereafter declared invalid, illegal, void or unenforceable.

5.13 Rescission and Withdrawal Right. Notwithstanding anything to the contrary contained in (and without limiting any similar provisions of) any of the other Transaction Documents, whenever any Purchaser exercises a right, election, demand or option under a Transaction Document and the Company does not timely perform its related obligations within the periods therein provided, then such Purchaser may rescind or withdraw, in its sole discretion from time to time upon written notice to the Company, any relevant notice, demand or election in whole or in part without prejudice to its future actions and rights.

5.14 Replacement of Securities. If any certificate or instrument evidencing any Securities is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation thereof (in the case of mutilation), or in lieu of and substitution therefor, a new certificate or instrument, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction. The applicant for a new certificate or instrument under such circumstances shall also pay any reasonable third-party costs (including customary indemnity) associated with the issuance of such replacement Securities.

5.15 Remedies. In addition to being entitled to exercise all rights provided herein or granted by law, including recovery of damages, each of the Purchasers and the Company will be entitled to specific performance under the Transaction Documents. The parties agree that monetary damages may not be adequate compensation for any loss incurred by reason of any breach of obligations contained in the Transaction Documents and hereby agree to waive and not to assert in any action for specific performance of any such obligation the defense that a remedy at law would be adequate.

5.16 Payment Set Aside. To the extent that the Company makes a payment or payments to any Purchaser pursuant to any Transaction Document or a Purchaser enforces or exercises its rights thereunder, and such payment or payments or the proceeds of such enforcement or exercise or any part thereof are subsequently invalidated, declared to be fraudulent or preferential, set aside, recovered from, disgorged by or are required to be refunded, repaid or otherwise restored to the Company, a trustee, receiver or any other Person under any law (including, without limitation, any bankruptcy law, state or federal law, common law or equitable cause of action), then to the extent of any such restoration the obligation or part thereof originally intended to be satisfied shall be revived and continued in full force and effect as if such payment had not been made or such enforcement or setoff had not occurred.

5.17 Independent Nature of Purchasers' Obligations and Rights. The obligations of each Purchaser under any Transaction Document are several and not joint with the obligations of any other Purchaser, and no Purchaser shall be responsible in any way for the performance or non-performance of the obligations of any other Purchaser under any Transaction Document. Nothing contained herein or in any other Transaction Document, and no action taken by any Purchaser pursuant hereto or thereto, shall be deemed to constitute the Purchasers as a partnership, an association, a joint venture or any other kind of entity, or create a presumption that the Purchasers are in any way acting in concert or as a group with respect to such obligations or the transactions contemplated by the Transaction Documents. Each Purchaser shall be entitled to independently protect and enforce its rights including, without limitation, the rights arising out of this Agreement or out of the other Transaction Documents, and it shall not be necessary for any other Purchaser to be joined as an additional party in any proceeding for such purpose. Each Purchaser has been represented by its own separate legal counsel in its review and negotiation of the Transaction Documents. For reasons of administrative convenience only, each Purchaser and its respective counsel have chosen to communicate with the Company through Thompson Hine LLP, the legal counsel of the Placement Agent. Thompson Hine LLP does not represent any of the Purchasers and only represents the Placement Agent. The Company has elected to provide all Purchasers with the same terms and Transaction Documents for the convenience of the Company and not because it was required or requested to do so by any of the Purchasers. It is expressly understood and agreed that each provision contained in this Agreement and in each other Transaction Document is between the Company and a Purchaser, solely, and not between the Company and the Purchasers collectively and not between and among the Purchasers.

5.18 Saturdays, Sundays, Holidays, etc. If the last or appointed day for the taking of any action or the expiration of any right required or granted herein shall not be a Business Day, then such action may be taken or such right may be exercised on the next succeeding Business Day.

5.19 Liquidated Damages. The Company's obligations to pay any partial liquidated damages or other amounts owing under the Transaction Documents is a continuing obligation of the Company and shall not terminate until all unpaid partial liquidated damages and other amounts have been paid notwithstanding the fact that the instrument or security pursuant to which such partial liquidated damages or other amounts are due and payable shall have been canceled.

