

Submission Data File

General Information	
Form Type*	424B4
Contact Name	M2 Compliance
Contact Phone	754-243-5120
Filer File Number*	333-268675
Filer CIK*	0001849296 (OKYO Pharma Ltd)
Filer CCC*	*****
Confirming Copy	No
Notify via Website only	No
Return Copy	Yes
Serial	No
Serial Company Name*	
SROS*	NONE
Depositor CIK	
Fee Table included*	N
ABS Asset Class Type	
ABS Sub Asset Class Type	
Sponsor CIK	
(End General Information)	

Document Information	
File Count*	12
Document Name 1*	form424b4.htm
Document Type 1*	424B4
Document Description 1	
Document Name 2*	form424b4_001.jpg
Document Type 2*	GRAPHIC
Document Description 2	
Document Name 3*	form424b4_002.jpg
Document Type 3*	GRAPHIC
Document Description 3	
Document Name 4*	form424b4_003.jpg
Document Type 4*	GRAPHIC
Document Description 4	
Document Name 5*	form424b4_005.jpg
Document Type 5*	GRAPHIC
Document Description 5	
Document Name 6*	form424b4_006.jpg
Document Type 6*	GRAPHIC
Document Description 6	
Document Name 7*	form424b4_007.jpg
Document Type 7*	GRAPHIC
Document Description 7	
Document Name 8*	form424b4_008.jpg
Document Type 8*	GRAPHIC
Document Description 8	
Document Name 9*	form424b4_009.jpg
Document Type 9*	GRAPHIC
Document Description 9	
Document Name 10*	form424b4_010.jpg
Document Type 10*	GRAPHIC
Document Description 10	
Document Name 11*	form424b4_011.jpg
Document Type 11*	GRAPHIC
Document Description 11	
Document Name 12*	form424b4_012.jpg
Document Type 12*	GRAPHIC
Document Description 12	
(End Document Information)	

Filed pursuant to Rule 424(b)(4)
Registration Statement No. 333-268675

PROSPECTUS

3,503,665 American Depositary Shares Representing 227,738,225 Ordinary Shares



OKYO Pharma Limited

We are offering on a “reasonable best efforts” basis 3,503,665 American Depositary Shares, or “ADSs,” of OKYO Pharma Limited at a public offering price of \$1.50 per ADS. Each ADS represents 65 ordinary shares. These securities are being sold in this offering to certain purchasers under a securities purchase agreement dated March 13, 2023 between us and the purchasers.

Our ADSs are listed on The Nasdaq Capital market under the symbol “OKYO.” On March 10, 2023, the last reported sale price of our ADSs was \$2.33 per ADS. Our ordinary shares are admitted to listing on the standard segment of Official List of the United Kingdom Financial Conduct Authority, or FCA, and to trading on the main market for listed securities, or Main Market, of London Stock Exchange plc, or LSE, under the symbol “OKYO.” On March 10, 2023, the last reported sale price of our ordinary shares was £0.0305 per share (equivalent to \$2.38 per ADS based on an exchange rate of £1.00 to \$1.1996. For a discussion of the factors considered in determining the public offering price of our ADSs, see “Plan of Distribution.”

Investing in our ADSs involves a high degree of risk. See “Risk Factors” beginning on page 10 of this prospectus for a discussion of information that you should consider before investing in our ADSs.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

We are an “emerging growth company,” or EGC, as defined under applicable Securities and Exchange Commission, or SEC, rules and, as such, have elected to comply with certain reduced public company reporting requirements for this and future filings.

We are also a “foreign private issuer,” as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are exempt from certain rules under the Exchange Act that impose certain disclosure obligations and procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, our officers, directors and principal shareholders are exempt from the reporting and “short-swing” profit recovery provisions under Section 16 of the Exchange Act. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

Because there is no minimum number of securities or minimum aggregate amount of proceeds for this offering to close, we may sell fewer than all of the securities offered hereby, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to pursue the business goals outlined in this prospectus. Because there is no escrow account and there is no minimum offering amount, investors could be in a position where they have invested in our company, but we are unable to fulfill our objectives due to a lack of interest in this offering. Also, any proceeds from the sale of securities offered by us will be available for our immediate use, despite uncertainty about whether we would be able to use such funds to effectively implement our business plan.

This is a self-underwritten offering. This prospectus is part of a registration statement that permits our officers and directors to sell the ADSs directly to the public with no commission or other remuneration payable to them for any ADSs that are sold by them. Our officers and directors will sell the ADSs and intend to offer them to friends, family members, and business acquaintances. In offering the securities on our behalf, our directors and officers will rely on the safe harbor from broker dealer registration set out in Rule 3a4-1 under the Securities Exchange Act of 1934. Our officers, directors, control persons and affiliates may purchase ADSs in this offering. This offering will terminate 45 days from the date of this prospectus, unless the offering is fully subscribed before that date or we decide to terminate the offering prior to that date. In either event, the offering may be closed without further notice to you. Any and all funds for securities purchased in the offering will be transmitted directly to us for our immediate use.

We may also engage registered broker-dealers to offer and sell the ADSs (each a “Placement Agent” and collectively, the “Placement Agents”). We may pay any such registered persons who make such sales a commission of up to a certain percentage of the aggregate purchase price of the shares sold by such Placement Agent in this offering and issue to the Placement Agent a warrant to purchase such number of ADSs in an amount not to exceed certain percentage of the number of ADSs sold by such Placement Agent in this offering, subject to the compliance with the maximum allowable fees under applicable, rules and regulations including the rules of the Financial Industry Regulatory Authority (“FINRA”) and the foreign equivalent agencies where the Placement Agent is regulated. However, we have not entered into any underwriting or agent agreement, arrangement or understanding for the sale of the securities being offered pursuant to this prospectus. This offering is intended to be made solely by the delivery of this prospectus and the accompanying subscription agreements to prospective investors. Any Placement Agent engaged by us for this offering would only be compensated based on the aggregate purchase price of the ADSs sold by such Placement Agent in this offering.

Delivery of the securities is expected to be made on or about March 15, 2023.

The date of this prospectus is March 13, 2023



Mission Statement

We are focused on the development of a next-generation drug to benefit the millions of people suffering from dry eye disease



TABLE OF CONTENTS

	Page
About This Prospectus	ii
Presentation of Financial Information	ii
Prospectus Summary	1
Risk Factors	10
Cautionary Statement Regarding Forward-Looking Statements	41
Market and Industry Data	42
Trademarks, Service Marks and Tradenames	42
Exchange Rate Information	42
Price Range of Our Ordinary Shares	43
Use of Proceeds	44
Dividend Policy	44
Capitalization	44
Dilution	45
Selected Consolidated Financial Data	47
Management's Discussion and Analysis of Financial Condition and Results of Operations	48
Business	59
Management	80
Certain Relationships and Related Party Transactions	89
Principal Shareholders	90
Description of Share Capital and Memorandum and Articles of Incorporation	91
Description of the American Depositary Shares	111
Ordinary Shares and ADSs Eligible For Future Sale	122
Certain U.S. and Guernsey Tax Considerations	123
Plan of Distribution	127
Expenses of This Offering	130
Legal Matters	130
Experts	130
Service of Process and Enforcement of Liabilities	130
Where You Can Find Additional Information	131
Index to Consolidated Financial Statements	F-1

We are responsible for the information contained in this prospectus and any free-writing prospectus we prepare or authorize. We have not authorized anyone to provide you with different information, and we take no responsibility for any other information others may give you. We are not making an offer to sell our ADSs in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained in this prospectus is accurate as of any date other than the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or the sale of any ADSs.

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

We are a non-cellular company limited by shares incorporated under the Companies (Guernsey) Law 2008, or the Guernsey Companies Law, and a majority of our outstanding securities are owned by non-U.S. residents. Under the rules of the SEC, we are currently eligible for treatment as a "foreign private issuer," or FPI. As an FPI, we will not be required to file periodic reports and financial statements with the SEC as frequently or as promptly as domestic registrants whose securities are registered under the Exchange Act.

ABOUT THIS PROSPECTUS

Unless otherwise indicated or the context otherwise requires, all references in this registration statement to the terms “OKYO,” “OKYO Pharma Limited,” the “Company,” “we,” “us” and “our” refer to OKYO Pharma Limited and our wholly owned subsidiary OKYO Pharma US Inc.

Solely for convenience, the trademarks, service marks and trade names in this registration statement may be referred to without the ® and ™ symbols, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent under applicable law, their rights thereto. This registration statement contains additional trademarks, service marks and trade names of others, which are the property of their respective owners. We do not intend to use or display other companies’ trademarks, service marks and trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

In this registration statement, unless otherwise stated, all references to “U.S. dollars” or “US\$” or “\$” or “cents” are to the currency of the United States of America, and all references to “Pounds Sterling” or “£” or “pence” are to the currency of the United Kingdom.

In this registration statement, any reference to any provision of any legislation shall include any amendment, modification, re-enactment or extension thereof. Words importing the singular shall include the plural and vice versa, and words importing the masculine gender shall include the feminine or neutral gender.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

OKYO discusses in this prospectus its business strategy, market opportunity, capital requirements, product introductions and development plans and the adequacy of our funding. Other statements contained in this prospectus, which are not historical facts, are also forward-looking statements. OKYO has tried, wherever possible, to identify forward-looking statements by terminology such as “may,” “will,” “could,” “should,” “expects,” “anticipates,” “intends,” “plans,” “believes,” “seeks,” “estimates” and other comparable terminology.

OKYO cautions investors that any forward-looking statements presented in this prospectus, or that OKYO may make orally or in writing from time to time, are based on the beliefs of, assumptions made by, and information currently available to, OKYO. These statements are based on assumptions, and the actual outcome will be affected by known and unknown risks, trends, uncertainties and factors that are beyond its control or ability to predict. Although OKYO believes that its assumptions are reasonable, they are not a guarantee of future performance, and some will inevitably prove to be incorrect. As a result, its actual future results can be expected to differ from its expectations, and those differences may be material. Accordingly, investors should use caution in relying on forward-looking statements, which are based only on known results and trends at the time they are made, to anticipate future results or trends. Certain risks are discussed in this prospectus and also from time to time in OKYO’s other filings with the SEC.

This prospectus and all subsequent written and oral forward-looking statements attributable to the Company or any person acting on its behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section. We do not undertake any obligation to release publicly any revisions to its forward-looking statements to reflect events or circumstances after the date of this prospectus.

In particular, you should consider the risks provided under “Risk factor summary” in this prospectus and in the Form 20-F for the fiscal year ended March 31, 2022 as filed with the SEC (the “2022 Form 20-F”) incorporated by reference in this prospectus.

PRESENTATION OF FINANCIAL INFORMATION

This prospectus includes our audited consolidated financial statements as of March 31, 2022 and 2021 and for the two years ended March 31, 2022, which are prepared in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. None of our financial statements were prepared in accordance with generally accepted accounting principles in the United States.

Our financial information is presented in U.S. dollars. For the convenience of the reader, in this prospectus, unless otherwise indicated, translations from Pounds Sterling into U.S. dollars were made at the rate of £1.00 to \$1.1996 which was the noon buying rate of the Federal Reserve Bank of New York on March 3, 2023. Such U.S. dollar amounts are not necessarily indicative of the amounts of U.S. dollars that could actually have been purchased upon exchange of Pounds Sterling at the dates indicated.

We have made rounding adjustments to some of the figures included in this prospectus. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that preceded them.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus and does not contain all of the information that you should consider in making your investment decision. Before investing in our ADSs or ordinary shares, you should carefully read this entire prospectus, including our consolidated financial statements and the related notes and the information set forth under the sections titled "Risk Factors," "Special Note Regarding Forward-Looking Statements," and "Management's Discussion and Analysis of Financial Condition and Results of Operations," in each case included elsewhere in this prospectus.

Overview

We are a preclinical biopharmaceutical company developing next-generation therapeutics to improve the lives of patients suffering from inflammatory eye diseases and ocular pain. Our research program is focused on a novel G Protein-Coupled Receptor, or GPCR, which we believe plays a key role in the pathology of these inflammatory eye diseases of high unmet medical need. Our therapeutic approach is focused on targeting inflammatory and pain modulation pathways that drive these conditions. We are presently developing OK-101, our lead preclinical product candidate, for the treatment of dry eye disease ("DED"). We also plan to evaluate its potential in benefiting patients with ocular neuropathic pain, uveitis and allergic conjunctivitis. We have also been evaluating OK-201, a bovine adrenal medulla, or BAM, lipidated-peptide preclinical analogue candidate that is currently in developmental stage.

On February 21, 2018, we announced that we successfully obtained (via assignment from Panetta Partners Ltd., a related party) a license from On Target Therapeutics LLC, or OTT, to patents owned or controlled by OTT and a sub-license from OTT to certain patents licensed by OTT from Tufts Medical Center Inc., or TMC, to support our ophthalmic disease drug programs. These licenses gave us the right to exploit the intellectual property, or IP estate which is directed to compositions-of-matter and methodologies for treating ocular inflammation, DED, with chemerin or lipid-linked chemerin analogues. We also have a license from TMC to a separate IP estate for treating symptoms of ocular neuropathic pain and uveitis associated pain. On August 6, 2019, we signed a collaborative agreement with TMC on a research program focused on ocular neuropathic pain.

On January 7, 2021, we announced the appointment of Mr. Gabriele Cerrone as Non-Executive Chairman and Director, and Gary S. Jacob, Ph.D. as Chief Executive Officer and Director. The addition of these two individuals was a significant step for us, highlighting a careful realignment of the strategic focus of our research and development program, with the aim of facilitating advancement of both of our preclinical programs. We believed this realignment would allow us to file investigational new drug, or IND, applications on our drug candidates with the U.S. Food and Drug Administration, or FDA, in the shortest time possible.

OK-101

OK-101, our lead preclinical product candidate, is focused on keratoconjunctivitis sicca, commonly referred to as DED, which is a multifactorial disease caused by an underlying inflammation resulting in the lack of lubrication and moisture in the surface of the eye. DED is one of the most common ophthalmic conditions encountered in clinical practice. Symptoms of DED include constant discomfort and irritation accompanied by inflammation of the ocular surface, visual impairment and potential damage to the ocular surface. There are presently approximately 20 million people suffering from DED in the U.S. alone (Farrand et al. AJO 2017; 182:90), with the disease affecting approximately up to 34% of the population aged 50+ (Dana et al. AJO 2019; 202:47), and with women representing approximately two-thirds of those affected (Matossian et al. J Womens Health (Larchmt) 2019; 28:502–514). Prevalence of DED is anticipated to increase substantially in the next 10-20 years due to aging populations in the U.S., Europe, Japan and China and use of contact lenses in the younger population. We believe this increase in prevalence of DED represents a major expanding economic burden to public healthcare. According to Market Research Report, Dry Eye Disease, December 2020, the global DED market in 2019 was approximately \$5.22 billion, with the market size expected to reach \$6.54 billion by 2027. In addition, DED causes approximately \$3.8 billion annually in healthcare costs and represents a major economic burden to public healthcare, accounting for more than \$50 billion to the U.S. economy annually.

At present, there are 5 prescription drugs available to treat DED: 1) Restasis (0.05% cyclosporine), 2) Cequa (0.09% cyclosporine), 3) Xiidra (5% lifitegrast), 4) Tyrvaya (0.03 mg varenicline), and 5) Eysuvis (0.25% loteprednol – a corticosteroid for short term use only). However, DED continues to be a major unmet medical need due to the large number of patients not well served by the treatments available to them through the medical community.

The development of new drugs to treat DED has been particularly challenging due to the heterogeneous nature of the patient population suffering from DED, and due to the difficulties in demonstrating an improvement in both signs and symptoms of the disease in well-controlled clinical trials. The evidence from over 40 years of scientific literature, however, suggests inflammation as the most common underlying element of DED. Consequently, development of new therapeutic agents that target inflammatory pathways is looking to be an attractive approach in improving symptoms in DED patients. Moreover, large number of dry eye patients suffer from ocular neuropathic pain, making their condition more resistant to topical anti-inflammatory therapy, and a drug capable of targeting both of these aspects of DED would be a significant addition to the ocular-care practitioner's arsenal for the treatment of DED.

The chemerin receptor (CMKLR1 or ChemR23) is a chemokine like GPCR expressed on select populations of cells including inflammatory mediators, epithelial and endothelial cells as well as neurons and glial cells in the dorsal root ganglion, spinal cord, and retina. Activation of CMKLR1 by chemerin has been shown to resolve the inflammation and pain in animal models of asthma and pain, respectively. We have been pioneering the development of OK-101, a lipidated-chemerin analogue, which is an agonist of CMKLR1, in treating DED and other ocular inflammatory conditions. OK-101 was first identified in a program developed by OTT using membrane-tethered ligand technology.

To expand our understanding of the structure-activity relationships of the lipidated-chemerin analogues, such as OK-101, as agonists of the chemerin receptor, we synthesized a small library of analogues of OK-101. We screened these analogues in a cell-line based receptor binding assay to characterize the agonist potency of these lipidated-chemerin analogues. This work has also been coupled to an evaluation of a subset of these analogues' potential in treating DED by using a variety of preclinical studies and dry eye animal model studies. After evaluating a number of our analogues in a mouse model of acute DED by looking at their ability to reduce corneal permeability, a measure of dry-eye effectiveness, as well as the analogues' impact on immune response, we determined that OK-101 was in fact the most potent analogue in reducing corneal permeability and down-regulating immune response. In addition, in a separate set of animal model experiments, OK-101 was shown to exhibit potent ocular pain-reducing activity in a ciliary nerve ligation mouse model of corneal neuropathic pain. Following these studies, we evaluated the ocular tolerance of OK-101 *via* repeated ocular instillation in rabbits followed by clinical ophthalmic observations. Rabbit ocular tolerance tests on OK-101 showed no adverse signs such as inflammation, chemosis or hyperemia and no signs of local irritation. With potential anti-inflammatory and neuropathic pain reducing characteristics, we are developing OK-101 for the treatment of DED.

Based on the results from the DED animal model, the neuropathic corneal pain model as well as the rabbit ocular tolerance studies, we moved forward over the past 18 months with plans to file an IND on OK-101 to treat DED to enable us to begin clinical trials soon thereafter. During the fourth quarter of 2021 we successfully manufactured a 200-gram batch of OK-101 drug substance needed for initiating the IND-enabling studies that were begun during the first quarter of 2022. In support of this work, we also had previously signed an agreement on April 13, 2021, with Ora, Inc., or Ora, a major clinical research organization, or CRO, specializing in ophthalmic drug development who have been providing us with the following services over the past 18 months:

- 1) Preparation of the OK-101 pre-IND briefing document used in the successful pre-IND meeting with FDA in February, 2022

- 2) Support with the OK-101 pre-IND meeting OKYO accomplished with FDA in February of 2022
- 3) Support for the planned regulatory publishing and submission of the OK-101 IND in electronic common technical document, or eCTD, format
- 4) Quality oversight for the recent successful development of the topical OK-101 formulation for future human studies
- 5) Quality oversight of the successful development and qualification of the drug stability analysis method for OK-101 along with successfully conducting stability studies to establish formulated drug product is stable for at least 90 days
- 6) Support for the recently completed 90 days animal toxicology studies in rabbit and dog

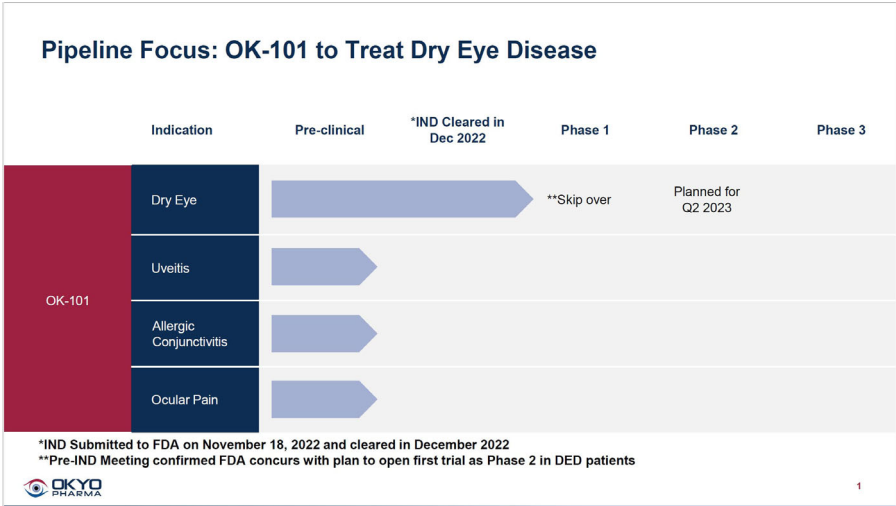
Over the past twelve months we accomplished the following:

- Completed topical formulation of the OK-101 drug product as well as initial stability studies
- Finalized the bioanalytical method development to support the OK-101 clinical program
- Completed batch manufacture of cGMP OK-101 for clinical trials
- Completed toxicokinetic method development
- Completed toxicology studies in rabbits and dogs
- Completed stability studies of formulated OK-101

We recently completed the final stages of a concerted effort to complete all IND enabling activities and filed with FDA the IND on OK-101 to treat DED on November 18, 2022. On December 22, 2022 we announced that we received clearance of the IND application from the FDA to enable us to initiate a Phase 2, first-in-human, clinical study of OK-101 for the treatment of DED.