5.20 Construction. The parties agree that each of them and/or their respective counsel have reviewed and had an opportunity to revise the Transaction Documents and, therefore, the normal rule of construction to the effect that any ambiguities are to be resolved against the drafting party shall not be employed in the interpretation of the Transaction Documents or any amendments thereto. In addition, each and every reference to share prices, ADSs, and shares of Ordinary Shares in any Transaction Document shall be subject to adjustment for reverse and forward share splits, share dividends, share combinations and other similar transactions of the ADSs and Ordinary Shares that occur after the date of this Agreement.

5.21 **WAIVER OF JURY TRIAL. IN ANY ACTION, SUIT, OR PROCEEDING IN ANY JURISDICTION BROUGHT BY ANY PARTY AGAINST ANY OTHER PARTY, THE PARTIES EACH KNOWINGLY AND INTENTIONALLY, TO THE GREATEST EXTENT PERMITTED BY APPLICABLE LAW, HEREBY ABSOLUTELY, UNCONDITIONALLY, IRREVOCABLY AND EXPRESSLY WAIVES FOREVER TRIAL BY JURY.**

(Signature Pages Follow)

IN WITNESS WHEREOF, the parties hereto have caused this Securities Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

QUOIN PHARMACEUTICALS, LTD.

By: ____
Name:
Title:
With a copy to (which shall not constitute notice):

Address for Notice:

Email:
Fax:

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK
SIGNATURE PAGE FOR PURCHASER FOLLOWS]

IN WITNESS WHEREOF, the undersigned have caused this Securities Purchase Agreement to be duly executed by their respective authorized signatories as of the date first indicated above.

Name of Purchaser: ____
Signature of Authorized Signatory of Purchaser: _________________________________
Name of Authorized Signatory: ____
Title of Authorized Signatory: ____
Email Address of Authorized Signatory:____
Facsimile Number of Authorized Signatory: ______________________________________
Address for Notice to Purchaser:
Address for Delivery of Warrant ADSs to the Purchaser (if not same address for notice):
DWAC for ADSs:
Subscription Amount: $_________________
ADSs: _________________
ADSs underlying the Pre-Funded Warrants: __________
ADSs underlying the Common Warrants: __________
EIN Number: ____________________

☐ Notwithstanding anything contained in this Agreement to the contrary, by checking this box (i) the obligations of the above-signed to purchase the securities set forth in this Agreement to be purchased from the Company by the above-signed, and the obligations of the Company to sell such securities to the above-signed, shall be unconditional and all conditions to Closing shall be disregarded, (ii) the Closing shall occur on the second (2nd) Trading Day following the date of this Agreement and (iii) any condition to Closing contemplated by this Agreement (but prior to being disregarded by clause (i) above) that required delivery by the Company or the above-signed of any agreement, instrument, certificate or the like or purchase price (as applicable) shall no longer be a condition and shall instead be an unconditional obligation of the Company or the above-signed (as applicable) to deliver such agreement, instrument, certificate or the like or purchase price (as applicable) to such other party on the Closing Date.

[SIGNATURE PAGES CONTINUE]

Exhibit A
Form of Common Warrant

(See Attached)

<u>Exhibit B</u>
Form of Pre-Funded Warrant

(See Attached)

Exhibit C
Form of Lock-Up Agreement

(See Attached)

Exhibit 5.1

S. HOROWITZ & CO.
A Century of Excellence

To:
Quoin Pharmaceuticals Ltd.

August 4, 2022
Ref: Q/13/1

Ladies and Gentlemen,

Re: **Registration Statement on Form F-1**

We have acted as Israeli counsel to Quoin Pharmaceuticals Ltd., a company organized under the laws of the State of Israel (the "**Company**"), in connection with the registration statement on Form F-1 (Registration Statement No. 333-266476) (as it may be amended or supplemented from time to time, the "**Registration Statement**") filed by the Company with the Securities and Exchange Commission (the "**Commission**") on the date hereof under the Securities Act of 1933, as amended (the **"Securities Act"**), with respect to the issuance and sale (the "**Offering**") of up to $12 million of: ordinary shares, no par value, of the Company ("**Ordinary Shares**"), represented by American Depository Shares ("**ADSs**"), and/or pre-funded warrants to purchase Ordinary Shares represented by ADSs (the "**Pre-Funded Warrants"**), and warrants to purchase Ordinary Shares represented by ADSs ("**Common Warrants**" and, together with the Pre-Funded Warrants, the "**Warrants**"), pursuant to a securities purchase agreement by and between the Company and each of the purchasers thereof (the "**Purchase Agreement**").