Based on ongoing consultations with Ora, we are now planning to commence the first human study with OK-101 in the second quarter of 2023, and because the drug is designed to be administered topically, we plan to skip the standard Phase 1 studies typically expected with orally delivered or injectable drug candidates in non-life-threatening conditions and open the first trial as a Phase 2 clinical trial in DED patients (See OKYO Pipeline below). This trial is anticipated to be conducted in approximately 200 to 250 DED patients. The study is being designed in conjunction with, and will be managed and monitored by Ora, well known for its leadership of ophthalmic clinical trial activities. The Phase 2 trial is expected to be completed in 6-9 months from enrollment of the first patient.

OKYO Pipeline



On February 15, 2022, we announced the successful completion of the pre-IND meeting facilitated by Ora with the FDA regarding development plans for OK-101 to treat DED. Both nonclinical and clinical development milestones were covered in the pre-IND meeting, with the FDA agreeing that our first human trial would be a Phase 2 safety and efficacy trial in DED patients. The FDA also provided guidance on the planned protocol for this trial in DED patients, concurring with one particular option OKYO has considered for the protocol which is to designate co-primary efficacy endpoints covering both a sign and a symptom of DED in the clinical trial. Notably, the final decision to designate any efficacy endpoints as primary endpoints in this trial would be highly significant as should this phase 2 trial then meet any prespecified primary endpoints, the trial should considerably affect the timeline to an NDA filing with the FDA for OK-101 to treat DED.

Additional Applicable Disease Indications for OK-101

A second related ophthalmic disease indication that is the target of our chemerin-based technology is uveitis. Uveitis is the third leading cause of blindness worldwide. The most common type of uveitis is an inflammation of the iris called iritis (anterior uveitis). Uveitis can damage vital eye tissue, leading to permanent vision loss. Uveitis is currently treated with corticosteroid eyedrops and injections that reduce inflammation, however, the long-term use of corticosteroids causes risk of cataract and glaucoma, requiring close monitoring for their potential side effects.

We believe that OK-101, in addition to its potential to treat DED, should also be evaluated to treat allergic conjunctivitis and uveitis. Correspondingly, once we have an IND on OK-101 in place and are clinically evaluating OK-101 to treat DED, we also plan to explore the drug candidate's potential to suppress the inflammation associated with allergic conjunctivitis and uveitis.

OK-201

MAS-Related G Protein-Coupled Receptors, or MRGPRs, mainly expressed in the sensory neurons, are involved in the perception of pain, thus making them a promising analgesic target. Activation of MRGPR by Bovine Adrenal Medulla, or BAM, peptide inhibits pain perception by modulating Ca²⁺ influx. OK-201, a BAM peptide analogue, licensed from TMC on May 1, 2018, is a potent agonist of human MRGPR and a promising candidate for the treatment of neuropathic and inflammatory pain.

On August 6, 2019, we signed a collaborative agreement with TMC and Pedram Hamrah, MD, Professor of Ophthalmology at Tufts University School of Medicine, Boston, MA as Principal Investigator to evaluate OK-201 and other proprietary lead compounds to suppress corneal neuropathic pain using a mouse ocular pain model recently developed in Dr. Hamrah's laboratory. Our goal was to further develop this lipidated peptide, as well as explore additional analogues, for their potential use in treating ocular pain, and for potentially treating long-term chronic pain.

On April 28, 2021, we announced positive results of OK-201, a non-opioid analgesic drug candidate delivered topically in Dr. Hamrah's mouse neuropathic corneal pain model, as a potential drug to treat acute and chronic ocular pain. Importantly, OK-201 demonstrated a reduced corneal pain response equivalent to that of gabapentin, a commonly used oral drug for neuropathic pain. These observations demonstrated preclinical 'proof-of-concept' for the topical administration of OK-201 as a potential non-opioid analgesic for ocular pain. Current treatments for corneal pain are limited to short term non-steroidal anti-inflammatory drugs, or NSAIDs, steroids, and oral gabapentin and opioids in severe cases.

Although the results with OK-201 were encouraging, due to subsequent success obtained with OK-101 (see section above on OK-101) in follow-on animal model studies utilizing the same mouse corneal neuropathic pain model as for OK-201, we have decided to maintain this drug candidate at the exploratory level while we focus our primary energy on the OK-101 program to treat DED, based on OK-101's combination of anti-inflammatory and corneal pain-reducing activities in animal models of these conditions.

SUMMARY OF RISKS AFFECTING OUR BUSINESS

Our business is subject to a number of risks of which you should be aware before making an investment decision. You should carefully consider all of the information set forth in this prospectus and, in particular, should evaluate the specific factors set forth in the section titled "Risk Factors" before deciding whether to invest in our ADSs. These important risks include, but are not limited to, the following:

- We have only recently committed to our new business and our product candidates are in the early stages of development and it may be some years until we generate revenue, if at all.

- Our product candidates have not been evaluated in clinical trials and results in the clinic may not be reproduced in human trials.
- There is a high degree of failure for product candidates as they progress through clinical trials and clinical trial data may be interpreted in varying ways which may delay, limit or prevent future regulatory approvals.
- The development of pharmaceutical products carries significant risk of failure in early and late stage development programs.
- We anticipate that we will continue to incur significant losses for the foreseeable future.
- We will need to spend extensively on further research activities and there can be no guarantee that we will have access to sufficient funds to fully realize our research and development plan or to commercialize any products derived from research activities.
- Even if we successfully develop a product which shows efficacy in human subjects there remain high barriers to commercial success.
- We face significant competition from pharmaceutical companies. We have competitors internationally, including major multinational pharmaceutical companies, universities and research institutions. In respect of OK-101 as an indication for the treatment of DED, there are a number of established companies engaged in the development and marketing of preparations addressing the DED market. In addition, there are a wide range of products addressing the DED market currently approved and marketed by a number of large and small pharmaceutical companies.
- The expiration of certain intellectual property rights or an inability to obtain, maintain or enforce adequate intellectual property rights for products that are marketed or in development may result in additional competition from other third-party products. Third parties may have blocking intellectual property rights which could prevent the sale of products by us or require that compensation be paid to such third parties.
- Our product candidates could infringe patents and other intellectual property rights of third parties.
- COVID-19 has adversely affected our business, and any new pandemic, epidemic or outbreak of an infectious disease may further adversely affect our business.
- The relationship of the UK with the EU could impact our ability to operate efficiently in certain jurisdictions or in certain markets.
- Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize our product candidates and the approval may be for a more narrow indication than we seek.
- If our competitors are able to obtain orphan drug exclusivity for products that constitute the same drug and treat the same indications as our product candidates, we may not be able to have competing products approved by applicable regulatory authorities for a significant period of time. In addition, even if we obtain orphan drug exclusivity for any of our products, such exclusivity may not protect us from competition.
- Even if we obtain regulatory approval for a product candidate, our product candidates will remain subject to regulatory oversight.

- Even if we obtain and maintain approval for our product candidates in a major pharmaceutical market such as the United States, we may never obtain approval for our product candidates in other major markets.
- We may seek a conditional marketing authorization in the United Kingdom and EU for some or all of our current product candidates, but we may not be able to obtain or maintain such designation.
- Healthcare legislative reform measures may have a negative impact on our business and results of operations.
- We are subject to governmental regulation and other legal obligations related to privacy, data protection and data security. Our actual or perceived failure to comply with such obligations could harm our business.
- We do not know whether an active, liquid and orderly trading market will develop for our ADSs or what the market price of our ADSs will be. As a result, it may be difficult for ADS holders to sell their ADSs.
- If you purchase ADSs in this offering, you will suffer immediate dilution of your investment.
- Holders of our ADSs may experience substantial dilution upon the exercise of outstanding options and warrants.
- Holders of our ADSs have fewer rights than our shareholders and must act through the depositary to exercise their rights.
- The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation.
- If we are a passive foreign investment company, there could be adverse U.S. federal income tax consequences to U.S. holders.

Corporate Information

We were originally incorporated in the British Virgin Islands as a British Virgin Islands Business Company on July 4, 2007 under the BVI Business Companies Act 2004 with company number 1415559 under the name Jellon Enterprises, Inc. Our legal and commercial name was changed to Minor Metals & Mining, Inc. on October 24, 2007, to Emerging Metals Limited on November 28, 2007, to West African Minerals Corporation on December 9, 2011, and to OKYO Pharma Corporation on January 10, 2018. On March 9, 2018, shareholders approved the cancellation of our AIM listing and migration to Guernsey. On July 3, 2018, following the approval of the Guernsey Companies Registry, we were registered under the Guernsey Companies Law under the name OKYO Pharma Limited, as a Guernsey company with limited liability, an indefinite life and company number 65220. We are domiciled in Guernsey. On July 17, 2018, our Ordinary Shares were admitted to listing on the standard segment of the Official List of the FCA and admitted to trading on the Main Market of the London Stock Exchange. We are subject to the Takeover Code.

Our registered office is located at Martello Court, Admiral Park, St. Peter Port, Guernsey GY1 3HB and our telephone number is +44 (0) 20 7495 2379. Our website address is www.okyopharma.com. The reference to our website is an inactive textual reference only and the information contained in, or that can be accessed through, our website is not a part of this registration statement. Our agent for service of process in the United States is OKYO Pharma US, Inc.

“OKYO,” the OKYO logo and other trademarks or service marks of OKYO Pharma Limited appearing in this prospectus are the property of OKYO or our subsidiary. This prospectus contains additional trade names, trademarks and service marks of others, which are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this prospectus may appear without the ® or ™ symbols.

Implications of Being an Emerging Growth Company

We are an EGC as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. As such, we may take advantage of certain exemptions from various reporting requirements that are applicable to other publicly traded entities that are not EGCs. These exemptions include:

- the option to present only two years of audited financial statements and related discussion in the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements (i.e., an auditor discussion and analysis);
- not being required to submit certain executive compensation matters to stockholder advisory votes, such as “say-on-pay,” “say-on-frequency,” and “say-on-golden parachutes;” and
- not being required to disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer’s compensation to median employee compensation.

Section 107 of the JOBS Act also provides that an EGC can take advantage of the extended transition period provided in Section 13(a) of the Exchange Act, for complying with new or revised accounting standards. As a result, an EGC can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies.

We will remain an EGC until the earliest of: (1) the last day of the first fiscal year in which our annual gross revenues exceed \$1.235 billion; (2) the last day of 2023; (3) the date that we become a “large accelerated filer” as defined in Rule 12b-2 under the Exchange Act, which would occur on the last day of any fiscal year that the aggregate worldwide market value of our common equity held by non-affiliates exceeds \$700 million as of the last business day of our most recently completed second fiscal quarter; or (4) the date on which we have issued more than \$1.0 billion in non-convertible debt securities during any three-year period.

Implications of Being a Foreign Private Issuer

We currently report under the Exchange Act as a non-U.S. company with FPI status. Even after we no longer qualify as an EGC, as long as we qualify as an FPI under the Exchange Act we will be exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including:

- the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act;
- the sections of the Exchange Act requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades made in a short period of time; 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 specific information, and current reports on Form 8-K upon the occurrence of specified significant events.

FPIs are also exempt from certain more stringent executive compensation disclosure rules. Thus, even if we no longer qualify as an EGC, but remain an FPI, we will continue to be exempt from the more stringent compensation disclosures required of companies that are neither an EGC nor an FPI.

THE OFFERING

ADSs offered by us	3,503,665 ADSs.
Per ADS offering price	\$1.50 per ADS
Ordinary shares to be outstanding after this offering (1)	1,642,956,193 ordinary shares, including ordinary shares represented by ADSs
ADSs	Each ADS represents 65 ordinary shares of no par value. The depositary will hold the ordinary shares underlying your ADSs and you will have rights as provided in the deposit agreement among us, the depositary, and holders and beneficial owners of ADSs from time to time. To better understand the terms of our ADSs, see “Description of the American Depositary Shares.” We also encourage you to read the deposit agreement, the form of which is filed as an exhibit to the registration statement of which this prospectus forms a part.
Reasonable Best Efforts	We have agreed to issue and sell on a “reasonable best efforts” basis 3,503,665 ADSs at a public offering price of \$1.50 per ADS See “Plan of Distribution” on page 127 of this prospectus.
Depositary	JPMorgan Chase Bank, N.A..
Use of proceeds	<p>We estimate that the net proceeds from our sale of ADSs in this offering will be approximately \$5.0 million, after deducting the estimated offering expenses payable by us.</p> <p>We intend to use the net proceeds we receive from this offering (i) to fund the initiation of the Phase 2 clinical trial of OK-101 in DED patients, (ii) repay the loan from Tiziana Life Sciences Ltd. in the amount of \$500,000 plus interest and (iii) for working capital and other general corporate purposes.</p> <p>See “Use of Proceeds” for additional information.</p>
Transfer Agent and Registrar	Computershare Investor Services (Guernsey) Limited
Risk factors	See “Risk Factors” and the other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our securities
Nasdaq symbol	“OKYO.”

(1) The number of ordinary shares to be outstanding after this offering is based on 1,415,217,968 ordinary shares outstanding as of March 10, 2023, and excludes:

- 81,820,000 ordinary shares issuable upon the exercise of share options at exercise prices of between \$0.054 and \$0.185 per ordinary share of which 35,155,667 ordinary shares are currently exercisable and 46,664,333 are exercisable between January 6, 2023 and January 31, 2032; and

- 35,909,090 ordinary shares that currently may be issued upon the exercise of warrants to purchase ordinary shares at exercise prices of between \$0.033 and \$0.054 per ordinary share.

Unless otherwise indicated, this prospectus reflects and assumes the following:

- no exercise of outstanding share options or warrants after March 10, 2023.

SUMMARY CONSOLIDATED FINANCIAL DATA

The following tables set forth our summary consolidated financial data for the periods indicated. We have derived the consolidated statement of operations data for the two years ended March 31, 2022 and the consolidated balance sheet data as of March 31, 2022 from our audited consolidated financial statements included elsewhere in this prospectus. The unaudited consolidated statement of operations data for the six months ended September 30, 2022 and 2021 and the unaudited consolidated balance sheet data as of September 30, 2022 have been derived from our unaudited consolidated financial statements for the periods included elsewhere in this prospectus. Our historical results are not necessarily indicative of the results that should be expected for any future period. You should read the following summary consolidated financial data together with the audited consolidated financial statements included elsewhere in this prospectus and the sections titled “Exchange Rate Information” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations.”

We maintain our books and records in Pounds Sterling, and we prepare our financial statements in accordance with IFRS as issued by the IASB. We report our financial results in U.S. dollars.

Consolidated Statement of Operations and Comprehensive Loss Data:

	Six Months Ended September 30,		Years Ended March 31,	
	2022 (unaudited)	2021 (unaudited)	2022	2021
Revenue	-	-	-	-
Operating expenses:				
Research and development	\$ (2,607,675)	\$ (479,700)	\$ (1,301,178)	\$ (173,821)
General and administrative	(2,936,714)	(2,254,393)	(4,916,388)	(3,192,385)
Total operating expenses	(5,544,389)	(2,734,092)	(6,217,566)	(3,366,206)
Other income (expense), net	-	(1,021)	-	(12,295)
Loss from operations	(5,544,389)	(2,735,114)	(6,217,566)	(3,378,501)
Tax provision	-	188,761	786,521	24,994
Net loss attributable to ordinary shareholders	(5,544,389)	(2,546,353)	(5,431,045)	(3,353,507)
Other comprehensive loss:				
Foreign currency translation adjustment	(62,581)	37,845	(837,152)	346,365
Total comprehensive loss	\$ (5,606,970)	(2,508,508)	\$ (6,268,197)	\$ (3,007,142)
Basic and diluted net loss per ordinary share	\$ (0.00)	(0.00)	\$ (0.01)	\$ (0.01)

Consolidated Balance Sheet Data:

	As of September 30, 2022	
	Actual	As Adjusted(1)
Cash and cash equivalents	\$ 705,076	\$ 5,710,544
Working capital	(350,187)	4,655,312
Total assets	1,768,056	6,773,554
Total shareholders’ equity (deficit)	(344,585)	4,660,913

(1) As adjusted to give effect to the sale by us of 3,503,665 ADSs (representing 227,738,225 ordinary shares) at a public offering price of \$1.50 per ADS in this offering, after deducting estimated offering expenses payable by us in connection with this offering.

RISK FACTORS

You should carefully consider the risks described below, together with all of the other information in this registration statement. The risks and uncertainties below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we believe to be immaterial may also adversely affect our business. If any of the following risks occur, our business, financial condition and results of operations could be seriously harmed and potential future investors in our ADSs could lose all or part of their investment. Further, if we fail to meet the expectations of the public market in any given period, the potential market price of our ADSs could decline. We operate in a highly competitive environment that involves significant risks and uncertainties, some of which are outside of our control. If any of these risks actually occurs, our business and financial condition could suffer and the potential market price of our ADSs could decline.

Risks Relating to Our Business

We have only recently committed to our new business and our product candidates are in the early stages of development and it may be some years until we generate revenue, if at all.

Our product candidates, OK-101 and OK-201, are both very early in the development stage and even the lead product candidate, OK-101, is still in the pre-clinical stage. Through our scientific collaborators, we have only recently completed initial pre-clinical studies with respect to OK-101 and OK-201 and our ability to generate product revenue, which is not expected to occur for several years, if ever, will depend heavily on the successful development of the product candidates, many stages of clinical trials, regulatory approval and eventual commercialization. We have only recently committed to our new business operating as a life sciences and biotechnology business. We currently generate no revenue from sales of any product and may never be able to develop or commercialize a marketable product.

Our product candidates have not been evaluated in clinical trials and results in the clinic may not be reproduced in human trials.

The early stages of our business strategy carry significant risks associated with product candidates which have not been evaluated in human clinical trials. Not only may encouraging results seen in pre-clinical trials not be indicative of results in later clinical trials but given that the product candidates have only been evaluated in mouse models to date, unexpected or adverse effects may be seen once the product candidates enter the human clinical trials stage which in turn may create significant hurdles to further development or lead to the abandonment of further development.

There is a high degree of failure for product candidates as they progress through clinical trials and clinical trial data may be interpreted in varying ways which may delay, limit or prevent future regulatory approvals.

Many companies in the life sciences and biotechnology sector have made significant initial progress only to suffer significant setbacks in later stage clinical trials and there is a high failure rate for product candidates as they proceed through clinical trials. Data obtained from pre-clinical and clinical activities is subject to varying interpretations which may delay, limit or prevent applications for regulatory approvals.

The development of pharmaceutical products carries significant risk of failure in early and late stage development programs.

The development of pharmaceutical products is inherently uncertain, even in late-stage product development programs. There is a high failure rate in the development of pharmaceutical products and there is a substantial risk of adverse, undesirable, unintended or inconclusive results from testing or pre-clinical or clinical trials, which may substantially delay, or halt entirely, or make uneconomic, any further development of our products and may prevent or limit the commercial use of such products.

While the pre-clinical development of OK-101 and initial studies in animal models have been encouraging, the scope of these studies is limited, and significant risks exist that OK-101 may never progress to a commercially viable product. Laboratory studies in animal models carry the risk that similar results may not be seen or reproduced in future tests and trials, and there can be no guarantee that a successful test in a mouse or other animal model will be capable of being reproduced in a human clinical trial. Small scale trials and the results thereof, can be misleading as to efficacy, safety and other findings, as the outcome may be influenced by laboratory or demographic factors and not due to the chemistry or biological effect of the drug candidate being evaluated. Larger scale trials often fail to produce the same positive results seen in small scale trials for a variety of reasons and clinical trials in humans frequently fail to reproduce efficacy seen in animal trials in the laboratory. Failure can often result after significant sums have been expended on research and often where initial trial results (both in animals and in humans) have shown very encouraging results.

Management initially intends to conduct laboratory and pre-clinical trials to establish safety and efficacy of our products. Due to the inherent risks involved in developing pharmaceutical products, there is a risk that some or all of our products will not ultimately be successfully developed or launched. In addition, the planned clinical trials may fail to show the desired safety and efficacy. This may be the case even if the FDA approves an IND application as positive data in animal studies may not be reflected or reproduced in human trials. Successful completion of one stage of development of a pharmaceutical product does not ensure that subsequent stages of development will be successful. Our inability to market any of our products currently under development would adversely affect our business and financial condition.

We are currently primarily dependent for our short to medium-term success on a single early-stage product, OK-101, which is a research product that has shown pre-clinical potential but has not yet been tested on humans and has not obtained the necessary approvals required to conduct Phase I clinical trials in humans.

Any commercial development of OK-101 is highly dependent on a number of factors, including:

- the successful conduct of human trials in the initial indications of DED;
- receipt of marketing approvals for OK-101 in the United States and other jurisdictions where separate approval is required and where we subsequently choose to market OK-101;
- launching commercial sales of OK-101, if and when approved;
- acceptance of OK-101 by patients, the medical community and third-party payers;
- OK-101 competing effectively with existing therapies and in particular with established products addressing the same clinical needs;
- OK-101 influencing the treatment guidelines in relevant territories; and
- further clinical trials to provide additional data to support commercialization of OK-101 and to permit wider label claims.