This opinion letter is furnished to you at your request in order to enable you to fulfill the requirements of Item 601(b)(5) of Regulation S-K in connection with the Registration Statement.

In connection therewith, we have examined and relied upon copies (which we have assumed, in each case, to be true, complete, in effect and up-to-date copies of the originals thereof) of (i) the Registration Statement, (ii) the Company's amended and restated articles of association, as currently in effect (the **"Articles"**), (iii) the resolutions adopted by the board of directors of the Company (the **"Board"**) effective August 4, 2022 (the **"Resolutions"**), and (iv) such other corporate records, agreements, documents and other instruments, and such certificates or comparable documents of public officials and of officers of the Company as we have deemed necessary and appropriate as a basis for the opinion set forth below.

In respect to the Resolutions provided to us by the Company, we assume that they (i) are a true, correct, complete and up-to-date record of the matters described therein; (ii) were signed by all of the directors of the Company who at the date of such Resolutions would have been entitled to attend and vote at a meeting of the Board; and (iii) have not been amended, revoked or rescinded and will remain in full force and effect in all respects and that no other resolutions have been passed or other action taken on or prior to the date of this letter which could affect the validity of such Resolutions.

In such examination, we have assumed the genuineness of all signatures, the legal capacity of all natural persons, the conformity to original documents of all documents submitted to us as copies, and the authenticity of the originals of such copies. We have also assumed the due authorization (other than by the Company in respect of the Warrants and the Purchase Agreement) by all requisite action, corporate or other, and execution and delivery by all the parties to such documents (including the Warrants and the Purchase Agreement) and the validity and binding effect of all such documents on the parties thereto. As to all questions of fact material to the opinion set forth below, we have relied upon certificates or comparable documents of officers and representatives of the Company, without independently verifying the accuracy of such certificates, documents, records or instruments. In making the examination of such documents, we have assumed that the parties thereto (other than in respect of the Warrants and the Purchase Agreement, the Company) had or will have the power, corporate or other, to enter into and perform all obligations thereunder.

We have also assumed that upon the actual issuance of any Ordinary Shares: (i) represented by ADSs, when issued and sold in the Offering as described in the Registration Statement and the prospectus; (ii) represented by ADSs issuable upon the exercise of the Warrants; and (iii) registered under the Registration Statement, the total number of Ordinary Shares issued will not exceed the total number of Ordinary Shares that the Company is then authorized to issue under its amended and restated articles of association.

On the basis of the foregoing, and in reliance thereon, we are of the opinion that upon (i) payment to the Company of the consideration per ADS in such amount and form as has been determined by the Board, the Ordinary Shares represented by ADSs, when issued and sold in the Offering as described in the Registration Statement and the prospectus, will be duly authorized, validly issued, fully paid and non-assessable, and (ii) the exercise of the Warrants in accordance with their respective terms and upon receipt by the Company of the applicable consideration therefor, the Ordinary Shares represented by ADSs issuable upon the exercise of the Warrants, when issued as aforesaid, will be validly issued, fully paid and non-assessable.

Members of our firm are admitted to the Bar in the State of Israel, this opinion is limited to the laws of the State of Israel in force as at the date hereof and we do not express any opinion as to the laws of any other jurisdiction. This opinion is strictly limited to the matters stated herein and is not to be read as extending by implication to any other matter in connection with the Registration Statement or otherwise.

We hereby consent to the use of this opinion as an exhibit to the Registration Statement and to the reference to our firm appearing under the caption "Legal Matters" in the prospectus forming part of the Registration Statement. In giving this consent, we do not thereby admit that we are within the category of persons whose consent is required under Section 7 of the Securities Act or the rules and regulations of the Commission promulgated thereunder.