If any of these milestones are not met, our business, financial condition, prospects and results of operations could be materially adversely affected.

Risks Related to Our Financial Position and Need for Capital.

We will need to raise substantial additional capital to develop and commercialize our product candidates and our failure to obtain funding when needed may force us to delay, reduce or eliminate our product development programs or collaboration efforts.

As of September 30, 2022, our cash and cash equivalents balance was approximately \$0.7 million and our working capital was approximately (\$0.4 million). Due to our recurring losses from operations and the expectation that we will continue to incur losses in the future, we will be required to raise additional capital to complete the development and commercialization of our current product candidates. We have historically relied upon private and public sales of our equity, as well as debt financings to fund our operations. In order to raise additional capital, we may seek to sell additional equity and/or debt securities or obtain a credit facility or other loan, which we may not be able to do on favorable terms, or at all. Our ability to obtain additional financing will be subject to a number of factors, including market conditions, our operating performance and investor sentiment. If we are unable to raise additional capital when required or on acceptable terms, we may have to significantly delay, scale back or discontinue the development and/or commercialization of our product candidate, restrict our operations or obtain funds by entering into agreements on unfavorable terms. Failure to obtain additional capital at acceptable terms would result in a material and adverse impact on our operations.

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain future financing.

Mazars LLP, our independent registered public accounting firm for the fiscal year ended March 31, 2022, has included an explanatory paragraph in their opinion that accompanies our audited consolidated financial statements as of and for the year ended March 31, 2022, indicating that liquidity position post December 2022 raises substantial doubt about our ability to continue as a going concern. The accompanying consolidated financial statements do not include any adjustments that might result if we are unable to continue as a going concern and, therefore, be required to realize our assets and discharge our liabilities other than in the normal course of business which could cause investors to suffer the loss of all or a substantial portion of their investment.

We anticipate that we will continue to incur significant losses for the foreseeable future.

The amount of our future net losses will depend, in part, on the rate of our future expenditures, including further research and development activity. The amount of net losses will also depend on our success in developing and commercializing OK-101 and other products that generate significant revenue. Any failure by us to become and remain profitable could depress the value of the ADSs and could impair our ability to expand our business, maintain our research and development efforts, diversify our product offerings or continue our operations.

We will need to spend extensively on further research activities and there can be no guarantee that we will have access to sufficient funds to fully realize our research and development plan or to commercialize any products derived from research activities.

We expect to incur further significant expenses in connection with our ongoing research and development activities in relation to our products in development, including the future funding of clinical studies, registration, manufacturing, marketing, sales and distribution. To finance fully our strategy, we may require more capital than is available from our existing cash balances.

Access to adequate additional financing, whether through debt financing, an equity capital raise or a suitable partnering transaction may not be available to us on acceptable terms, or at all. Further, while the potential economic impact brought by, and the duration of the COVID-19 pandemic is difficult to assess or predict, the impact of the COVID-19 pandemic on the global financial markets may reduce our ability to access capital, which could negatively impact our short-term and long-term liquidity. If we are unable to raise capital, we could be forced to delay, reduce or eliminate our research and development programs or commercialization efforts. Any additional equity fundraising may be dilutive for our shareholders.

Any of these events could have a material adverse effect on our business financial condition, prospects and results of operation and may lead us to delay, reduce or abandon research and development programs or commercialization of some of our products.

Risks Related to Commercialization of Our Product Candidates

Even if we successfully develop a product which shows efficacy in human subjects there remain high barriers to commercial success

Even if we were to receive regulatory approval for OK-101 or any other products, we may be unable to commercialize them.

There are a number of factors that may inhibit our efforts to commercialize OK-101 or any other products on our own, including:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade adequate numbers of potential practitioners to prescribe any future products;
- unforeseen costs and expenses associated with creating an independent sales and marketing organization;
- costs of marketing and promotion above those anticipated by us; and
- the inability to secure a suitable level of pricing and/or reimbursement approval from the relevant regulatory authorities in the countries we are targeting.

While we may only seek to enter into arrangements with third parties to perform sales and marketing services in non-core territories, any such arrangements could result in our product revenues (or the profitability of such product revenues) being lower than if we were to market and sell the products itself. In addition, we may not be successful in entering into arrangements with third parties to sell and market our products or may be unable to do so on terms that are favorable to us. Acceptable third parties may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our products, which in turn would have a material adverse effect on our business, prospects, financial condition and results of operations.

We have also invested and will continue to invest resources into the development of other products, such as OK-201. Even where these products are successfully developed and marketing approval is secured from relevant regulatory authorities, these products might not achieve commercial success. Factors which could limit commercial success of a product include but are not limited to:

- limited market acceptance or a lack of recognition of the unmet medical need for the product amongst prescribers;
- new competitor products entering the market;
- the number and relative efficacy, safety or cost of competitive products;
- an inability to supply a sufficient amount of the product to meet market demand;
- insufficient funding being available to market the product adequately;
- an inability to enforce intellectual property rights, or the existence of third-party intellectual property rights;

- safety concerns arising pre- or post-launch resulting in negative publicity or product withdrawal or narrowing of the product label and the group of persons who may receive the product;
- labelling being restricted/narrowed in the future and in the future by regulatory agencies; and
- refusals by government or other healthcare payors to fund the purchase of the products by healthcare providers at a commercially viable level (or at all) or otherwise to restrict the availability of approved products on other grounds.

If any of the foregoing were to occur, it could materially and adversely affect our business, financial condition, prospects and results of operations.

We face significant competition from pharmaceutical companies. We have competitors internationally, including major multinational pharmaceutical companies, universities and research institutions. In respect of OK-101 as an indication for the treatment of DED, there are a number of established companies engaged in the development and marketing of preparations addressing the DED market. In addition, there are a wide range of products addressing the DED market currently approved and marketed by a number of large and small pharmaceutical companies

Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development teams, proven marketing and manufacturing organizations and well-established sales forces. Our competitors may succeed in developing, acquiring or licensing drug products that are more effective or less costly than products which we are currently developing or which it may develop.

Established pharmaceutical companies may invest heavily to accelerate the discovery and development of products that could make our products less competitive. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability or safety in order to overcome price competition and to be commercially successful. Accordingly, our competitors may succeed in obtaining patent protection, receiving approval from the FDA, the European Medicines Agency, or EMA, or that of another relevant regulatory authority or discovering, developing and commercializing pharmaceutical products before we do, which would have a material adverse effect on our business.

The availability and price of our competitors' products could limit the demand, and the price we are able to charge, for any of our products, if approved for sale. We will not achieve our business plan if acceptance 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 products for use in limited circumstances. Competition from lower-cost generic pharmaceuticals may also result in significant reductions in sales volumes or prices for our products, which could materially adversely affect our business, prospects, financial condition and results of operations.

We are dependent on third party supply, development and manufacturing and clinical service relationships and on single manufacturing sites for certain products. Our business strategy utilizes the expertise and resources of third parties in a number of areas, including the conduct of clinical trials, other product development, manufacture and the protection of our intellectual property rights in various geographical locations. This strategy creates risks for us by placing critical aspects of our business in the hands of third parties whom we may not be able to manage or control adequately and who may not always act in our best interests.

Where we are dependent upon third parties for the development or manufacture of certain products, our ability to procure our development or manufacture in a manner which complies with regulatory requirements may be constrained, and our ability to develop and deliver such material on a timely and competitive basis may be materially adversely affected, which may impact revenues.

Regulatory requirements for pharmaceutical products tend to make the substitution of suppliers and contractors costly and time-consuming. Alternative suppliers may not be able to manufacture products effectively or obtain the necessary manufacturing licenses from relevant regulatory authorities. The unavailability of adequate commercial quantities, the inability to develop alternative sources, a reduction or interruption in supply of contracted services, or a significant increase in the price of materials and services, could have a material adverse effect on our ability to manufacture and market our products or to fulfill orders from our distributors or licensees, which in turn would have a material adverse impact on our cash flows.

Insurance coverage and reimbursement may be limited, unavailable or may be reduced over time in certain market segments for our products.

Government authorities and third-party payers, such as private health insurers, decide which pharmaceutical products they will cover and the amount of reimbursement. Reimbursement may depend upon a number of factors, including the payer's determination that use of a product is:

- a covered benefit under the payor's health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payer is a time-consuming and costly process that could require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products.

We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement, or to demonstrate commercial value compared to existing established treatments. Even if we are able to furnish the requested data, there is no guarantee that a third-party payor will cover a product. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

We may, in the future, seek approval to market our products in the EU, the US and in selected other jurisdictions. In the EU, the pricing of prescription pharmaceuticals is subject to national governmental control and pricing negotiations with governmental authorities can, in some circumstances, take several years after obtaining marketing approval for a product. In addition, market acceptance and sales of our products will depend significantly on the availability of adequate coverage and reimbursement from third-party payers and may be affected by existing and future healthcare reform measures.

The continuing efforts of governments, insurance companies, managed care organizations and other payers of healthcare services to contain or reduce costs of healthcare and/or impose price controls may materially adversely affect our ability to set prices for our products, generate revenues and achieve or maintain profitability. Any reduction in government reimbursement programs may result in a similar reduction in payments from private payers, which may materially adversely affect our business, prospects, financial condition and results of operations.

Risks Related to Our Intellectual Property

The expiration of certain intellectual property rights or an inability to obtain, maintain or enforce adequate intellectual property rights for products that are marketed or in development may result in additional competition from other third-party products. Third parties may have blocking intellectual property rights which could prevent the sale of products by us or require that compensation be paid to such third parties

The extent of our success will, to a significant degree, depend on our ability to establish, maintain, defend and enforce adequate intellectual property rights and to operate without infringing the proprietary or intellectual property rights of third parties. We have been granted, or have in-licensed rights under, a number of key patent families for OK-101 (or other proprietary rights), and patent applications are pending in the U.S., the EU, and certain other jurisdictions. We may develop or acquire further technology or products that are not patentable or otherwise protectable. The strength of patents in the pharmaceutical field involves complex legal and scientific questions and can be uncertain. Patents or other rights might not be granted under any pending or future applications filed or in-licensed by us and any claims allowed might not be sufficiently broad to protect our technologies and products from competition. Competitors may also successfully design around key patents held by us, thereby avoiding a claim of infringement. There is a risk that not all relevant prior art has been identified with respect to any particular patent or patent application and the existence of such prior art may invalidate any patents granted (or result in a patent application not proceeding to grant). Patents or other registerable rights might also be revoked for other reasons after grant. Third parties may challenge the validity, enforceability or scope of any granted patents. Our defense of our proprietary rights could involve substantial costs (even if successful) and could result in declarations of invalidity or significantly narrow the scope of those rights, limiting their value.

Competitors may have filed applications or been granted patents, or obtained additional patents and proprietary rights, which relate to and could be infringed by our products. An adverse outcome with respect to third party rights such as claims of infringement of patents or third-party proprietary rights by us could subject us to significant liabilities or require us to obtain a license for the continued use of the affected rights, which may not be available on acceptable terms or at all, or require us to cease commercialization and development efforts, or the sale of the relevant products, in whole or in part in the relevant jurisdictions.

We could be subject to claims for compensation by third parties claiming an ownership interest in the intellectual property rights relating to a commercially successful product. This may include claims from employee inventors in territories which permit such claims even where we own the intellectual property rights in question. Any such failure to defend our proprietary intellectual property could have a material adverse effect on our business, prospects, financial condition and results of operations.

We may not be able to obtain, maintain, defend or enforce the intellectual property rights covering our products

To date, we have had certain patents licensed to us in jurisdictions we consider to be important to our business. However, we cannot predict:

- the degree and range of protection any patents will afford against competitors and competing technologies, including whether third parties will find ways to invalidate or otherwise circumvent the patents by developing a competitive product that falls outside its scope;
- if, or when any patents will be granted;
- that granted patents will not be contested, invalidated or found unenforceable;
- whether or not others will obtain patents claiming aspects similar to those covered by the Company's patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings, or whether such litigation or proceedings will be initiated by third parties against us, which may be costly and time consuming; and
- whether third parties will claim that our technology infringes upon their rights.

While we believe that we have novel composition of matter on the OK-101 peptide and novel methods of its use in treating DED, we cannot be sure that these patent applications will issue as patents. Each patent office has different patentability requirements, but we believe that the license patent applications contain patentable subject matter. The process for issuance of a patent involves correspondence with each local patent office in the jurisdictions in which the patent application is filed. That process, patent prosecution, involves a discussion of any relevant prior art and typically a discussion of the scope of the claims. The patent prosecution process can take several years depending on the jurisdiction and is not in the control of the patent owner, but in the control of the local patent office. We cannot be sure the outcome of the patent prosecution will be successful and result in issued patents.

Patent protection is of importance to us in maintaining our competitive position in our planned product lines and a failure to obtain or retain adequate protection could have a material adverse effect on our business, prospects, financial condition and results of operations.

We may not be able to prevent disclosure of our trade secrets, know-how or other proprietary information.

We rely on trade secret protection to protect our interests in proprietary know-how and in processes for which patents are difficult to obtain or enforce. If we are unable to protect our trade secrets adequately the value of our technology and products could be significantly diminished. Furthermore, our employees, consultants, contract personnel or third-party partners, either accidentally or through willful misconduct, may cause serious damage to our programs and/or our strategy by disclosing confidential information to third parties. It is also possible that confidential information could be obtained by third parties as a result of breaches of our physical or electronic security systems. Any disclosure of confidential data into the public domain or to third parties could allow third parties to access confidential information and use it in competition with us. In addition, others may independently discover the confidential information. Any action to enforce our rights against any misappropriation or unauthorized use and/or disclosure of confidential information is likely to be time-consuming and expensive, and may ultimately be unsuccessful, or may result in a remedy that is not commercially valuable. Any such loss of confidential information or failure to enforce our rights in relation to such confidential information, or unsatisfactory outcome of any related litigation could have a material adverse effect on our business, prospects, financial condition or results of operation.

Our product candidates could infringe patents and other intellectual property rights of third parties.

Our commercial success depends upon our ability, and the ability of any third party with which we may partner to develop, manufacture, market and sell our products and use our patent-protected technologies without infringing the patents of third parties.

Our products may infringe or may be alleged to infringe existing patents or patents that may be granted in the future which may result in costly litigation and could result in our having to pay substantial damages or limit our ability to commercialize our products.

Because some patent applications in Europe, the U.S. and many foreign jurisdictions may be maintained in secrecy until the patents are issued, patent applications in such jurisdictions are typically not published until 18 months after filing, and publications in the scientific literature often lag behind actual discoveries. Accordingly, we cannot be certain that others have not filed patents that may cover our technologies, our products or the use of our products. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our products or the use of our products. As a result, we may become party to, or threatened with, future adversarial proceedings or litigation regarding patents with respect to our products and technology.

If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid, and we may not be able to do this. If we are found to infringe a third party's patent, we could be required to obtain a license from such third party to continue developing and marketing our products and technology or we may elect to enter into such a license in order to settle litigation or in order to resolve disputes prior to litigation. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we are able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies that are licensed to us and could require us to make substantial royalty payments. We could also be forced, including by court order, to cease commercializing the infringing technology or products. A finding of infringement could prevent us from commercializing our products or force us to cease some of our business operations, which could materially harm our business. Claims that we have misappropriated the confidential information or trade secrets of third parties could have a similarly negative impact on our business.

Any such claims are likely to be expensive to defend, and some of our competitors may be able to sustain the costs of complex patent litigation more effectively than us can because they have substantially greater resources. Moreover, even if we are successful in defending any infringement proceedings, we may incur substantial costs and divert management's time and attention in doing so, which could materially adversely affect our business, prospects, results of operations or financial condition.

Risks Related to Our Operations

Risks relating to managing growth, employee matters and other risks relating to our business

Growth may place significant demands on our management and resources. We expect to experience growth in the number of our employees and the scope of our operations in connection with the continued development and, in due course, the potential commercialization of our products.

This potential growth will place a significant strain on our management and operations, and we may have difficulty managing this future potential growth.

We are highly dependent on our current executive officers and their services are critical to the successful implementation of our product development and regulatory strategies. While suitable contracts of employment are in place including six to 12 months' notice periods for all executive officers, they may give notice to terminate their employment with us at any time. The loss of the services of any of our executive officers and our inability to find suitable replacements could harm our business, prospects, financial condition, results of operations and ability to achieve the successful development or commercialization of our products.

Challenges in identifying and retaining key personnel could impair our ability to conduct and grow our operations effectively. Our ability to compete in the highly competitive pharmaceutical industry depends upon our ability to attract and retain highly qualified management and sales teams. We are intending to recruit our own commercial team and expand our existing central infrastructure team. Many of the other pharmaceutical companies and academic institutions that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. We might not be able to attract or retain these key persons on conditions that are economically acceptable. Our inability to attract and retain these key persons could have a material adverse effect on our business, prospects, financial conditions and results of operation.

COVID-19 has adversely affected our business, and any new pandemic, epidemic or outbreak of an infectious disease may further adversely affect our business.

In December 2019, a novel strain of coronavirus, COVID-19, spread globally, substantially impacting the global economy and our operations, including interrupting preclinical and clinical trial activities and disrupting our supply chain. The spread of an infectious disease, including COVID-19, may also result in the inability of our suppliers to source or deliver components or raw materials necessary for our clinical supply on a timely basis or at all. In addition, hospitals may reduce staffing and reduce or postpone certain treatments in response to the spread of an infectious disease. Such events may result in a period of business disruption, and in reduced operations, or doctors and medical providers may be unwilling to participate in our clinical trials, any of which could materially affect our business, financial condition and results of operations. The extent to which COVID-19 impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. A significant pandemic as with COVID-19, or any other infectious disease, could result in a widespread health crisis that could adversely affect the economies and financial markets worldwide, resulting in an economic downturn that could impact our business, financial condition and results of operations.

We may become subject to product liability claims.

We face an inherent risk of product liability and associated adverse publicity as a result of the clinical testing of our products and sales of our products once marketing approval is received from relevant regulatory authorities.

Criminal or civil proceedings might be filed against us any by study subjects, patients, relevant regulatory authorities, pharmaceutical companies, and any other third party using or marketing our products. Any such product liability claims may include allegations of defects in manufacturing or design, negligence, strict liability, a breach of warranties and a failure to warn of dangers inherent in the product.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products, if approved. Even if we successfully defend ourselves against such product liability claims it could require significant financial and management resources. Regardless of the merits or eventual outcome, product liability claims may result in:

- decreased demand for our products due to negative public perception;
- injury to our reputation;
- withdrawal of clinical study participants or difficulties in recruiting new study participants;
- initiation of investigations by regulators;
- costs to defend or settle the related litigation;
- diversion of management's time and our resources;
- substantial monetary awards to patients, study participants or subjects;
- product recalls, withdrawals or labelling, marketing or promotional restrictions;
- loss of revenues from product sales; or
- the inability to commercialize any of our products, if approved.

Although we will maintain levels of insurance customary for our sector to cover our current and future business operations, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. In such cases, we would have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts.

If we or our partners, licensees and subcontractors were unable to obtain and maintain appropriate insurance coverage at an acceptable cost, or to protect ourselves in any way against actions for damages, this would seriously affect the marketing of our products and, more generally, be detrimental to our business, prospects, results of operations or financial condition.

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

We are exposed to the risk of employees, independent contractors, principal investigators, consultants, commercial partners or vendors engaging in fraud or other misconduct. Misconduct could include intentional failures to comply with FDA or EMA regulations or those of other relevant regulatory authorities, to provide accurate information to the FDA, EMA or other relevant regulatory authorities, or to comply with manufacturing standards we have established.

In particular, sales, marketing and business arrangements in the life sciences and biotechnology sector are subject to extensive laws and regulations intended to prevent fraud, misconduct, bribery 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 studies, which could result in regulatory sanctions and serious harm to our reputation. 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 or relevant regulatory authority investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions, and our reputation.

We may be vulnerable to disruptions of information technology systems or breaches of data security. We are dependent on information technology systems and infrastructure to operate our business. In the ordinary course of our business, we collect, store and transmit confidential information, including intellectual property, proprietary business information and personal information. It is important that we do so in a secure manner to maintain confidentiality and integrity of such confidential information. Any failure to do so could adversely affect our business, prospects, results of operation or financial condition.

The relationship of the UK with the EU could impact our ability to operate efficiently in certain jurisdictions or in certain markets.

The UK formally exited the EU on January 31, 2020, which is commonly known as Brexit. Under the terms of its departure, the UK entered a transition period during which it continued to follow all EU rules until December 31, 2020, or the Transition Period. On December 30, 2020, the UK and EU signed the Trade and Cooperation Agreement, which includes an agreement on free trade between the two parties.

There is considerable uncertainty resulting from a lack of precedent and the complexity of the UK and EU's intertwined legal regimes as to how Brexit (following the Transition Period) will impact the medical devices industry in Europe. Since a significant proportion of the regulatory framework in the UK applicable to our business and product candidates is derived from EU directives and regulations, Brexit could materially impact the regulatory regime with respect to the development, manufacture, importation, approval and commercialization of our product candidates in the UK or the EU. The impact will largely depend on the model and means by which the UK's relationship with the EU is governed post-Brexit and the extent to which the UK chooses to diverge from the EU regulatory framework. For example, following the Transition Period, the UK will no longer be covered by the centralized procedures for obtaining EU-wide marketing authorizations and our product candidates will therefore require a separate marketing authorization for such products to be marketed in the UK. It is also unclear as to whether the relevant authorities in the EU and the UK are adequately prepared for the additional administrative burden caused by Brexit. Any delay in obtaining, or an inability to obtain, any marketing approvals, as a result of Brexit or otherwise, would prevent us from, or delay commercialization of, product candidates in the UK and/or the EEA and restrict our ability to generate revenue and achieve and sustain profitability.

If any of these outcomes occur, we may be forced to restrict or delay efforts to seek regulatory approval in the UK for its product candidates, which could significantly and materially harm our business. There is a degree of uncertainty regarding the overall impact that Brexit will have on process to obtain regulatory approval in the UK for product candidates.

Further, the UK's withdrawal from the EU has resulted in the relocation of the EMA from the UK to the Netherlands. This relocation has caused, and may continue to cause, disruption in the administrative and medical scientific links between the EMA and the UK Medicines and Healthcare Products Regulatory Agency, including delays in granting clinical trial authorization or marketing authorization, disruption of importation and export of medical devices, active substance and other components of new drug formulations, and disruption of the supply chain for clinical trial product and final authorized formulations. The cumulative effects of the disruption to the regulatory framework may add considerably to the development lead time to marketing authorization and commercialization of product candidates in the EU and/or the UK. Brexit may also result in a reduction of funding to the EMA once the UK no longer makes financial contributions to EU institutions, such as the EMA. If funding to the EMA is so reduced, it could create delays in the EMA issuing regulatory approvals for our product candidates and, accordingly, have a material adverse effect on our business, financial condition, results of operations or prospects.

Risks Related to Government Regulation

Even if we complete the necessary clinical trials, we cannot predict when, or if, we will obtain regulatory approval to commercialize our product candidates and whether the approval may be for a narrower indication than we seek.

We cannot commercialize a product candidate until the appropriate regulatory authorities have reviewed and approved the product candidate. The FDA must review and approve any new pharmaceutical product before it can be marketed and sold in the United States. The FDA regulatory review and approval process, which includes evaluation of preclinical studies and clinical trials of a product candidate and proposed labeling, as well as the evaluation of the manufacturing process and manufacturers' facilities, all of which is lengthy, expensive and uncertain. To obtain approval, we must, among other things, demonstrate with substantial evidence from well-controlled clinical trials that the product candidate is both safe and effective for each indication where approval is sought. Even if our product candidates meet the FDA's safety and effectiveness endpoints in clinical trials, the FDA may not complete their review processes in a timely manner, or we may not be able to obtain regulatory approval. The FDA has substantial discretion in the review and approval process and may refuse to file our application for substantive review or may determine after review of our data that our application is insufficient to allow approval of our product candidates. The FDA may require that we conduct additional preclinical studies, clinical trials or manufacturing validation studies and submit that data before it will reconsider our application. Additional delays may result if an FDA Advisory Committee or other regulatory authority recommends non-approval or restrictions on approval. In addition, we may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory authority policy during the period of product development, clinical trials and the review process.

The FDA, EMA or other regulatory authorities also may approve a product candidate for more limited indications than requested or may impose significant limitations in the form of narrow indications, warnings or a risk evaluation and mitigation strategy, or REMS. These regulatory authorities may require precautions or contraindications with respect to conditions of use or may grant approval subject to the performance of costly post-marketing clinical trials. In addition, the FDA, EMA or other regulatory authorities may not approve the labeling claims that are necessary or desirable for the successful commercialization of our product candidates. Any of the foregoing scenarios could harm the commercial prospects for our product candidates and negatively impact our business, financial condition, results of operations and prospects.

Delays in obtaining regulatory approval of our manufacturing process and facility or disruptions in our manufacturing process may delay or disrupt our product development and commercialization efforts.

We do not currently operate manufacturing facilities for clinical or commercial production of our product candidates. Before we can begin to commercially manufacture our product candidates, whether in a third-party facility or in our own facility, if and when established, we must obtain regulatory approval from the FDA for our manufacturing process and facility. A manufacturing authorization must also be obtained from the appropriate European Union regulatory authorities and from other foreign regulatory authorities, as applicable. In order to obtain approval, we will need to ensure that all of our processes, methods and equipment are compliant with cGMP, and perform extensive audits of vendors, contract laboratories and suppliers. If any of our vendors, contract laboratories or suppliers are found to be non-compliant with cGMP, we may experience delays or disruptions in manufacturing while we work with these third parties to remedy the violation or while we work to identify suitable replacement vendors. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures. In complying with cGMP, we will be obligated to expend time, money and effort in production, record keeping and quality control to assure that the product meets applicable specifications and other requirements. If we fail to comply with these requirements, we would be subject to possible regulatory action and may not be permitted to sell any product candidate that we may develop.

If we or our third-party manufacturers fail to comply with applicable cGMP regulations, the FDA, EMA and other regulatory authorities can impose regulatory sanctions including, among other things, refusal to approve a pending application for a new product candidate or suspension or revocation of a pre-existing approval. Such an occurrence may cause our business, financial condition, results of operations and prospects to be harmed.

Additionally, if the supply of our products from our third-party manufacturers to us is interrupted for any reason, including due to regulatory requirements or actions (including recalls), adverse financial developments at or affecting the supplier, failure by the supplier to comply with cGMP requirements, contamination, business interruptions or labor shortages or disputes, there could be a significant disruption in commercial supply of our products. We do not currently have a backup manufacturer of our product candidate supply for clinical trials or commercial sale. An alternative manufacturer would need to be qualified through a supplement to its regulatory filing, which could result in further delays. The regulatory authorities also may require additional clinical trials if a new manufacturer is relied upon for commercial production. Switching manufacturers may involve substantial costs and could result in a delay in our desired clinical and commercial timelines.

If our competitors are able to obtain orphan drug exclusivity for products that constitute the same drug and treat the same indications as our product candidates, we may not be able to have competing products approved by applicable regulatory authorities for a significant period of time. In addition, even if we obtain orphan drug exclusivity for any of our products, such exclusivity may not protect us from competition.

Regulatory authorities in some jurisdictions, including the United States and the European Union, may designate products for relatively small patient populations as orphan drugs. Under the Orphan Drug Act of 1983, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, which is generally defined as having a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user-fee waivers. In the European Union, the EMA's Committee for Orphan Medicinal Products grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10,000 persons in the European Union. Additionally, orphan drug designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the drug in the European Union would be sufficient to justify the necessary investment in developing the drug or biologic product. In Europe, orphan drug designation entitles a party to a number of incentives, such as protocol assistance and scientific advice specifically for designated orphan medicines, and potential fee reductions depending on the status of the sponsor.

The designation as an orphan product does not guarantee that any regulatory agency will accelerate regulatory review of, or ultimately approve, that product candidate, nor does it limit the ability of any regulatory agency to grant orphan drug designation to product candidates of other companies that treat the same indications as our product candidates prior to our product candidates receiving exclusive marketing approval.

Generally, if a product candidate with an orphan drug designation receives the first marketing approval for the indication for which it has such designation, the product is entitled to a period of marketing exclusivity, which precludes the FDA or the EMA from approving another marketing application for a product that constitutes the same drug treating the same indication for that marketing exclusivity period, except in limited circumstances. If another sponsor receives such approval before we do (regardless of our orphan drug designation), we will be precluded from receiving marketing approval for our product for the applicable exclusivity period. The applicable period is seven years in the United States and 10 years in the European Union. The exclusivity period in the European Union can be reduced to six years if a product no longer meets the criteria for orphan drug designation or if the product is sufficiently profitable so that market exclusivity is no longer justified. Orphan drug exclusivity may be revoked if any regulatory agency determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantity of the product to meet the needs of patients with the rare disease or condition.

Even if we obtain orphan drug exclusivity for a product candidate, that exclusivity may not effectively protect the product candidate from competition because different drugs can be approved for the same condition. In the United States, even after an orphan drug is approved, the FDA may subsequently approve another drug for the same condition if the FDA concludes that the latter drug is not the same drug or is clinically superior in that it is shown to be safer, more effective or makes a major contribution to patient care. In the European Union, marketing authorization may be granted to a similar medicinal product for the same orphan indication if:

- the second applicant can establish in its application that its medicinal product, although similar to the orphan medicinal product already authorized, is safer, more effective or otherwise clinically superior;
- the holder of the marketing authorization for the original orphan medicinal product consents to a second orphan medicinal product application; or

- the holder of the marketing authorization for the original orphan medicinal product cannot supply sufficient quantities of orphan medicinal product.

Even if we obtain regulatory approval for a product candidate, our product candidates will remain subject to regulatory oversight.

Even if we obtain regulatory approval for our product candidates, they will be subject to ongoing regulatory requirements for manufacturing, labeling, packaging, storage, advertising, promotion, sampling, record-keeping and submission of safety and other post-market information. Any regulatory approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the quality, safety and clinical effectiveness of the product.

Some of our product candidates are classified as biologics in the United States, and therefore, can only be sold if we obtain a biologics license application, or BLA, from the FDA. The holder of an approved BLA also must submit new or supplemental applications and obtain FDA approval for certain changes to the approved product, product labeling or manufacturing process. In addition, the holder of a BLA approval must comply with the FDA's advertising and promotion requirements, such as those related to the prohibition on promoting products for uses or in patient populations that are not described in the product's approved labeling (known as "off-label use"). Advertising and promotional materials must comply with FDA rules and are subject to FDA review, in addition to other potentially applicable federal and state laws.

In addition, product manufacturers and their facilities are subject to payment of user fees and continual review and periodic inspections by the FDA and other regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the BLA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that product (in addition to our being obligated as holder of a BLA to monitor and report adverse events and any failure of a product to meet the BLA specifications), a regulatory authority may impose restrictions relative to that product, the manufacturing facility or us, 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 our product candidates, a regulatory or enforcement authority may:

- issue a warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending BLA or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;
- restrict the marketing or manufacturing of the product;
- seize or detain the product or otherwise require the withdrawal of the product from the market;
- refuse to permit the import or export of the product; 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 product candidates and adversely affect our business, financial condition, results of operations and prospects.

In addition, the FDA's policies, and those of the EMA and other regulatory authorities, may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability, which would negatively impact our business, financial condition, results of operations and prospects.

Even if we obtain and maintain approval for our product candidates in a major pharmaceutical market such as the United States, we may never obtain approval for our product candidates in other major markets.

In order to market any products in a country or territory, we must establish and comply with numerous and varying regulatory requirements of such countries or territories regarding safety and effectiveness. Clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. Approval procedures vary among countries and can involve additional product testing and validation and additional administrative review periods. Seeking regulatory approvals in all major markets could result in significant delays, difficulties and costs for us and may require additional preclinical studies or clinical trials, which would be costly and time consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates in those countries. For example, in many jurisdictions outside of the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products would also be subject to approval. Satisfying these and other regulatory requirements is costly, time-consuming, uncertain and subject to unanticipated delays. In addition, our failure to obtain regulatory approval in any country may delay or have negative effects on the process for regulatory approval in other countries. We currently do not have any product candidates approved for sale in any jurisdiction, whether in the United States, Europe or any other international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, our target market will be reduced and our ability to realize the full market potential of our product candidates will be compromised.

We may seek a conditional marketing authorization in Europe for some or all of our current product candidates, but we may not be able to obtain or maintain such designation.

As part of its marketing authorization process, the EMA may grant marketing authorizations for certain categories of medicinal products on the basis of less complete data than is normally required, when doing so may meet unmet medical needs of patients and serve the interest of public health. In such cases, it is possible for the Committee for Medicinal Products for Human Use, or CHMP, to recommend the granting of a marketing authorization, subject to certain specific obligations to be reviewed annually, which is referred to as a conditional marketing authorization.

This may apply to medicinal products for human use that fall under the jurisdiction of the EMA, including those that aim at the treatment, the prevention, or the medical diagnosis of seriously debilitating or life-threatening diseases and those designated as orphan medicinal products.

A conditional marketing authorization may be granted when the CHMP finds that, although comprehensive clinical data referring to the safety and therapeutic utility of the medicinal product have not been supplied, all the following requirements are met:

- the risk-benefit balance of the medicinal product is positive;
- it is likely that the applicant will be in a position to provide the comprehensive clinical data;
- unmet medical needs will be fulfilled; and
- the benefit to public health of the immediate availability on the market of the medicinal product concerned outweighs the risk inherent in the fact that additional data is still required.

The granting of a conditional marketing authorization is restricted to situations in which only the clinical part of the application is not yet fully complete. Incomplete preclinical or quality data may only be accepted if duly justified and only in the case of a product intended to be used in emergency situations in response to public health threats. Conditional marketing authorizations are valid for one year, on a renewable basis. The holder will be required to complete ongoing trials or to conduct new trials with a view to confirming that the benefit-risk balance is positive. In addition, specific obligations may be imposed in relation to the collection of pharmacovigilance data.

Granting a conditional marketing authorization allows medicines to reach patients with unmet medical needs earlier than might otherwise be the case and will ensure that additional data on a product is generated, submitted, assessed and acted upon.

Healthcare legislative reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

In the United States, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, or the MMA, changed the way Medicare covers and pays for pharmaceutical products. The MMA expanded Medicare coverage for outpatient drug purchases by adding a new Medicare Part D program and introduced a new reimbursement methodology based on average sales prices for Medicare Part B physician-administered drugs. In addition, the MMA authorized Medicare Part D prescription drug plans to limit the number of drugs that will be covered in any therapeutic class in their formularies. The MMA's cost reduction initiatives and other provisions could decrease the coverage and price that we receive for any approved products. While the MMA 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 MMA may result in a similar reduction in payments from private payors. Similar regulations or reimbursement policies may be enacted in international markets, which could similarly impact our business.

In March 2010, the PPACA (as amended by the Health Care and Education Reconciliation Act of 2010) was passed, which substantially changes the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The PPACA, among other things: (i) addresses a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; (ii) increases the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extends the rebate program to individuals enrolled in Medicaid managed care organizations; (iii) establishes annual fees and taxes on manufacturers of certain branded prescription drugs; (iv) expands the availability of lower pricing under the 340B drug pricing program by adding new entities to the program; and (v) establishes a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. Additionally, in the United States, the Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biologic products that are demonstrated to be biosimilar or "interchangeable" with an FDA-approved biologic product. This new pathway could allow competitors to reference data from biologic products already approved after 12 years from the time of approval. This could expose us to potential competition by lower-cost biosimilars even if we commercialize a product candidate faster than our competitors. Moreover, the creation of this abbreviated approval pathway does not preclude or delay a third party from pursuing approval of a competitive product candidate via the traditional approval pathway based on their own clinical trial data.

Additional changes that may affect our business include those changes governing enrollment in federal healthcare programs, reimbursement changes, rules regarding prescription drug benefits under the health insurance exchanges and fraud and abuse and enforcement. Continued implementation of the PPACA and the passage of additional laws and regulations may result in the expansion of new programs such as Medicare payment for performance initiatives, and may impact existing government healthcare programs, such as by improving the physician quality reporting system and feedback program.

For each state that does not choose to expand its Medicaid program, there likely will be fewer insured patients overall, which could impact the sales, business and financial condition of manufacturers of branded prescription drugs. Where patients receive insurance coverage under any of the new options made available through the PPACA, manufacturers may be required to pay Medicaid rebates on that resulting drug utilization. The U.S. federal government also has announced delays in the implementation of key provisions of the PPACA. The implications of these delays for our and our potential partners' business and financial condition, if any, are not yet clear.

In addition, there have been judicial and congressional challenges to certain aspects of the PPACA, and we expect the current administration and Congress will likely continue to seek legislative and regulatory changes, including repeal and replacement of certain provisions of the PPACA. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the PPACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the PPACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. More recently, the U.S. House of Representatives passed legislation known as the American Health Care Act of 2017, and Senate Republicans have released a draft bill known as the Better Care Reconciliation Act of 2017, each of which would repeal certain aspects of the PPACA if ultimately enacted. The prospects for enactment of these legislative initiatives remain uncertain. Further, Congress also could consider other legislation to replace elements of the PPACA. We cannot know how efforts to repeal and replace the PPACA or any future healthcare reform legislation will impact our business.

We expect that the PPACA, as well as other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize our products.

The Department of Health and Human Services Office of Inspector General issued final regulations on November 30, 2020 to eliminate safe harbor protection under the anti-kickback statute for drug price reductions that pharmaceutical manufacturers pay to Medicare and Medicaid plan sponsors and their pharmacy benefit managers. The proposal reflects a clear intent to substantially alter many of the current drug discount and services compensation practices among pharmaceutical manufacturers and Medicare and Medicaid managed care organizations and their pharmacy benefit managers. The proposal also reflects a skepticism that current drug discount and compensation practices among manufacturers and pharmacy benefit managers are sufficiently transparent to health plans to ensure that all appropriate cost reductions and value is passed through to health plans and reflected in lower health plans costs and lower premiums for beneficiaries. The Biden Administration has delayed the effective date of this rule until January 1, 2023, and a lawsuit initiated by the Pharmaceutical Care Management Administration has challenged this final rule. If the regulation becomes effective it could result in lower prices for pharmaceutical products in general.

The Centers for Medicare and Medicaid Services issued an interim final rule on November 20, 2020 that would tie prices for certain drugs under Medicare Part B to the lowest price for those drugs available in certain countries that are members of the Organization for Economic Co-operation and Development. This "most favored nation" drug pricing rule is also the subject of lawsuits, and a federal court has placed an injunction on the implementation of the rule. This rule, if finalized, could also result in lower prices for pharmaceutical products in general.

The Biden Administration will have the opportunity to address these regulations as well as drug pricing, health care access, and other health care reform issues. Any further legislative or administrative action to reduce reimbursement or health benefits to beneficiaries under the Medicare or Medicaid program could affect the payment we could collect from sale of any product in the United States.

We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

We are subject to stringent and changing privacy laws, regulations and standards as well as contractual obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could harm our reputation, subject us to significant fines and liability, or otherwise adversely affect our business or prospects.

We are subject to data privacy and protection laws, regulations, policies and contractual obligations that apply to the collection, transmission, storage, processing and use of personal information or personal data, which among other things, impose certain requirements relating to the privacy, security and transmission of personal information.

The legislative and regulatory landscape for privacy and data protection continues to evolve in jurisdictions worldwide, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Failure to comply with laws, regulations and other obligations governing personal information could result in enforcement actions against us, including fines, imprisonment of company officials and public censure, processing penalties, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business, financial condition, results of operations or prospects.

The regulatory framework for the collection, use, retention, safeguarding, disclosure, sharing, transfer and other processing of personal information worldwide is rapidly evolving and is likely to remain uncertain for the foreseeable future. Globally, virtually every jurisdiction in which we operate has established its own data security and privacy frameworks with which we must comply. For example, the collection, use, disclosure, transfer or other processing of personal data regarding individuals in the European Union, including personal health data, is subject to the European Union General Data Protection Regulation (EU) 2016/679, or the GDPR, which took effect across all member states of the European Union, or EU, in May 2018 and similar legislation in the United Kingdom. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, establishing a legal basis for processing, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data that requires the adoption of administrative, physical and technical safeguards, providing notification of data breaches to appropriate data protection authorities or data subjects, establishing means for data subjects to exercise rights in relation to their personal data and taking certain measures when engaging third-party processors. The GDPR increases our obligations with respect to clinical trials conducted in the EU by expanding the definition of personal data to include coded data and requiring changes to informed consent practices and more detailed notices for clinical trial subjects and investigators. In addition, the GDPR also imposes strict rules on the transfer of personal data to countries outside the European Economic Area, or EEA, including the United States and, as a result, increases the scrutiny for transfers of personal data from clinical trial sites located in the EU to the United States. The United Kingdom and Switzerland have adopted similar restrictions.

Further, Brexit and ongoing developments in the United Kingdom have created uncertainty with regard to data protection regulation in the United Kingdom.

Privacy and data security requirements are also either in place or underway in the United States. There are a broad variety of data protection laws that may be applicable to our activities, and a range of enforcement agencies at both the state and federal levels that can review companies for privacy and data security concerns based on general consumer protection laws. The Federal Trade Commission and state attorneys general can all be aggressive in reviewing privacy and data security protections for consumers. New laws also are being considered or have been implemented at both the state and federal levels. For example, the California Consumer Privacy Act of 2018, or the CCPA, which became effective on January 1, 2020, requires companies that process information on California residents to make new disclosures to consumers about their data collection, use and sharing practices, provides such individuals with new data privacy rights (including the ability to opt out of certain disclosures of personal information), imposes new operational requirements for covered businesses, provides a private right of action for data breaches and creates a statutory damages framework. Virginia became the second state to adopt a comprehensive privacy legislation on March 2, 2021 with enactment of the Virginia Consumer Data Protection Act. Many other states are considering similar legislation, and a broad range of legislative measures also have been introduced at the federal level. Although there are limited exemptions for clinical trial data under the CCPA, the CCPA and other similar laws could impact our business activities depending on how it is interpreted and exemplifies the vulnerability of our business to the evolving regulatory environment related to personal data.