This opinion letter is rendered as of the date hereof, including facts, laws, rules and regulations as existing or in effect on the date hereof, and we disclaim any obligation to advise you of facts, circumstances, events or developments that may be brought to our attention after the date hereof that may alter, affect or modify the opinion expressed herein.

Very truly yours,

/s/ S. Horowitz & Co.

S. Horowitz & Co.

BLANKROME

1271 Avenue of the Americas |New York, NY 10020
blankrome.com

Phone: ***(212) 885-5000***
Fax: ***(212) 885-5001***

August 4, 2022

Quoin Pharmaceuticals Ltd.
Azrieli Center, Round Tower, 30th Floor
132 Menachem Begin Blvd
Tel Aviv 6701101
Israel

Ladies and Gentlemen:

We have acted as U.S. counsel to Quoin Pharmaceuticals Ltd., a company organized under the laws of the State of Israel (the "**Company**"), in connection with the filing by the Company with the Securities and Exchange Commission (the "**Commission**") of a Registration Statement on Form F-1 (Registration Statement No. 333-266476; as it may be amended or supplemented from time to time, the "**Registration Statement**") for the purpose of registering under the Securities Act of 1933, as amended (the "**Securities Act**") the sale of the following securities (the "**Offering**"): ordinary shares, no par value, of the Company ("**Ordinary Shares**") represented by American Depositary Shares ("**ADSs**") and/or pre-funded warrants to purchase Ordinary Shares represented by ADSs (the "**Pre-Funded Warrants**"), and warrants to purchase Ordinary Shares represented by ADSs ("**Common Warrants**" and, together with the Pre-Funded Warrants, the "**Warrants**") pursuant to a securities purchase agreement (the "**Securities Purchase Agreement**") to be entered into by and between the Company and each of the purchasers thereof (the "**Purchasers**").

In our capacity as U.S. counsel to the Company, we have reviewed the Registration Statement and the forms of the Securities Purchase Agreement and the Warrants filed as exhibits thereto and the original or certified copies of such records of the Company and such agreements, certificates of public officials, certificates of officers or representatives of the Company and others, and such other documents as we deem relevant and necessary as a basis for the opinion hereinafter expressed. In such examination we have assumed the genuineness of all signatures on original documents and the conformity to original documents of all copies submitted to us as conformed or photostat copies. As to various questions of fact material to such opinion, we have relied upon statements or certificates of officials and representatives of the Company and others.

We have assumed further that the Company is a company duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is organized and has all requisite power, authority and legal right to enter into the Securities Purchase Agreement and to issue the Warrants. We have assumed further that the Securities Purchase Agreement and the Warrants will be duly authorized, executed and delivered by the Company and the Purchasers, as applicable, and that the Securities Purchase Agreement will constitute the valid and binding obligation of the Purchasers, enforceable against the Purchasers in accordance with its terms.

We have also assumed that the total number of Ordinary Shares represented by ADSs issuable upon exercise of the Warrants will not exceed the total number of Ordinary Shares that the Company is then authorized to issue under its governing documents.

We have relied as to certain matters on information obtained from public officials, officers of the Company, and other sources believed by us to be responsible.

Based upon the foregoing, it is our opinion that, when the Registration Statement has become effective under the Securities Act and when the Warrants have been duly executed and delivered in accordance with their terms and have been duly issued and sold as contemplated in the Registration Statement, the Warrants will be the valid and binding obligations of the Company, enforceable against the Company in accordance with their terms, subject to bankruptcy, insolvency, fraudulent transfer, reorganization, moratorium, conservatorship and other laws of general applicability relating to or affecting creditors' rights and to general principles of equity.

We express no opinion as to: (i) waivers of defenses, subrogation and related rights, rights to trial by jury, rights to object to venue, or other rights or benefits bestowed by operation of law; (ii) releases or waivers of unmatured claims or rights; (iii) indemnification, contribution, exculpation, or arbitration provisions, or provisions for the non-survival of representations, to the extent they purport to indemnify any party against, or release or limit any party's liability for, its own breach or failure to comply with statutory obligations, or to the extent such provisions are contrary to public policy; or (iv) provisions for liquidated damages and penalties, penalty interest and interest on interest.