Additionally, regulations promulgated pursuant to the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended, establish privacy and security standards that limit the use and disclosure of individually identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information and ensure the confidentiality, integrity and availability of electronic protected health information. These provisions may be applicable to our business or that of our collaborators, service providers, contractors or consultants. Determining whether protected health information has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and may be subject to changing interpretation. If we are unable to properly protect the privacy and security of protected health information, we could be found to have violated these privacy and security laws and/or breached certain contracts with our business partners (including as a business associate). Further, if we fail to comply with applicable privacy laws, such as, to the extent applicable, HIPAA privacy and security standards, we could face significant civil and criminal penalties. In the United States, the Department of Health and Human Services' and state attorney's general enforcement activity can result in financial liability and reputational harm, and responses to such enforcement activity can consume significant internal resources. In addition, state attorneys general are authorized to bring civil actions seeking either injunctions or damages in response to violations that threaten the privacy of state residents. We cannot be sure how these regulations will be interpreted, enforced or applied to our operations. In addition to the risks associated with enforcement activities and potential contractual liabilities, our ongoing efforts to comply with evolving laws and regulations at the federal and state level may be costly and require ongoing modifications to our policies, procedures and systems.

Given the breadth and depth of changes in data protection obligations, preparing for and complying with the GDPR, CCPA and similar laws' requirements are rigorous and time-intensive and require significant resources and a review of our technologies, systems and practices, as well as those of any third-party collaborators, service providers, contractors or consultants that process or transfer personal data. Changes involving the GDPR, CCPA or other laws or regulations associated with the enhanced protection of certain types of sensitive data, such as healthcare data or other personal information from our clinical trials, could require us to change our business practices and put in place additional compliance mechanisms, may interrupt or delay our development, regulatory and commercialization activities and increase our cost of doing business, and could expose us to government enforcement actions, regulatory investigations, private litigation and significant fines, penalties and remediation costs and could have a material adverse effect on our business, financial condition or results of operations. Additionally, any failure by our third-party collaborators, service providers, contractors or consultants to comply with applicable law, regulations or contractual obligations related to data privacy or security could result in proceedings against us by governmental entities or others, fines, reputational harm and other liabilities.

We may publish privacy policies and other documentation regarding our collection, processing, use and disclosure of personal information and/or other confidential information. Although we endeavor to comply with our published policies and other documentation, we may at times fail to do so or may be perceived to have failed to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees or vendors fail to comply with our published policies and documentation. Such failures can subject us to potential foreign, local, state and federal action if they are found to be deceptive, unfair, or misrepresentative of our actual practices. Moreover, subjects about whom we or our partners obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights or failed to comply with data protection laws or applicable privacy notices even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

It is possible that new and existing laws may be interpreted and applied in a manner that is inconsistent with our practices and our efforts to comply with the evolving data protection rules may be unsuccessful. If so, this could result in government-imposed fines, or penalties or orders requiring that we change our practices, which could adversely affect our business. We must devote significant resources to understanding and complying with this changing landscape. Failure to comply with federal, state and foreign laws regarding privacy and security of personal information could expose us to government-imposed fines and penalties under such laws, penalties or orders requiring that we change our practices, claims for damages or other liabilities, regulatory investigations and enforcement actions, litigation and significant costs for remediation, reputational harm, diminished profits and earnings, additional reporting requirements and/or oversight, any of which could adversely affect our business, our results of operations or prospects. We also face a threat of consumer class actions related to these laws and the overall protection of personal data. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity. Any of the foregoing could have a materially adverse effect on our reputation and our business, financial condition, results of operations or prospects.

We are subject to the U.K. Bribery Act, the U.S. Foreign Corrupt Practices Act and other anti-corruption laws, as well as export control laws, import and customs laws, trade and economic sanctions laws and other laws governing our operations.

Our operations are subject to anti-corruption laws, including the U.K. Bribery Act 2010, or the U.K. Bribery Act, the U.S. Foreign Corrupt Practices Act of 1977, or the FCPA, the U.S. domestic bribery statute contained in 18 §201, the U.S. Travel Act, and other anti-corruption laws that apply in countries where we do business. The U.K. Bribery Act, the FCPA and these other laws generally prohibit us and our employees and intermediaries from authorizing, promising, offering, or providing, directly or indirectly, improper or prohibited payments, or anything else of value, to government officials or other persons to obtain or retain business or gain some other business advantage. Under the U.K. Bribery Act, we may also be liable for failing to prevent a person associated with us from committing a bribery offense. We and our commercial partners operate in a number of jurisdictions that pose a high risk of potential U.K. Bribery Act or FCPA violations, and we participate in collaborations and relationships with third parties whose corrupt or illegal activities could potentially subject us to liability under the U.K. Bribery Act, FCPA or local anti-corruption laws, even if we do not explicitly authorize or have actual knowledge of such activities. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions and embargoes on certain countries and persons, anti-money laundering laws, import and customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the U.K. Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we are not in compliance with the U.K. Bribery Act, the FCPA and other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of the U.K. Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws by United Kingdom, United States or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

Our relationships with customers, physicians and third-party payors will be subject, directly or indirectly, to federal and state healthcare fraud and abuse laws, false claims laws, health information privacy and security laws and other healthcare laws and regulations. If we are found in violation of these laws and regulations, we may be required to pay a penalty or be suspended from participation in federal or state healthcare programs, which may adversely affect our business, financial condition and results of operations.

If we obtain FDA approval for our product candidates and begin commercializing them in the United States, our operations will be directly, or indirectly through our prescribers, customers and purchasers, subject to various federal and state fraud and abuse laws and regulations, including, without limitation, the federal Anti-Kickback Statute, the federal civil and criminal false claims laws and Physician Payments Sunshine Act of 2010 and regulations. These laws will impact, among other things, our proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy laws by both the U.S. federal government and the states in which we conduct our business. The laws that will affect our operations include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind, in return for either the referral of an individual, or the purchase, leasing, furnishing or arranging for the purchase, lease or order of a good, facility, item or service reimbursable under a federal healthcare program, such as the Medicare and Medicaid programs. This statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on the one hand, and prescribers, purchasers and formulary managers on the other. The PPACA amended the intent requirement of the federal Anti-Kickback Statute, such that a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it;

- federal civil and criminal false claims laws and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid or other government payors that are false or fraudulent. The PPACA provides, and recent government cases against pharmaceutical and medical device manufacturers support the view that federal Anti-Kickback Statute violations and certain marketing practices, including off-label promotion, may implicate the False Claims Act of 1863;
- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit, among other things, a person from knowingly and willfully executing a scheme or from making false or fraudulent statements to defraud any healthcare benefit program, regardless of the payor (e.g., public or private);
- HIPAA (as amended by the Health Information Technology for Economic and Clinical Health Act of 2009), and their implementing regulations, which impose certain requirements relating to the privacy, security and transmission of individually identifiable health information without appropriate authorization by entities subject to the rule, such as health plans, health care clearinghouses and health care providers, and their respective business associates that perform certain functions or activities that involve the use or disclosure of protected health information on their behalf;
- federal transparency laws, including the federal Physician Payment Sunshine Act, that require 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 the CMS information related to: (i) payments or other "transfers of value" made to physicians and teaching hospitals and (ii) ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- state and foreign law equivalents of each of the above federal laws, state and local 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, 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.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our business activities could be subject to challenge under one or more of such laws. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant criminal, civil and administrative sanctions including monetary penalties, damages, fines, disgorgement, individual imprisonment, and exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, reputational harm, and we may be required to curtail or restructure our operations, any of which could adversely affect our ability to operate our business and our results of operations.

The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with multiple jurisdictions with different compliance and/or reporting requirements increases the possibility that a healthcare company may run afoul of one or more of the requirements.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur substantial costs.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the generation, handling, use, storage, treatment, manufacture, transportation and disposal of, and exposure to, hazardous materials and wastes, as well as laws and regulations relating to occupational health and safety. We contract with third parties that conduct operations on our behalf that involve the use of hazardous and flammable materials, including chemicals and biologic materials. Our contractors also produce and dispose of hazardous waste products. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our contractors' use of hazardous materials, we could be held liable for any resulting damages and any liability could exceed our resources, and our clinical trials or regulatory approvals could be suspended. We also could incur significant costs associated with civil or criminal fines and penalties. Our third-party contractors may not carry specific biological or hazardous waste insurance coverage, and their property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

Although we maintain workers' compensation insurance for certain costs and expenses that we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for toxic tort claims that may be asserted against us in connection with our storage or disposal of biologic, hazardous or radioactive materials.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could adversely affect our business, financial condition, results of operations and prospects.

Computer system failures, cyber-attacks or deficiencies in our or related parties' cyber security could result in a material disruption of our product development programs, compromise sensitive information related to our business or trigger contractual and legal obligations, any of which could potentially expose us to liability or reputational harm or otherwise adversely affect our business and financial results.

We have implemented our security measures designed to protect the information (including but not limited to intellectual property, proprietary business information and personal information) in our possession, custody or control. Our internal computer systems and those of current and future third parties (such as vendors, CROs, collaborators or others) on which we rely may fail and are vulnerable to breakdown, breach, interruption or damage from computer viruses, computer hackers, malicious code, employee error or malfeasance, theft or misuse, denial-of-service attacks, sophisticated nation-state and nation-state-supported actors, unauthorized access, natural disasters, terrorism, war, telecommunication and electrical failures or other compromise. Despite our security practices, there is a risk that we may be subject to phishing and other cyberattacks in the future. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased.

We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations or hostile foreign governments or agencies. Our information technology and other internal infrastructure systems, including corporate firewalls, servers, leased lines and connection to the Internet, face the risk of systemic failure that could disrupt our operations. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on third parties for the manufacture of our product candidates or any future product candidates and to conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on our business.

To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate use, disclosure of or access to confidential or proprietary information, we could incur liability, our competitive position could be harmed and the further development and commercialization of our product candidates or any future product candidates could be hindered or delayed. If we were to experience a significant cybersecurity breach of our information systems or data, the costs associated with the investigation, remediation and potential notification of the breach to counterparties, data subjects, regulators or others could be material. In addition, our remediation efforts may not be successful. Moreover, if the information technology systems of our vendors, CROs, collaborators or other contractors or consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. If we do not allocate and effectively manage the resources necessary to build and sustain the proper technology and cybersecurity infrastructure, we could suffer significant business disruption, including transaction errors, supply chain or manufacturing interruptions, processing inefficiencies, data loss or the loss of or damage to intellectual property or other proprietary information. Furthermore, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding clinical trial participants or employees, could harm our reputation, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, cause us to breach our contractual obligations, subject us to mandatory corrective action, and otherwise subject us to liability under laws, regulations and contracts that protect the privacy and security of personal information, which could result in significant legal and financial exposure and reputational damages. As cyber threats continue to evolve, we may be required to incur significant additional expenses in order to enhance our protective measures or to remediate any information security vulnerability.

The financial exposure from the events referenced above could either not be insured against or not be fully covered through any insurance that we maintain. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages as a result of the events referenced above.

In addition, in response to the ongoing COVID-19 pandemic, varying parts of our workforce are currently working remotely on a part- or full-time basis. This could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations or prospects.

Risks Related to the Ownership of Our Securities

Holders of our ADSs may experience substantial dilution upon the exercise of outstanding options, warrants and convertible loan notes.

As of March 10, 2023, there were 81,820,000 ordinary shares issuable upon the exercise of share options at exercise prices of between \$0.054 and \$0.185 per ordinary share of which 35,155,667 ordinary shares are currently exercisable and 46,664,333 are exercisable between January 6, 2023 and January 31, 2032. In addition, there were 35,909,090 ordinary shares that currently may be issued upon the exercise of warrants to purchase ordinary shares at exercise prices of between \$0.033 and \$0.054 per ordinary share. The exercise of such options and warrants will result in dilution of your investment. As a result of this dilution, you may receive significantly less than the full purchase price you paid for our securities in the event of liquidation.

Holders of our ADSs have fewer rights than our shareholders and must act through the depositary to exercise their rights.

Holders of our ADSs do not have the same rights as our shareholders and may only exercise their voting rights with respect to the underlying ordinary shares in accordance with the provisions of the deposit agreement. Holders of the ADSs will appoint the depositary or its nominee as their representative to exercise the voting rights attaching to the ordinary shares represented by the ADSs. When a general meeting is convened, if you hold ADSs, you may not receive sufficient notice of a shareholders' meeting to permit you to withdraw the ordinary shares underlying your ADSs to allow you to vote with respect to any specific matter. We will make all commercially reasonable efforts to cause the depositary to extend voting rights to you in a timely manner, but we cannot assure you that you will receive voting materials in time to instruct the depositary to vote, and it is possible that you, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote. Furthermore, the depositary will not be liable 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, you may not be able to exercise your right to vote and you may lack recourse if your ADSs are not voted as you request. In addition, in your capacity as an ADS holder, you will not be able to call a shareholders' meeting.

The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation.

We are incorporated under the laws of Guernsey. The rights of holders of ordinary shares and, therefore, certain of the rights of any potential future holders of ADSs, are governed by the laws of Guernsey, including the provisions of the Guernsey Companies Law, and by our Memorandum and Articles of Incorporation, or Articles. These rights differ in certain respects from the rights of shareholders in typical U.S. corporations. See "Description of Share Capital and Memorandum and Articles of Incorporation —Differences in Corporate Law" in this report for a description of the principal differences between the provisions of the Guernsey Companies Law applicable to us and, for example, the Delaware General Corporation Law relating to stockholders' rights and protections.

If we engage in future acquisitions or strategic partnerships, this may increase our capital requirements, dilute our shareholders, cause us to incur debt or assume contingent liabilities and subject us to other risks.

We intend to continue to evaluate various acquisitions and strategic partnerships, including licensing or acquiring complementary drugs, intellectual property rights, technologies or businesses. Any potential acquisition or strategic partnership may entail numerous risks, including:

- increased operating expenses and cash requirements;
- the assumption of additional indebtedness or contingent liabilities;
- assimilation of operations, intellectual property and drugs of an acquired company, including difficulties associated with integrating new personnel;
- the diversion of our management's attention from our existing drug programs and initiatives in pursuing such a strategic partnership, merger or acquisition;
- retention of key employees, the loss of key personnel and uncertainties in our ability to maintain key business relationships;
- risks and uncertainties associated with the other party to such a transaction, including the prospects of that party and their existing drugs or drug candidates and regulatory approvals; and
- our inability to generate revenue from acquired technology and/or drugs sufficient to meet our objectives in undertaking the acquisition or even to offset the associated acquisition and maintenance costs.

As an FPI, we are exempt from a number of rules under the U.S. securities laws and are permitted to file less information with the SEC than U.S. public companies.

We are an FPI, as defined in the SEC rules and regulations and, consequently, we are not subject to all of the disclosure requirements applicable to companies organized within the United States. For example, we are exempt from certain rules under the Exchange Act, that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents or authorizations applicable to a security registered under the Exchange Act. In addition, our officers and directors are exempt from the reporting and “short-swing” profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. public companies. Accordingly, there may be less publicly available information concerning our company than there is for U.S. public companies.

As an FPI, we will file an annual report on Form 20-F within four months of the close of each fiscal year ended March 31 and reports on Form 6-K relating to certain material events promptly after we publicly announce these events. However, because of the above exemptions for FPIs, our ADS holders will not be afforded the same protections or information generally available to investors holding shares in public companies organized in the United States.

While we are an FPI, we are not subject to certain Nasdaq corporate governance rules applicable to U.S. listed companies.

We are entitled to rely on a provision in Nasdaq’s corporate governance rules that allows us to follow the laws of Guernsey and rules applicable to companies admitted to listing on the standard segment of the Official List of the FCA and to trading on the Main Market of the London Stock Exchange, including, but not limited to, the Listing Rules and the Disclosure Guidance and Transparency Rules, or DTRs, of the FCA with regard to certain aspects of corporate governance. This allows us to follow certain corporate governance practices that differ in significant respects from the corporate governance requirements applicable to U.S. companies listed on Nasdaq.

For example, we have elected to rely on the exemption allowing us to follow the laws of Guernsey and rules applicable to companies admitted to listing on the standard segment of the Official List of the FCA and to trading on the Main Market of the London Stock Exchange instead of Nasdaq regulations that require a listed U.S. company to (i) have a majority of the board of directors consist of independent directors, (ii) require non-management directors to meet on a regular basis without management present and (iii) promptly disclose any waivers of the code for directors or executive officers that should address certain specified items.

In accordance with our Nasdaq listing, our audit committee is required to comply with the provisions of Section 301 of the Sarbanes-Oxley Act and Rule 10A-3 of the Exchange Act, both of which are also applicable to Nasdaq-listed U.S. companies. Because we have elected to rely on the exemption allowing us to follow the laws of Guernsey and rules applicable to companies admitted to listing on the standard segment of the Official List of the FCA and to trading on the Main Market of the London Stock Exchange, however, our audit committee is not subject to additional Nasdaq requirements applicable to listed U.S. companies, including an affirmative determination that all members of the audit committee are “independent,” using more stringent criteria than those applicable to us as an FPI. Furthermore, Nasdaq’s corporate governance rules require listed U.S. companies to, among other things, seek shareholder approval for the implementation of certain equity compensation plans and issuances of ordinary shares, however as an FPI, we may elect to follow the laws of Guernsey and rules applicable to companies admitted to listing on the Main Market of the London Stock Exchange in lieu of these Nasdaq requirements.

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

As an FPI, we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. We may no longer be an FPI as early as September 30, 2023 (the end of our second fiscal quarter in the fiscal year following this Nasdaq listing), which would require us to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers as of April 1, 2024. In order to maintain our current status as an FPI, either (a) a majority of our outstanding voting securities must be either directly or indirectly owned of record by non-residents of the United States or (b)(i) a majority of our executive officers or directors cannot be U.S. citizens or residents, (ii) more than 50% of our assets must be located outside the United States and (iii) our business must be administered principally outside the United States. If we lose our status as an FPI, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for FPIs. We may also be required to make changes in our corporate governance practices in accordance with various SEC and Nasdaq rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as an FPI. As a result, we expect that a loss of FPI status would increase our legal and financial compliance costs and is likely to make some activities highly time-consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors.

We are an emerging growth company within the meaning of the Securities Act of 1933, or the Securities Act, and will take advantage of certain reduced reporting requirements.

We are an EGC, as defined in the JOBS Act. For as long as we continue to be an EGC, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not EGCs, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, or Section 404, exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. As an EGC, we are required to report only two years of financial results and selected financial data compared to three and five years, respectively, for comparable data reported by other public companies. We may take advantage of these exemptions until we are no longer an EGC. We could be an EGC for up to five years, although circumstances could cause us to lose that status earlier, including if the aggregate market value of our ADSs held by non-affiliates exceeds \$700 million as of any September 30 (the end of our second fiscal quarter) before that time, in which case we would no longer be an EGC as of the following December 31 (our fiscal year-end). We cannot predict if investors will find our ADSs less attractive because we may rely on these exemptions. If some investors find our ADSs less attractive as a result, there may be a less active trading market for our ADSs and the price of our ADSs may be more volatile in the event that we decide to make an offering of our ADSs following our Nasdaq listing.

If we fail to establish and maintain proper internal controls, our ability to produce accurate financial statements or comply with applicable regulations could be impaired.

Section 404(a) of the Sarbanes-Oxley Act, or Section 404(a), requires that beginning with our second annual report following our IPO, management assess and report annually on the effectiveness of our internal control over financial reporting and identify any material weaknesses in our internal control over financial reporting. Although Section 404(b) of the Sarbanes-Oxley Act, or Section 404(b), requires our independent registered public accounting firm to issue an annual report that addresses the effectiveness of our internal control over financial reporting, we have opted to rely on the exemptions provided in the JOBS Act, and consequently will not be required to comply with SEC rules that implement Section 404(b) until such time as we are no longer an EGC.

We expect our first Section 404(a) assessment will take place for our annual report for the fiscal year ending March 31, 2023. The presence of material weaknesses could result in financial statement errors which, in turn, could lead to errors in our financial reports, delays in our financial reporting, which could require us to restate our operating results or our auditors may be required to issue a qualified audit report. We might not identify one or more material weaknesses in our internal controls in connection with evaluating our compliance with Section 404 (a). In order to maintain and improve the effectiveness of our disclosure controls and procedures and internal control over financial reporting, we will need to expend significant resources and provide significant management oversight.

Implementing any appropriate changes to our internal control may require specific compliance training of our directors and employees, entail substantial costs in order to modify our existing accounting systems, take a significant period of time to complete and divert management's attention from other business concerns. These changes may not, however, be effective in maintaining the adequacy of our internal control.

If either we are unable to conclude that we have effective internal control over financial reporting or, at the appropriate time, our independent auditors are unwilling or unable to provide us with an unqualified report on the effectiveness of our internal control over financial reporting as required by Section 404(b), then in the event we have decided to make an offering of our ADSs following our Nasdaq listing, investors may lose confidence in our operating results, the price of our ADSs could decline and we may be subject to litigation or regulatory enforcement actions. In addition, if we are unable to meet the requirements of Section 404, we may not be able to remain listed on Nasdaq.

We will incur significant increased costs as a result of operating as a company that publicly listed on Nasdaq in the United States, and our management will be required to devote substantial time to new compliance initiatives.

As a U.S. public company, and particularly after we no longer qualify as an EGC, we will incur significant legal, accounting and other expenses that we did not incur previously. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act of 1987, the listing requirements of Nasdaq and other applicable securities rules and regulations impose various requirements on non-U.S. reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our senior management and other personnel 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 that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors.

However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Pursuant to Section 404, we will be required to furnish a report by our senior management on our internal control over financial reporting. However, while we remain an EGC, we will not be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To prepare for eventual compliance with Section 404, once we no longer qualify as an EGC, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

ADSs holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could augur less favorable results to the plaintiff(s) in any such action.

The deposit agreement governing the ADSs representing our ordinary shares provides that holders and beneficial owners of ADSs irrevocably waive the right to a trial by jury in any legal proceeding arising out of or relating to the deposit agreement or the ADSs, including claims under federal securities laws, against us or the depositary to the fullest extent permitted by applicable law. If this jury trial waiver provision is prohibited by applicable law, an action could nevertheless proceed under the terms of the deposit agreement with a jury trial. To our knowledge, the enforceability of a jury trial waiver under the federal securities laws has not been finally adjudicated by a federal court. However, we believe that a jury trial waiver provision is generally enforceable under the laws of the State of New York, which govern the deposit agreement, by a court of the State of New York or a federal court, which have non-exclusive jurisdiction over matters arising under the deposit agreement, applying such law. In determining whether to enforce a jury trial waiver provision, New York courts and federal courts will consider whether the visibility of the jury trial waiver provision within the agreement is sufficiently prominent such that a party has knowingly waived any right to trial by jury. We believe that this is the case with respect to the deposit agreement and the ADSs. In addition, New York courts will not enforce a jury trial waiver provision in order to bar a viable setoff or counterclaim sounding in fraud or one which is based upon a creditor's negligence in failing to liquidate collateral upon a guarantor's demand, or in the case of an intentional tort claim (as opposed to a contract dispute), none of which we believe are applicable in the case of the deposit agreement or the ADSs. No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with any provision of the federal securities laws. If you or any other holder or beneficial owner of ADSs brings a claim against us or the depositary in connection with matters arising under the deposit agreement or the ADSs, you or such other holder or beneficial owner may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us and / or the depositary. If a lawsuit is brought against us and / or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may augur different results than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action, depending on, among other things, the nature of the claims, the judge or justice hearing such claims, and the venue of the hearing.

Claims of U.S. civil liabilities may not be enforceable against us.

We are incorporated under the laws of Guernsey. Certain members of our board of directors and senior management are non-residents of the United States, and all or a substantial portion of our assets and the assets of such persons are located outside the United States. As a result, it may not be possible to serve process on such persons or us in the United States or to enforce judgments obtained in U.S. courts against them or us based on civil liability provisions of the securities laws of the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce judgments obtained in U.S. courts against them or us, including judgments predicated upon the civil liability provisions of the U.S. federal securities laws.

See "Description of Share Capital and Memorandum and Articles of Incorporation—Enforcement of Civil Liabilities." Additionally, it may be difficult to assert securities law claims in actions originally instituted outside of the United States. Foreign courts may refuse to hear a securities law claim because foreign courts may not be the most appropriate forum in which to bring such a claim. Even if a foreign court agrees to hear a claim, it may determine that the law of the jurisdiction in which the foreign court resides, and not U.S. law, is applicable to the claim. Further, 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, and certain matters of procedure would still be governed by the law of the jurisdiction in which the foreign court resides.

The rights afforded to shareholders are governed by Guernsey law. Not all rights available to shareholders under English law or U.S. law will be available to shareholders.

The rights afforded to shareholders will be governed by Guernsey law and by our Articles, and these rights differ in certain respects from the rights of shareholders in typical English companies and U.S. corporations. In particular, Guernsey law significantly limits the circumstances under which shareholders of companies may bring derivative actions and, in most cases, only the corporation may be the proper claimant or plaintiff for the purposes of maintaining proceedings in respect of any wrongful act committed against it. Neither an individual nor any group of shareholders has any right of action in such circumstances. In addition, Guernsey law does not afford appraisal rights to dissenting shareholders in the form typically available to shareholders of a U.S. corporation.

The insolvency laws of Guernsey and other jurisdictions may not be as favorable to you as the U.S. bankruptcy laws.

We are incorporated under the laws of Guernsey. In the event of a bankruptcy, insolvency or similar event, proceedings could be initiated in Guernsey or another relevant jurisdiction. The bankruptcy, insolvency, administrative and other laws of our and our subsidiaries' jurisdictions of organization or incorporation may be materially different from, or in conflict with, each other and those of the United States, including in the areas of rights of creditors, shareholders, priority of governmental and other creditors and duration of the proceeding. The application of these laws, or any conflict among them, could call into question whether any particular jurisdiction's law should apply, adversely affecting your ability to enforce your rights under the ordinary shares underlying our ADSs in those jurisdictions or limit any amounts that you may receive.

If we are a passive foreign investment company, there could be adverse U.S. federal income tax consequences to U.S. holders.

Under the Internal Revenue Code of 1986, or the Internal Revenue Code, we will be a PFIC for any taxable year in which (1) 75% or more of our gross income consists of passive income or (2) 50% or more of the average quarterly value of our assets consists of assets that produce, or are held for the production of, passive income. For purposes of these tests, passive income includes dividends, interest, gains from the sale or exchange of investment property and certain rents and royalties. In addition, for purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another corporation is treated as if it held its proportionate share of the assets and received directly its proportionate share of the income of such other corporation. If we are a PFIC for any taxable year during which a U.S. Holder (as defined below under “Certain U.S. and Guernsey Tax Considerations-Material U.S. Federal Income Tax Considerations for U.S. Holders”) holds our shares, the U.S. Holder may be subject to adverse tax consequences regardless of whether we continue to qualify as a PFIC, including ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements.

We do not believe that we were a PFIC for our taxable year ended March 31, 2022 but cannot provide any assurances regarding our PFIC status for any past, current or future taxable years. The determination of whether we are a PFIC is a fact-intensive determination made on an annual basis applying principles and methodologies which in some circumstances are unclear and subject to varying interpretation. In particular, the characterization of our assets as active or passive may depend in part on our current and intended future business plans, which are subject to change. In addition, for our current and future taxable years, the total value of our assets for PFIC testing purposes may be determined in part by reference to the market price of our ordinary shares or ADSs from time to time, which may fluctuate considerably. Under the income test, our status as a PFIC depends on the composition of our income which will depend on the transactions we enter into in the future and our corporate structure. The composition of our income and assets is also affected by how, and how quickly, we spend the cash we raise in any offering.

In certain circumstances, a U.S. Holder of shares in a PFIC may alleviate some of the adverse tax consequences described above by making, where available, a qualified electing fund, or QEF, election to include in income its pro rata share of the corporation’s income on a current basis or a mark-to-market election. A U.S. Holder may make a QEF election with respect to our ordinary shares or ADSs only if we agree to furnish such U.S. Holder annually with a PFIC annual information statement as specified in the applicable U.S. Treasury Regulations. We currently do not intend to prepare or provide the information that would enable U.S. Holders to make a QEF election if we are treated as a PFIC for any taxable year, and prospective investors should assume that a QEF election will not be available. A U.S. Holder may be able to make a mark-to-market election with respect to our ADSs if our ADSs are treated as “marketable stock.” Generally, stock will be considered marketable stock if it is “regularly traded” on a “qualified exchange” within the meaning of applicable U.S. Treasury regulations. A class of stock is regularly traded during any calendar year during which such class of stock is traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. Our ADSs will be marketable stock as long as they remain listed on Nasdaq and are regularly traded. There can be no assurance that our ADSs will be regularly traded.

For further discussion of the PFIC rules and the adverse U.S. federal income tax consequences in the event we are classified as a PFIC, see the section of this report entitled “Certain U.S. and Guernsey Tax Considerations-Material U.S. Federal Income Considerations for U.S. Holders.”

A change in our tax residence could have a negative effect on our future profitability.

Although we are incorporated under the laws of Guernsey, our affairs are, and are intended to continue to be, managed and controlled in the United Kingdom for tax purposes and therefore we are resident in the United Kingdom for U.K. and Guernsey tax purposes. It is possible that in the future, whether as a result of a change in law or the practice of any relevant tax authority or as a result of any change in the conduct of our affairs or for any other reason, we could become, or be regarded as having become, a resident in a jurisdiction other than the United Kingdom. If we cease to be a U.K. tax resident, we may be subject to a charge to U.K. corporation tax on chargeable gains on our assets and to unexpected tax charges in other jurisdictions on our income. Similarly, if the tax residency of any of our subsidiaries were to change from their current jurisdiction for any of the reasons listed above, we may be subject to a charge to local capital gains tax on the assets.

We may be unable to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments or benefit from favorable U.K. tax legislation.

As a U.K. resident trading entity, we are subject to U.K. corporate taxation. Due to the nature of our business, we have generated losses since inception. As of March 31, 2022, we had cumulative carryforward tax losses of \$15,870,525. Subject to any relevant restrictions, we expect these to be available to carry forward and offset against future operating profits. As a company that carries out extensive research and development activities, we benefit from the U.K. research and development tax credit regime for small and medium-sized companies, whereby we are able to surrender the trading losses that arise from our qualifying research and development activities for a payable tax credit of up to 33.35% of eligible research and development expenditures. Qualifying expenditures largely comprise employment costs for research staff, consumables and certain internal overhead costs incurred as part of research projects. Certain subcontracted qualifying research expenditures are eligible for a cash rebate of up to 21.67%. The majority of our pipeline research, clinical trials management and manufacturing development activities are eligible for inclusion within these tax credit cash rebate claims. Our ability to continue to claim payable research and development tax credits in the future may be limited because we may no longer qualify as a small or medium-sized company.

We may benefit in the future from the United Kingdom's "patent box" regime, which allows certain profits attributable to revenues from patented products to be taxed at an effective rate of 10%. We are the exclusive licensee or owner of several patent applications which, if issued, would cover our product candidates, and accordingly, future upfront fees, milestone fees, product revenues and royalties could be taxed at this tax rate. When taken in combination with the enhanced relief available on our research and development expenditures, we expect a long-term lower rate of corporation tax to apply to us. If, however, there are unexpected adverse changes to the U.K. research and development tax credit regime or the "patent box" regime, or for any reason we are unable to qualify for such advantageous tax legislation, or we are unable to use net operating loss and tax credit.

Changes and uncertainties in the tax system in the countries in which we have operations could materially adversely affect our financial condition and results of operations and reduce net returns to our shareholders.

Our tax position could be adversely impacted by changes in tax rates, tax laws, tax practice, tax treaties or tax regulations or changes in the interpretation thereof by the tax authorities in the United Kingdom, the United States and other jurisdictions as well as being affected by certain changes currently proposed by the Organization for Economic Co-operation and Development and their action plan on Base Erosion and Profit Shifting. Such changes may become more likely as a result of recent economic trends in the jurisdictions in which we operate, particularly if such trends continue.

Our actual effective tax rate may vary from our expectation and that variance may be material. A number of factors may increase our future effective tax rates, including: (1) the jurisdictions in which profits are determined to be earned and taxed; (2) the resolution of issues arising from any future tax audits with various tax authorities; (3) changes in the valuation of our deferred tax assets and liabilities; (4) increases in expenses not deductible for tax purposes, including transaction costs and impairments of goodwill in connection with acquisitions; (5) changes in the taxation of share-based compensation; (6) changes in tax laws or the interpretation of such tax laws, and changes in generally accepted accounting principles; and (7) challenges to the transfer pricing policies related to our structure.

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, Her Majesty's Revenue & Customs, or HMRC, the U.S. Internal Revenue Service, or IRS, or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies, including methodologies for valuing developed technology and amounts paid with respect to our intellectual property development. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a "permanent establishment" under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions.

A tax authority may take the position that material income tax liabilities, interest and penalties are payable by us, for example where there has been a technical violation of contradictory laws and regulations that are relatively new and have not been subject to extensive review or interpretation, in which case we expect that we might contest such assessment. High-profile companies can be particularly vulnerable to aggressive application of unclear requirements. Many companies must negotiate their tax bills with tax inspectors who may demand higher taxes than applicable law appears to provide. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable.

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 ordinary shares represented by ADSs. 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. With a public offering price of \$1.50 per ADS, you will experience an immediate increase of approximately \$1.81 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.

We will use our reasonable best efforts to solicit offers to purchase the securities in this offering. 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.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This registration statement contains forward-looking statements that involve substantial risks and uncertainties. All statements contained in this registration statement, other than statements of historical fact, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "may," "might," "will," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "potential," "continue" and "ongoing," or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. The forward-looking statements and opinions contained in this registration statement are based upon information available to us as of the date of this registration statement and, while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. Forward-looking statements include statements about:

- the development of product candidates, including statements regarding the timing of initiation, completion and the outcome of clinical studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- our ability to obtain and maintain regulatory approval of our product candidates in the indications for which we plan to develop them, and any related restrictions, limitations or warnings in the label of an approved drug or therapy;
- our plans to research, develop, manufacture and commercialize our product candidates;
- the timing of our regulatory filings for our product candidates;
- the size and growth potential of the markets for our product candidates;
- our ability to raise additional capital;
- the impact of COVID-19 on our business and operations;
- our commercialization, marketing and manufacturing capabilities and strategy;
- our expectations regarding our ability to obtain and maintain intellectual property protection;
- our ability to attract and retain qualified employees and key personnel;
- our ability to contract with third party suppliers and manufacturers and their ability to perform adequately;
- our estimates regarding future revenue, expenses and needs for additional financing; and
- regulatory developments in the United States, European Union and other jurisdictions.

You should refer to the section titled “Risk Factors” for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this registration statement will prove to be accurate.

Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

You should read this registration statement and the documents that we have filed as exhibits to this registration statement completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

MARKET AND INDUSTRY DATA

Certain industry data and market data included in this prospectus were obtained from independent third-party surveys, market research, publicly available information, reports of governmental agencies, and industry publications and surveys. All of the market data used in this prospectus involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We believe that the information from these industry publications and surveys included in this prospectus is reliable. The industry in which we operate is subject to a high degree of uncertainty and risk due to a variety of factors, including those described in “Risk Factors.” These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

TRADEMARKS, SERVICE MARKS AND TRADENAMES

Solely for convenience, the trademarks, service marks, logos and trade names referred to in this prospectus are without the ® and ™ 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 licensors to these trademarks, service marks, and trade names. For the avoidance of doubt, “OKYO,” the OKYO logo and other trademarks or service marks of OKYO Pharma Limited appearing in this prospectus are the property of OKYO or our subsidiary. This prospectus contains additional trademarks, service marks, and trade names of others, which are the property of their respective owners. All trademarks, service marks, and trade names appearing in this prospectus are, to our knowledge, the property of their respective owners. We do not intend our use or display of other companies’ trademarks, service marks, copyrights, or trade names to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

EXCHANGE RATE INFORMATION

Fluctuations in the exchange rate between Pounds Sterling and the U.S. dollar will affect the U.S. dollar amounts received by potential future owners of our ADSs on conversion of dividends, if any, paid in Pounds Sterling on the ordinary shares and will affect the potential future U.S. dollar price of our ADSs on Nasdaq.

The table below shows the period end, average, high and low exchange rates of U.S. dollars per Pound Sterling for the periods shown. Average rates are computed by using the noon buying rate of the Federal Reserve Bank of New York for the U.S. dollar on the last business day of each month during the relevant year indicated or each business day during the relevant month indicated. The rates set forth below are provided solely for your convenience and may differ from the actual rates used in the preparation of our consolidated financial statements included in this registration statement and other financial data appearing in this registration statement.

Year Ended March 31,	Period End	Average Rate for Period (U.S. dollars per pound Sterling)	High	Low
2017	1.2537	1.3087	1.4800	1.2118
2018	1.4027	1.4264	1.3265	1.2398
2019	1.3032	1.4332	1.2524	1.3142
2020	1.4540	1.2712	1.3349	1.1492
2021	1.3795	1.3074	1.4106	1.2129
2022	1.1573	1.2457	1.3274	1.0703

Month	Period End	High	Low
(U.S. dollars per Pound Sterling)			
April 2021	1.3838	1.3977	1.3734
May 2021	1.4188	1.4188	1.3873
June 2021	1.3806	1.4179	1.3806
July 2021	1.3913	1.3966	1.3615
August 2021	1.3747	1.3929	1.3625
September 2021	1.3470	1.3862	1.3439
October 2021	1.3804	1.3821	1.3569
November 2021	1.3252	1.3679	1.3252
December 2021	1.3500	1.3500	1.3188
January 2022	1.3439	1.3724	1.3385
February 2022	1.3419	1.3636	1.3360
March 2022	1.3152	1.3365	1.3044
April 2022	1.2565	1.3116	1.2443
May 2022	1.2624	1.2624	1.1827
June 2022	1.2162	1.2594	1.2011
July 2022	1.2183	1.2183	1.1827
August 2022	1.1647	1.2278	1.1647
September 2022	1.1600	1.1600	1.1473
October 2022	1.1515	1.1096	1.1615
November 2022	1.1962	1.2102	1.1183
December 2022	1.2077	1.2408	1.2032
January 2023	1.2379	1.2379	1.1970
February 2023	1.1948	1.2308	1.1948
March 2023 (to March 3, 2023)	1,1996	1.2034	1.1942

On March 3, 2023 the exchange rate published by the Federal Reserve Bank of New York was \$1.1996 per £1.00.

Information presented on a constant currency basis in this prospectus is calculated by translating current year results at prior year average exchange rates. Management reviews and analyzes business results excluding the effect of foreign currency translation because they believe this better represents our underlying business trends.

PRICE RANGE OF OUR ORDINARY SHARES AND ADSs

The principal trading market for our ordinary shares is the Main Market of the LSE, where our ordinary shares have been listed since July 17, 2018 under the symbol “OKYO.” Prior to this date we were listed on the AIM market of the London Stock Exchange since 2014. The following table sets forth, for the periods indicated, the reported high and low closing prices on the LSE for our ordinary shares in Pounds Sterling. See “Exchange Rate Information” on page 42 for the exchange rates applicable to the periods set forth below.

The following table presents, for the periods indicated, the reported high and low sale prices, including intra-day sales, of our ordinary shares on the LSE in Pounds Sterling and U.S. dollars. For the convenience of the reader, we have translated Pounds Sterling amounts in the table below into U.S. dollars at the noon buying rate of the Federal Reserve Bank of New York on March 3, 2023 which was £1.00 to \$1.1996.

	Price Per Ordinary Share £		Price Per Ordinary Share \$	
	High	Low	High	Low
Year Ended March 31, 2023				
First Quarter	0.063	0.028	0.075	0.033
Second Quarter	0.043	0.024	0.051	0.028
Third Quarter	0.037	0.023	0.044	0.027
Fourth Quarter (to March 10, 2023)	0.054	0.019	0.065	0.022
Year Ended March 31, 2022				
First Quarter	0.078	0.060	0.093	0.071
Second Quarter	0.065	0.040	0.078	0.048
Third Quarter	0.085	0.041	0.102	0.049
Fourth Quarter	0.083	0.048	0.099	0.057
Year Ended March 31, 2021				
First Quarter	0.055	0.017	0.066	0.020
Second Quarter	0.180	0.053	0.215	0.063
Third Quarter	0.121	0.071	0.145	0.085
Fourth Quarter	0.120	0.076	0.143	0.091
Year Ended March 31, 2020				
First Quarter	0.021	0.011	0.025	0.013
Second Quarter	0.059	0.021	0.071	0.025
Third Quarter	0.043	0.017	0.051	0.020
Fourth Quarter	0.023	0.013	0.027	0.015

On March 10, 2023, the last reported sale price of our ordinary shares on LSE was £0.0305 per ordinary share (\$0.0369 per ordinary share based on the exchange rate set forth above).

Our American Depositary Shares, or ADSs, have been trading on the Nasdaq Capital Market under the symbol “OKYO” since May 17, 2022. The following table sets forth, for the periods indicated, the reported high and low closing sale prices of our ADSs on the Nasdaq Capital Market in U.S. dollars.

Monthly:	Price Per ADS \$	
	High	Low

May 2022 (from May 17, 2022)	3.62	2.03
June 2022	2.21	1.92
July 2022	2.35	1.95
August 2022	2.62	1.96
September 2022	3.40	2.50
October 2022	2.70	2.06
November 2022	2.35	2.01
December 2022	2.23	1.69
January 2023	2.73	1.83
February 2023	3.74	2.08
March 2023	2.57	2.23

On March 10, 2023, the last reported sale price of our ADSs on the Nasdaq Capital Market was \$2.33 per ADS.

USE OF PROCEEDS

We estimate that the net proceeds from this offering will be approximately \$5.0 million, after deducting the estimated offering expenses payable by us.