Our opinion herein reflects only the application of applicable laws of the State of New York, and we have not considered, and we express no opinion as to the laws of any other jurisdiction. This opinion is limited to the laws of the State of New York as in effect on the date hereof.

We consent to the filing of this opinion as Exhibit 5.2 to the Registration Statement. We also consent to the reference to our firm under the heading "**Legal Matters**" in the prospectus which is part of said Registration Statement. In giving this consent, we do not thereby admit that we are within the category of persons whose consent is required under Section 7 of the Securities

Act or the rules and regulations of the Commission promulgated thereunder. This opinion letter is limited to the matters set forth herein, and no opinion may be inferred or implied beyond the matters expressly set forth herein. This opinion letter is not a guaranty nor may one be inferred or implied.

Very truly yours,

/s/ BLANK ROME LLP

BLANK ROME LLP

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to include in this Registration Statement on Form F-1 of Quoin Pharmaceuticals Ltd. our report dated April 13, 2022 (except for Notes 2 and 17 as to which the date is August 2, 2022), which includes an emphasis of a matter regarding the Company's ability to continue as a going concern, relating to the consolidated financial statements of Quoin Pharmaceuticals Ltd. as of December 31, 2021 and 2020 and for the years then ended. We also consent to the reference to our Firm under the heading "Experts" in this Registration Statement.

/s/ Friedman LLP

East Hanover, New Jersey
August 4, 2022

FORM F-1/A
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933
(Form Type)

QUOIN PHARMACEUTICALS LTD.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered and Carry Forward Securities

	Security Type	Security Class Title(1)	Fee Calculation or Carry Forward Rule	Amount Registered	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price(2)	Fee Rate	Amount of Registration Fee	Carry Forward Form Type	Carry Forward File Number	Carry Forward Initial Effective Date	Filing Fee Previously Paid in Connection with Unsold Securities to be Carried Forward
Newly Registered Securities												
Fees to be paid	Equity	Ordinary shares, no par value per share (“Ordinary Shares”), represented by American Depositary Shares (“ADSs”)(3)	Rule 457(o)			$14,000,000.00	0.0000927	$1,297.80(4)				
	Other	Pre-Funded Warrants to purchase Ordinary Shares represented by ADSs	Other									
	Other	Common Warrants to purchase Ordinary Shares represented by ADSs	Other									

	Equity	Ordinary Shares represented by ADSs issuable upon the exercise of Pre-Funded Warrants	Other									
	Equity	Ordinary Shares represented by ADSs issuable upon the exercise of Common Warrants	Other									
Fees Previously Paid								——				
Carry Forward Securities												
Carry Forward Securities												
Total Offering Amounts						$14,000,000.00		$1,297.80				
Total Fees Previously Paid								$1,168.02				
Total Fee Offsets								$0.00				
Net Fee Due								$129.78				

(1) Pursuant to Rule 416 under the Securities Act of 1933, as amended (the "Securities Act"), there are also being registered such additional securities that may be issued because of events such as recapitalizations, stock dividends, stock splits and reverse stock splits, and similar transactions.

(2) Estimated solely for the purpose of determining the amount of the registration fee in accordance with Rule 457(o) under the Securities Act.

(3) American Depositary Shares ("ADSs") issuable upon deposit of ordinary shares registered hereby have been registered under a separate registration statement on Form F-6 (Registration No. 333-212698) filed with the Securities and Exchange Commission. Each ADS represents five thousand (5,000) ordinary shares ("Ordinary Shares"). The proposed maximum aggregate offering price of the Ordinary Shares represented by ADSs proposed to be sold in the offering will be reduced on a dollar-for-dollar basis based on the aggregate offering price of the Pre-Funded Warrants offered and sold in the offering (plus the aggregate exercise price of the Ordinary Shares represented by ADSs issuable upon exercise of the Pre-funded Warrants), and as such the proposed aggregate maximum offering price of the Ordinary Shares represented by ADSs and Pre-Funded Warrants (including Ordinary Shares represented by ADSs issuable upon exercise of the Pre-funded Warrants), if any, is $14,000,000.00.

(4) Calculated pursuant to Rule 457(o) under the Securities Act based on an estimate of the proposed maximum aggregate offering price.