We intend to use the net proceeds as follows:

- approximately \$3 million to fund the initiation of the Phase 2 clinical trial of OK-101 in DED patients; and
- \$500,000 plus interest for repayment of the loan from Tiziana Life Sciences Ltd. dated February 9, 2023. The loan accrues interest at the rate of 16% per annum and is repayable upon the earlier of (i) a fundraise by us and (ii) August 9, 2023.
- the remainder to fund working capital and other general corporate purposes.

The expected use of the net proceeds from this offering represents our intentions based upon our current plans and business conditions. We may also use a portion of the net proceeds to in-license, acquire, or invest in additional products or assets, businesses, or technologies, although currently we have no specific agreements, commitments, or understandings in this regard. As of the date of this prospectus, we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the closing of this offering or the amounts that we will actually spend on the uses set forth above. Predicting the costs necessary to develop product candidates can be difficult. The amounts and timing of our actual expenditures and the extent of clinical development may vary significantly depending on numerous factors, including the progress of our development efforts, the status of and results from ongoing clinical trials or clinical trials we may commence in the future, as well as any collaborations that we may enter into with third parties and any unforeseen cash needs. As a result, our management will retain broad discretion over the allocation of the net proceeds from this offering.

We anticipate that our existing cash resources, together with the net proceeds from the offering, will enable us to fund our operating expenses and capital expenditure requirements for at least the 12 months after the date of this prospectus. We have based this estimate on assumptions that may prove to be incorrect, and we could use our available capital resources sooner than we currently expect.

Pending their use, we plan to invest the net proceeds from the offering in short- and intermediate-term interest-bearing obligations and certificates of deposit. The goal with respect to the investment of these net proceeds is capital preservation and liquidity so that such funds are readily available to fund our operations.

DIVIDEND POLICY

We have never paid or declared any cash dividends on our ordinary shares, and we do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Pursuant to the Guernsey Companies Law, we may only pay a dividend if the directors who authorize the dividend make a prior solvency statement in statutory form.

CAPITALIZATION

You should read the information in this “Capitalization” section together with “Selected Consolidated Financial Data,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our consolidated financial statements and the related notes appearing elsewhere in this prospectus.

The table below sets forth our cash and short-term deposits and short-term investments and capitalization as of September 30, 2022 derived from our audited consolidated financial statements included elsewhere in this prospectus:

- on an actual basis; and

- on an adjusted basis to give effect to the sale by us of 3,503,665 ADSs (representing 227,738,225 ordinary shares), at a public offering price of of \$1.50 per ADS, after deducting the estimated offering expenses payable by us in connection with this offering.

	As of September 30, 2022	
	Actual	As Adjusted
	\$	\$
Cash and cash equivalents	705,046	5,710,544
Equity:		
Share premium	125,830,402	130,835,900
Other reserves	(8,204,564)	(8,204,564)
Accumulated loss	(117,970,423)	(117,970,423)
Total shareholders' equity (deficit)	(344,585)	4,660,913
Total capitalization	(344,585)	4,660,913

The table above excludes:

- 81,820,000 ordinary shares issuable upon the exercise of share options at exercise prices of between \$0.054 and \$0.185 per ordinary share of which 35,155,667 ordinary shares are currently exercisable and 46,664,333 are exercisable between January 6, 2023 and January 31, 2032; and
- 35,909,090 ordinary shares that currently may be issued upon the exercise of warrants to purchase ordinary shares at exercise prices of between \$0.033 and \$0.054 per ordinary share.

DILUTION

If you invest in our ADSs in this offering, your interest will be diluted to the extent of the difference between the public offering price per ADS paid by purchasers in this offering and our pro forma as adjusted net tangible book value per ADS after completion of this offering.

At September 30, 2022, we had a historical net tangible book value of (\$0.0002) per ordinary share (equal to (\$0.02) per ADS). Net tangible book value per ordinary share represents the amount of our total assets less our total liabilities, excluding goodwill and other intangible assets, divided by the total number of our ordinary shares outstanding as of September 30, 2022.

After giving effect to the sale by us of 3,503,665 ADSs (representing 227,738,225 ordinary shares) at a public offering price of \$1.50 per ADS in this offering, after deducting the estimated offering expenses payable by us in connection with this offering, our as adjusted net tangible book value as of September 30, 2022 would have been \$4.66 million, (equal to \$0.18 per ADS). This represents an immediate increase in net tangible book value of \$0.003 per ordinary share (equal to \$0.20 per ADS) to existing shareholders and an immediate dilution of \$0.02 per ordinary share (equal to \$1.32 per ADS) to new investors purchasing ADSs in this offering. Dilution per ADS or ordinary share to new investors is determined by subtracting the as adjusted net tangible book value per ADS or ordinary share after this offering from the public offering price per ADS paid by new investors.

The following table illustrates this dilution to new investors purchasing ADSs in this offering.

	As of	
	September 30, 2022	
Public offering price per ADS	\$	1.50
Historical net tangible book value per ADS	\$	(0.02)
Increase in historical net tangible book value per ADS attributable to this offering		0.20
As adjusted net tangible book value per ADS after this offering		0.18
Dilution per ADS to new investors in this offering	\$	1.32

The table above excludes:

- 81,820,000 ordinary shares issuable upon the exercise of share options at exercise prices of between \$0.054 and \$0.185 per ordinary share of which 35,155,667 ordinary shares are currently exercisable and 46,664,333 are exercisable between January 6, 2023 and January 31, 2032; and
- 35,909,090 ordinary shares that currently may be issued upon the exercise of warrants to purchase ordinary shares at exercise prices of between \$0.033 and \$0.054 per ordinary share.

To the extent that share options or warrants are exercised, or we issue additional ADSs or ordinary shares in the future, there will be further dilution to investors participating in this offering. In addition, we may choose to raise additional capital because of market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our shareholders.

SELECTED CONSOLIDATED FINANCIAL DATA

The following tables set forth our selected consolidated financial data for the periods indicated. We have derived the consolidated statement of comprehensive income for the two years ended March 31, 2022 and the consolidated balance sheet data as of March 31, 2022 and 2021 from our audited consolidated financial statements included elsewhere in this prospectus. The unaudited consolidated statement of operations data for the six months ended September 30, 2022 and 2021 and the unaudited consolidated balance sheet data as at September 30, 2022 have been derived from our unaudited consolidated financial statements for the periods included elsewhere in this prospectus.

We maintain our books and records in Pounds Sterling, and we prepare our financial statements in accordance with IFRS as issued by the IASB. We report our financial results in U.S. dollars.

Consolidated Statement of Operations and Comprehensive Loss Data:

	Six Months Ended September 30,		Years Ended March 31,	
	2022	2021	2022	2021
	(unaudited)	(unaudited)		
Consolidated statement of operations data:				
Operating expenses:				
Research and development	\$ (2,607,675)	\$ (479,700)	\$ (1,301,178)	\$ (173,821)
General and administrative	(2,936,714)	(2,254,393)	(4,916,388)	(3,192,385)
Total operating expenses	(5,544,389)	(2,734,093)	(6,217,566)	(3,366,206)
Other income (expense), net	-	(1,021)	-	(12,295)
Loss from operations	(5,544,389)	(2,735,114)	(6,217,566)	(3,378,501)
Tax provision	-	188,761	786,521	24,994
Net loss attributable to ordinary shareholders	\$ (5,544,389)	\$ (2,546,353)	(5,431,045)	(3,353,507)
Other comprehensive loss:				
Foreign currency translation adjustment	(62,581)	37,845	(837,152)	346,365
Total comprehensive loss	\$ (5,606,970)	\$ (2,508,508)	\$ (6,268,197)	\$ (3,007,142)
Basic and diluted loss per share	\$ (0.00)	\$ (0.00)	\$ (0.01)	\$ (0.00)

Consolidated Balance Sheet Data:

	As of September 30,	As of March 31,	
	2022	2022	2021
	(unaudited)		
Cash and cash equivalents	\$ 705,046	\$ 2,700,724	\$ 6,889,329
Working capital	(350,186)	2,942,177	5,279,384
Total assets	1,768,056	4,300,593	7,091,322
Total shareholders' equity/(deficit)	\$ (344,585)	\$ 2,947,402	\$ 5,319,408

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

The following discussion of our financial condition and results of operations should be read in conjunction with the audited consolidated historical financial statements as of March 31, 2022 and 2021.

The following discussion includes forward-looking statements that reflect our plans, estimates and beliefs and involves risks and uncertainties. Our actual results could differ materially from those discussed in these statements. Factors that could cause or contribute to these differences include, but are not limited to, those discussed below and elsewhere in this registration statement, particularly in "Risk Factors" and elsewhere in this prospectus.

Overview

We are a preclinical biopharmaceutical company developing next-generation therapeutics to improve the lives of patients suffering from inflammatory eye diseases and ocular pain. Our research program is focused on a novel G Protein-Coupled Receptor, or GPCR, which we believe plays a key role in the pathology of these inflammatory eye diseases of high unmet medical need. Our therapeutic approach is focused on targeting inflammatory and pain modulation pathways that drive these conditions. We are presently developing OK-101, our lead preclinical product candidate, for the treatment of dry-eye disease (DED). On November 18, 2022, we filed a new drug application (IND) with the Food and Drug Administration (FDA) on OK-101 to treat DED, and plan to open a Phase 2 clinical trial of OK-101 in DED patients in the second quarter of 2023. We also plan to evaluate OK-101's potential in benefiting patients with ocular neuropathic pain, uveitis and allergic conjunctivitis. We have also been evaluating OK-201, a bovine adrenal medulla, or BAM, lipidated-peptide preclinical analogue candidate for the treatment of neuropathic ocular pain, and plan on maintaining this drug candidate at the exploratory level while we focus our primary energies on the OK-101 program.

On February 21, 2018, we announced that we successfully obtained (via assignment from Panetta Partners Limited, a related party) a license from OTT to patents owned or controlled by OTT and a sub-license from OTT to certain patents licensed by OTT from TMC to support our ophthalmic disease drug programs. These licenses gave us the right to exploit the IP estate which is directed to compositions-of-matter and methodologies for treating ocular inflammation, DED with chemerin or lipid-linked chemerin analogues. We also have a license from TMC to a separate IP estate for treating symptoms of ocular neuropathic pain and uveitis associated pain. On August 6, 2019, we signed a collaborative agreement with TMC on a research program focused on ocular neuropathic pain.

Foreign currency translations

Items included in the financial statements are measured using the currency of the primary economic environment in which the entity operates (the functional currency). The consolidated financial statements are presented in U.S. dollars, which is our presentation currency.

Foreign currency transactions are translated into the functional currency using exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of foreign currency transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in the income statement.

The financial statements of overseas subsidiary undertakings are translated into U.S. dollars on the following basis:

- Assets and liabilities at the rate of exchange ruling at the year-end date.
- Profit and loss account items at the average rate of exchange for the year.

Exchange differences arising from the translation of the net investment in foreign entities, borrowings and other currency instruments designated as hedges of such investments, are taken to equity (and recognized in the statement of comprehensive income) on consolidation.

Components of Our Results of Operations

Revenues

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the near future. If our development efforts for our product candidates are successful and result in regulatory approval, we may generate revenue in the future from product sales.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the research and development of our product candidates and are expensed as incurred. These expenses consist of:

- expenses incurred under agreements with CROs, CMOs, as well as investigative sites and consultants that conduct our preclinical studies and other scientific development services;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing materials for preclinical studies;
- employee-related expenses, including salaries, related benefits, travel and share-based compensation expense for employees engaged in research and development functions;
- costs related to compliance with regulatory requirements;
- facilities costs, depreciation and other expenses, which include rent and utilities; and
- fees for maintaining our third-party licensing agreements.

We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our service providers.

Our direct research and development expenses are tracked on a program-by-program basis for our product candidates and consist primarily of external costs, such as fees paid to outside consultants, CROs and CMOs in connection with our preclinical development, manufacturing and clinical development activities. Our direct research and development expenses by program also include fees incurred under our license agreements. We do not allocate employee costs or facility expenses, including depreciation or other indirect costs, to specific programs because these costs are deployed across multiple programs and, as such, are not separately classified. We use internal resources primarily to oversee the research and development as well as for managing our preclinical development, process development, manufacturing and clinical development activities. These employees work across multiple programs and, therefore, we do not track their costs by program.

The table below summarizes our research and development expenses incurred by program:

	Six months ended September 30,		Year ended March 31,	
	2022	2021	2022	2021
Direct research and development expense by program:				
OK-101	\$ 2,607,675	\$ 365,668	\$ 1,300,664	\$ 170,417
OK-201	-	114,032	514	3,404
Total direct research and development expense	\$ 2,607,675	\$ 479,700	\$ 1,301,178	\$ 173,821
Total research and development expense	\$ 2,607,675	\$ 479,700	\$ 1,301,178	\$ 173,821

Research and development activities are central to our business model. Product candidates 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 and related product manufacturing expenses. As a result, we expect that our research and development expenses will increase substantially over the next several years as we increase personnel costs and prepare for regulatory filings related to our product candidates. We also expect to incur additional expenses related to milestone, royalty payments and maintenance fees payable to third parties with whom we have entered into license agreements to acquire the rights related to our product candidates.

The successful development and commercialization of our product candidates is highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the preclinical and clinical development of any of our product candidates or when, if ever, material net cash inflows may commence from any of our product candidates. This uncertainty is due to the numerous risks and uncertainties associated with development and commercialization, including the uncertainty of:

- the scope, progress, outcome and costs of our preclinical development activities, clinical trials and other research and development activities;
- establishing an appropriate safety profile with IND- and CTA-enabling studies;
- successful patient enrollment in, and the initiation and completion of, clinical trials;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- development and timely delivery of commercial-grade drug formulations that can be used in our clinical trials and for commercial launch;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulation;
- launching commercial sales of our product candidates, if and when approved, whether alone or in collaboration with others; and
- maintaining a continued acceptable safety profile of the product candidates following approval.

We may never succeed in achieving regulatory approval for any of our product candidates. We may obtain unexpected results from our clinical trials. We may elect to discontinue, delay or modify clinical trials.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries, related benefits, travel and share-based compensation expense for personnel in executive, finance and administrative functions. General and administrative expenses also include professional fees for legal, consulting, accounting and audit services.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support our continued research activities and development of our product candidates. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance, director and officer insurance costs, as well as investor and public relations expenses associated with being a public company.

Realization Bonus Expenses

This is an extraordinary expense item for this year and includes the expenses for a realization bonus which became payable, triggered by a fundraising event during the year.

Impairment of an asset

This is an extraordinary expense item for this year and includes the expenses for the impairment of a non-current asset.

Disposal of Intellectual Property

This is an extraordinary expense item for this year and includes the expenses related to the disposal of intellectual property during the year.

Other Income (Expense)

Other expense consists of interest on a convertible loan note.

Taxation

The tax expense for a period represents the total of current taxation and deferred taxation. The charges in respect of current taxation are based on the estimated taxable profit for the relevant year. Taxable profit for the year is based on the profit as shown in the income statement, as adjusted for items of income or expenditure which are not deductible or chargeable for tax purposes. The current tax liability for the year is calculated using tax rates which have either been enacted or substantively enacted at the relevant balance sheet date.

Under UK tax legislation, small and medium entity research and development relief allows us to claim back up to 14.5% of our surrenderable losses as a tax cash credit.

Results of Operations

The results of operations that follow reflect the historic periods under review and should not be taken as indicative of future performance.

Comparison of Six Months Ended 30 September 2022 and 2021 and Years Ended March 31, 2022 and 2021

The following tables summarizes our results of operations for the six months ended September 30, 2022 and 2021 and the years ended March 31, 2022 and 2021:

	Six Months Ended September 30,		
	2022	2021	Change
Operating Expenses:			
Research and development	\$ (2,607,675)	\$ (479,700)	\$ (2,127,975)
General and administrative	(2,936,714)	(2,254,393)	(682,321)
Total Operating expenses	<u>(5,544,389)</u>	<u>(2,734,093)</u>	<u>(2,810,296)</u>
Other Income/ (Expense)	-	(1,021)	1,021
Tax credit	-	188,761	(188,761)
Net Loss	<u>\$ (5,544,389)</u>	<u>\$ (2,546,353)</u>	<u>\$ (2,998,036)</u>
Other comprehensive loss:			
Foreign currency translation adjustment	<u>(62,581)</u>	<u>37,845</u>	<u>(100,426)</u>
Total Comprehensive (Loss)	<u>\$ (5,606,970)</u>	<u>\$ (2,508,508)</u>	<u>\$ (3,098,462)</u>
	Year Ended March 31,		
	2022	2021	Change
Operating Expenses:			
Research and development	\$ (1,301,178)	\$ (173,821)	\$ (1,127,357)
General and administrative	\$ (4,916,388)	\$ (3,192,385)	\$ (1,724,003)
Total Operating expenses	<u>\$ (6,217,566)</u>	<u>\$ (3,366,206)</u>	<u>\$ (2,851,360)</u>
Other Income/ (Expense)	-	(12,295)	12,295
Tax credit	786,521	24,994	761,527
Net Loss	<u>\$ (5,431,045)</u>	<u>\$ (3,353,507)</u>	<u>\$ (2,077,538)</u>
Other comprehensive loss:			
Foreign currency translation adjustment	<u>(837,152)</u>	<u>346,365</u>	<u>(1,183,517)</u>
Total Comprehensive (Loss)	<u>\$ (6,268,197)</u>	<u>\$ (3,007,142)</u>	<u>\$ (3,261,055)</u>

Research and Development Expenses

Research and development activities were \$2,607,675 for the six months ended September 30, 2022 compared to \$479,700 for the six months ended September 30, 2021. The increase of \$2,127,975 is due to the increased activities undertaken for the IND filing in November 2022.

Research and development activities were \$1,301,178 for the year ended March 31, 2022 compared to \$173,821 for the year ended March 31, 2021 an increase of \$1,127,357. The increase is due to an increase in research and development activity after the temporary pause in research and development activity in 2020 while the Scientific Advisory Board and management team were established.

General and Administrative Expenses

General and administrative expenses were \$2,936,714 and \$2,254,393 for the six months ended September 30, 2022 and 2021. The increase is predominantly due to the increase in activity in the Company.

General and Administrative expenses were \$4,916,388 for the year ended March 31, 2022 as compared to \$3,192,385 for the year ended March 31, 2021, an increase of \$1,724,003. The increase is predominantly due to the establishment of a management team and an increase in activity in the Company.

Income Tax Credit

Income tax credits of \$786,521 and \$24,994 are recognized for the years ended March 31, 2022 and 2021, respectively. The credits are obtained at a rate of 14.5% of 230% of our qualifying research and development expenditure, respectively. The increase in the provision is due primarily to an increase in qualifying research and development expenditure incurred in the year ending March 31, 2022, plus more qualifying research and development expenditure identified for the year ending March 31, 2021 than was provided for.

Liquidity and Capital Resources

Since our inception, we have not generated any revenue and have incurred operating losses and negative cash flows from our operations. We have funded our operations to date primarily with proceeds from the sale of ordinary shares, ADSs, and convertible loan notes.

As of March 31, 2022, we had cash and cash equivalents of \$2,700,723.

Through March 31, 2022, we had received net cash proceeds of \$1,378,387 from exercise of warrants.

Through September 30, 2022, we received net cash proceeds of \$1,853,892 from the issuance of ADSs in connection with an IPO on the Nasdaq Capital Market. Cash received from these financings are invested in a money market fund with a focus on liquidity and capital preservation.

On February 1, 2023, we entered into a services agreement with TraDigital Marketing Group for certain consulting services in the area of strategic advisory, sponsored editorial content and digital marketing services. The term of the agreement is from February 1, 2023 to April 30, 2023 and shall automatically renew unless we cancel in writing with thirty (30) days' notice. We have the option to terminate the agreement after March 18, 2023. We paid \$360,000 to TraDigital upon execution of the agreement and a retainer fee of \$10,000 per month. In addition, we issued 2,177,500 ordinary shares to TraDigital and an additional 2,177,500 ordinary shares are to be issued on March 18, 2023 provided that the agreement has not been terminated by us.

Cash Flows

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

	Six Months Ended September 30,		Year Ended March 31,	
	2022	2021	2022	2021
Net cash used in operating activities	\$ (3,540,537)	\$ (3,044,672)	\$ (5,468,065)	\$ (1,600,198)
Net cash used in investing activities	(2,699)	-	(1,669)	(18,114)
Net cash provided by/ (used in) financing activities	1,853,892	1,446,335	2,153,270	7,826,939
Effect of exchange rate changes on cash and cash equivalents	(306,334)	(106,844)	(872,141)	(445,216)
Net decrease in cash and cash equivalents	<u>\$ (1,689,344)</u>	<u>\$ (1,598,335)</u>	<u>\$ (3,316,464)</u>	<u>\$ (6,208,627)</u>

Net Cash Used in Operating Activities

Our use of cash in each of the six months ended September 30, 2022 and 2021 resulted primarily from our net losses, adjusted for non-cash charges and changes in components of working capital. Net cash used in operating activities of \$3,540,537 during the six months ended September 30, 2022 increased by \$480,869 compared to the six months ended September 30, 2021. The increase in net cash used in operating activities was primarily due to the increased activity in the Company.

Our use of cash in each of the years ended March 31, 2022 and 2021, resulted primarily from our net losses, adjusted for non-cash charges and changes in components of working capital. Net cash used in operating activities of \$5,468,065 during the year ended March 31, 2022 increased by \$3,867,867 compared to the year ended March 31, 2021. The increase in net cash used in operating activities was primarily due to increased activity.

Net Cash Used in Investing Activities

During the six months ended September 30, 2022, we used \$2,699 of cash in investing activities for the purchase of IT equipment.

During the year ended March 31, 2022, we used \$1,669 of cash in investing activities for the purchases of property and equipment.

During the year ended March 31, 2021 we used \$18,114 of cash in investing activities for the purchases of property and equipment and a loan to West African Minerals Ltd.

Net Cash Provided by Financing Activities

During the six months ended September 30, 2022 and 2021, net cash provided by financing activities was \$1,853,892 and \$1,446,335, respectively, consisting of net cash proceeds from our sale and issuance of ordinary shares, entering into fixed term convertible loan agreements and the exercise of warrants.

During the years ended March 31, 2022 and 2021, net cash provided by financing activities was \$2,153,270 and \$7,826,938, respectively, consisting of net cash proceeds from our sale and issuance of ordinary shares, entering into fixed term convertible loan agreements and the exercise of warrants.

Funding Requirements

We expect our expenses to increase substantially in connection with our ongoing activities, particularly as we advance the preclinical activities, manufacturing and clinical trials of our product candidates and as we:

- seek regulatory approvals for any product candidates that successfully complete clinical trials;
- establish a sales, marketing and distribution infrastructure in anticipation of commercializing any product candidates for which we may obtain marketing approval and intend to commercialize on our own or jointly;
- hire additional clinical, medical and development personnel;
- expand our infrastructure and facilities to accommodate our growing employee base; and
- maintain, expand and protect our intellectual property portfolio.

We believe that our existing cash will enable us to fund our operating expenses and capital expenditure requirements for the foreseeable future. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we expect. If we receive regulatory approval for our other product candidates, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution.

Because of the numerous risks and uncertainties associated with research, development and commercialization of pharmaceutical product candidates, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on and could increase significantly as a result of many factors, including:

- the scope, progress, outcome and costs of our preclinical development activities, clinical trials and other research and development activities;
- the costs, timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- the costs of future activities, including product sales, marketing, manufacturing and distribution, for any of our product candidates for which we receive marketing approval;
- the revenue, if any, received from commercial sale of our products, should any of our product candidates receive marketing approval;
- the costs and timing of hiring new employees to support our continued growth;
- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims; and
- the extent to which we acquire technologies.

Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through equity offerings. To the extent that we raise additional capital through the sale of equity, your ownership interest will be diluted. If we raise additional funds through other third-party funding, collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity financings when needed, we may be required to delay, limit, reduce or terminate our product development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

Borrowings

On May 29, 2020, we entered into a fixed term unsecured loan agreement with existing shareholders for \$606,980 at an interest rate of 20% per annum to be repaid no later than 48 months after the date of the agreement. On May 4, 2021, \$167,434 of the fixed term loan agreement plus the associated interest accrued, was converted and 62,920,000 shares were issued accordingly at a price of \$0.006 per share. On February 24, 2022, all remaining fixed term loan agreements plus the associated interest accrued were converted and 165,176,000 shares were issued accordingly at a price of \$0.006 per share.

On July 27, 2020, we entered into a fixed term unsecured loan agreement with existing shareholders for \$4,828,250 at an interest rate of 2.15% per annum to be repaid no later than 36 months after the date of the agreement. On May 4, 2021, the fixed term loan agreement plus the associated interest accrued, was converted and 43,889,863 shares were issued accordingly at a price of \$0.117 per share.

On August 17, 2020, we entered into a fixed term unsecured loan agreement with existing shareholders for \$1,982,485 at an interest rate of 2.15% per annum to be repaid no later than 36 months after the date of the agreement. On May 4, 2021 the fixed term loan agreement plus the associated interest accrued, was converted and 18,021,226 shares were issued accordingly at a price of \$0.117 per share.

On September 3, 2020, we entered into a fixed term unsecured loan agreement with existing shareholders for \$689,750 at an interest rate of 2.15% per annum to be repaid no later than 36 months after the date of the agreement. On May 4, 2021 the fixed term loan agreement plus the associated interest accrued, was converted and 6,269,980 shares were issued accordingly at a price of \$0.117 per share.

The loans were converted into ordinary shares in May 2021 and February 2022.

In August 2022, we secured a short-term credit facility from Tiziana Life Sciences Ltd., a related party, for \$2,000,000 in order to support short term liquidity. The loan is available for a period of 6 months upon first draw-down and carries an interest rate of 16% per annum, with additional default interest of 4% if the loan is not repaid after the 6-month period.

In February 2023, an additional short-term credit facility from Tiziana Life Sciences Ltd., was secured for \$500,000 in order to support short term liquidity. The loan is to be repaid upon the earlier of (i) a fundraise or (ii) a period of 6 months upon first draw-down and carries an interest rate of 16% per annum, with additional default interest of 4% if the loan is not repaid after the 6-month period.

Contractual Obligations

The following table summarizes our contractual commitments and obligations as of September 30, 2022 and March 31, 2022.

As of September 30, 2022				
(in thousands)	Total	Less than 1 Year	Between 1 and 5 Years	More than 5 Years
Borrowings	\$ -	-	-	-
Operating lease obligations	\$ 19	\$ 19	-	-
Total	\$ 19	\$ 19	-	-
As at March 31, 2022				
(in thousands)	Total	Less than 1 Year	Between 1 and 5 Years	More than 5 Years
Borrowings	\$ -	-	-	-
Operating lease obligations	\$ 19	\$ 19	-	-
Total	\$ 19	\$ 19	-	-

Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risks in the ordinary course of our business, which are principally limited to interest rate fluctuations and foreign currency exchange rate fluctuations. We maintain significant amounts of cash and cash equivalents that are in excess of federally insured limits in various currencies, placed with one or more financial institutions for varying periods according to expected liquidity requirements.

Interest Rate Risk

Our exposure to interest rate sensitivity is impacted by changes in the underlying U.S. and U.K. bank interest rates. Our surplus cash and cash equivalents have been invested in interest-bearing savings and money market accounts from time to time. We have not entered into investments for trading or speculative purposes. Due to the conservative nature of our investment portfolio, which is predicated on capital preservation of investments with short-term maturities, we do not believe an immediate one percentage point change in interest rates would have a material effect on the fair market value of our portfolio, and therefore we do not expect our operating results or cash flows to be significantly affected by changes in market interest rates.

Foreign Currency Exchange Risk

We maintain our consolidated financial statements in the functional currency pounds Sterling. Monetary assets and liabilities denominated in currencies other than the functional currency are translated into the functional currency at rates of exchange prevailing at the balance sheet dates. Non-monetary assets and liabilities denominated in foreign currencies are translated into the functional currency at the exchange rates prevailing at the date of the transaction. Exchange gains or losses arising from foreign currency transactions are included in the determination of net income (loss) for the respective periods.

For financial reporting purposes, our consolidated financial statements are prepared using the functional currency, and translated into the U.S. dollar. Assets and liabilities are translated at the exchange rates at the balance sheet dates and revenue and expenses are translated at the average exchange rates and shareholders' equity is translated based on historical exchange rates. Translation adjustments are not included in determining net income (loss) but are included in foreign exchange adjustment to accumulate other comprehensive loss, a component of shareholders' equity.

We do not currently engage in currency hedging activities in order to reduce our currency exposure, but we may begin to do so in the future. Instruments that may be used to hedge future risks may include foreign currency forward and swap contracts. These instruments may be used to selectively manage risks, but there can be no assurance that we will be fully protected against material foreign currency fluctuations.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with IFRS as issued by the IASB. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in our consolidated financial statements, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Accrued Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, communicating with our personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual costs. We make estimates of our accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of these estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses include fees paid to:

- vendors in connection with preclinical development activities;
- CROs and investigative sites in connection with preclinical studies and clinical trials; and
- CMOs in connection with drug substance and drug product formulation of preclinical study and clinical trial materials.

We base our expenses related to preclinical studies on our estimates of the services received and efforts expended pursuant to quotes and contracts with multiple research institutions and CROs that conduct and manage preclinical studies and clinical trials on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided and result in a prepayment of the expense. Payments under some of these contracts depend on factors such as the successful enrollment of patients and the completion of clinical trial milestones. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from the estimate, we adjust the accrual or the amount of prepaid expenses accordingly. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of accrued research and development expenses.

Valuation of Share-Based Compensation and Tranche Obligations

Share-Based Compensation

We recognize compensation expense for equity option awards based on the grant date fair value of the option award. For equity option awards that vest based on a service condition, the share-based compensation expense is recognized on a straight-line basis over the requisite service period. For equity option awards that contain both performance and service conditions, we recognize share-based compensation expense ratably over the requisite service period when the achievement of a performance-based milestone is probable based on the relative satisfaction of the performance condition as of the reporting date. We use the fair value of our ordinary shares to determine the fair value of the equity option awards.

The calculation of the fair value of equity-settled share-based awards and the resulting charge to the statement of comprehensive income requires assumptions to be made regarding future events and market conditions. These assumptions include the future volatility of the Company's ordinary share price. These assumptions are then applied to a recognized valuation model in order to calculate the fair value of the awards.

Where employees, directors or advisers are rewarded using share-based payments, the fair value of the employees', directors' or advisers' services are determined by reference to the fair value of the share options / warrants awarded. Their value is appraised at the date of grant and excludes the impact of any nonmarket vesting conditions (for example, profitability and sales growth targets). Warrants issued in association with the issue of convertible loan notes are also considered as share based payments and a share-based payment charge is calculated for these too.

In accordance with IFRS 2, a charge is made to the statement of comprehensive income for all share-based payments including share options based upon the fair value of the instrument used. A corresponding credit is made to a reserve, or Share Based Payment Reserve, in the case of options / warrants awarded to employees, directors or advisers, and ordinary shares to be issued.

Reserve in the case of warrants issued in association with the issue of convertible loan notes, net of deferred tax where applicable.

If vesting periods or other vesting conditions apply, the expense is allocated over the vesting period, based on the best available estimate of the number of share options / warrants expected to vest. Non-market vesting conditions are included in assumptions about the number of options / warrants that are expected to become exercisable.

Estimates are subsequently revised, if there is any indication that the number of share options / warrants expected to vest differs from previous estimates. No adjustment is made to the expense or share issue cost recognized in prior periods if fewer share options ultimately are exercised than originally estimated.

Upon exercise of share options / warrants, the proceeds received are allocated to share capital with any excess being recorded as share premium.

Where share options are cancelled, this is treated as an acceleration of the vesting period of the options. The amount that otherwise would have been recognized for services received over the vesting period is recognized immediately within the statement of comprehensive income.

We expect the impact of our share-based compensation expense for share option awards granted to employees, directors and other service providers to grow in future periods due to the potential increases in the value of our ordinary shares and headcount.

In conducting the valuations, we considered all objective and subjective factors that we believed to be relevant for each valuation conducted, including our best estimate of our business condition, prospects and operating performance at each valuation date. Within the valuations performed, a range of factors, assumptions and methodologies were used. The significant factors included:

- the lack of an active public market for our ordinary shares;

- our results of operations, financial position and the status of our research and preclinical development efforts;
- the material risks related to our business;
- our business strategy;
- the market performance of publicly traded companies in the life sciences and biotechnology sectors;
- the prices paid in recent transactions involving our ordinary shares;
- the likelihood of achieving a liquidity event for the holders of our ordinary shares, such as an IPO, given prevailing market conditions; and
- any recent contemporaneous valuations of our ordinary shares prepared in accordance with methodologies outlined in the practice aid.

The dates of our valuations have not always coincided with the dates of our share grants. In determining the value of our ordinary shares set forth in the table above, our board of directors considered, among other things, the most recent sale and issuance of our ordinary shares, our stage of research and development, our operating and financial performance and current business conditions.

The estimates of fair value of our ordinary shares are highly complex and subjective. There are significant judgments and estimates inherent in the determination of the fair value of our ordinary shares. These judgments and estimates include assumptions regarding our future operating performance, and the determinations of the appropriate valuation methods. The assumptions underlying these valuations represent management's best estimates, which involve inherent uncertainties and the application of management judgment. If we had made different assumptions, our stock-based compensation expense, net loss and net loss per share could have been materially different. If we had made different assumptions, our net loss and net loss per ordinary share could have been materially different.

Taxation

The tax expense for a period represents the total of current taxation and deferred taxation. The charges in respect of current taxation are based on the estimated taxable profit for the relevant year. Taxable profit for the year is based on the profit as shown in the income statement, as adjusted for items of income or expenditure which are not deductible or chargeable for tax purposes. The current tax liability for the year is calculated using tax rates which have either been enacted or substantively enacted at the relevant balance sheet date.

Deferred tax is provided in full, using the liability method on temporary differences arising between the tax base of assets and liabilities and their carrying values in the financial statements. The deferred tax is not accounted for if it arises from initial recognition of an asset or liability in a transaction other than a business combination that at the time of the transaction affects neither accounting nor taxable profit or loss. Deferred tax is determined using tax rates which have been enacted or substantively enacted at the balance sheet date and are expected to apply when the related deferred tax asset is realized, or the deferred income tax liability is settled.

Deferred tax assets are recognized to the extent that it is probable that future taxable profits will be available against which the temporary differences can be utilized.

Deferred tax is provided on temporary differences arising on investments in subsidiaries and associates, except where the timing of the reversal of the temporary difference is controlled by the group and it is probable that the temporary difference will not reverse in the foreseeable future.

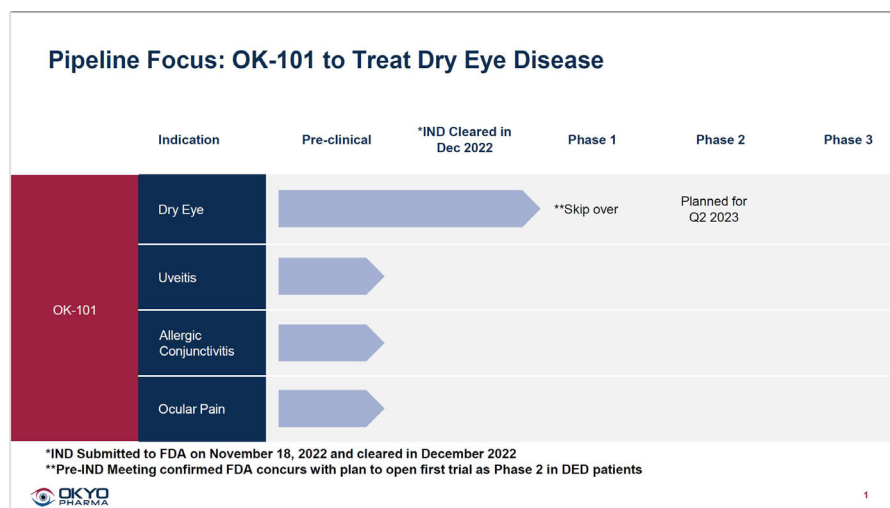
BUSINESS

Overview

We are a preclinical biopharmaceutical company developing next-generation therapeutics to improve the lives of patients suffering from inflammatory eye diseases and ocular pain. Our research program is focused on a novel G Protein-Coupled Receptor, or GPCR, which we believe plays a key role in the pathology of these inflammatory eye diseases of high unmet medical need. Our therapeutic approach is focused on targeting inflammatory and pain modulation pathways that drive these conditions. We are presently developing OK-101, our lead preclinical product candidate, for the treatment of dry eye disease ("DED"). We also plan to evaluate its potential in benefiting patients with ocular neuropathic pain, uveitis and allergic conjunctivitis. We have also been evaluating OK-201, a bovine adrenal medulla, or BAM, lipidated-peptide preclinical analogue candidate for the treatment of neuropathic ocular pain, and plan on maintaining this drug candidate at the exploratory level while we focus our primary energy on the OK-101 program.

On November 18, 2022 we filed with FDA an IND on OK-101 to treat DED, and plan to open a Phase 2 trial in DED patients in the second quarter of 2023 (see Figure 1).

Figure 1. OKYO Pipeline



The evidence from over 40 years of scientific literature suggests inflammation as the most common underlying characteristic of DED. An increase in the levels of inflammatory cytokines in both conjunctiva and tears is known to cause the chronic inflammation associated with DED. Consequently, development of new therapeutic agents that target inflammatory pathways is crucial in improving symptoms in DED patients. Moreover, a number of DED patients suffer from ocular neuropathic pain, making their condition more resistant to topical anti-inflammatory therapy, and a drug capable of targeting both of these aspects of DED would be a significant addition to the ocular-care practitioner's arsenal for the treatment of DED. On February 21, 2018, we announced that we successfully obtained (via assignment from Panetta Partners Limited, a related party) a license from OTT to patents owned or controlled by OTT and a sub-license from OTT to certain patents licensed by OTT from TMC to support our ophthalmic disease drug programs. These licenses gave us the right to exploit the IP estate which is directed to compositions-of-matter and methodologies for treating ocular inflammation, DED with chemerin or lipid-linked chemerin analogues. We also have a license from TMC to a separate IP estate for treating symptoms of ocular neuropathic pain, uveitis and associated pain. The scope of our use of the TMC IP granted to us through the sublicense with OTT is commensurate with the scope of use of the IP granted to OTT from TMC. This intellectual property forms the basis of our OK-101 program, which is discussed in greater detail below.

OK-101

OK-101, our lead preclinical product candidate, is focused on keratoconjunctivitis sicca, commonly referred to as DED, which is a multifactorial disease caused by an underlying inflammation resulting in the lack of lubrication and moisture in the surface of the eye. DED is one of the most common ophthalmic conditions encountered in clinical practice. Symptoms of DED include constant discomfort and irritation accompanied by inflammation of the ocular surface, visual impairment and potential damage to the ocular surface. There are presently approximately 20 million people suffering from DED in the U.S. alone (Farrand et al. AJO 2017; 182:90), with the disease affecting approximately up to 34% of the population aged 50+ (Dana et al. AJO 2019; 202:47), and with women representing approximately two-thirds of those affected (Matossian et al. J Womens Health (Larchmt) 2019; 28:502–514). Prevalence of DED is anticipated to increase substantially in the next 10-20 years due to aging populations in the U.S., Europe, Japan and China and use of contact lenses in the younger population. We believe this increase in prevalence of DED represents a major expanding economic burden to public healthcare. According to Market Research Report, Dry Eye Disease, December 2020, the global DED market in 2019 was approximately \$5.22 billion, with the market size expected to reach \$6.54 billion by 2027. In addition, DED causes approximately \$3.8 billion annually in healthcare costs and represents a major economic burden to public healthcare, accounting for more than \$50 billion to the U.S. economy annually.

At present, there are five major prescription drugs available to treat DED: 1) Restasis (0.05% cyclosporine), 2) Cequa (0.09% cyclosporine), 3) Xiidra (5% lifitegrast), 4) Tyrvaya (0.03mg varenicline), and 5) Eysuvis (0.25% loteprednol – a corticosteroid for short term use only). However, DED continues to be a major unmet medical need due to the large number of patients not well served by the treatments available to them through the medical community.

The development of new drugs to treat DED has been particularly challenging due to the heterogeneous nature of the patient population suffering from DED, and due to the difficulties in demonstrating an improvement in both signs and symptoms of the disease in well-controlled clinical trials. OK-101 is designed to target a chemokine-like receptor 1, or CMKLR1, or CHEMR23, which is a G protein-coupled receptor (See Figure 2) expressed on macrophages, neutrophils, monocytes, plasmacytoid/myeloid dendritic cells, natural killer cells and nonhemopoietic cell types, such as endothelial and epithelial cells as well as neurons and glial cells in the dorsal root ganglion, spinal cord, and retina. Activation of CMKLR1 by its endogenous peptide ligand chemerin is known to modulate inflammation and pain, but natural ligands for CMKLR1 have short half-lives due to rapid inactivation. Discovery of OK-101, a stable, high potency CMKLR1 agonist by On Target Therapeutics (technology licensed exclusively to OKYO Pharma) provided an important step toward the development of a new class of anti-inflammatory therapeutics that can be applied to the treatment of ophthalmic diseases including DED, uveitis and ocular pain.

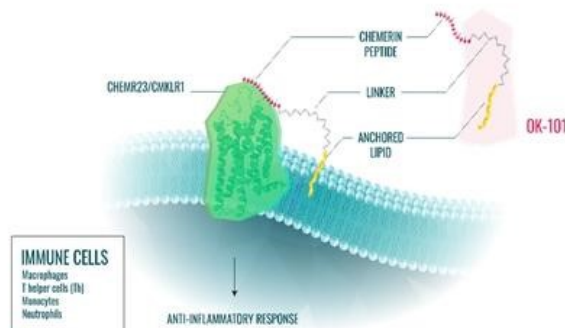


Figure 2. OK-101 binds to CHEMR23 receptor producing an anti-inflammatory response.

A key driver in the development of OK-101 to treat DED, uveitis and other ocular conditions was an analysis of the inherent advantages and difficulties associated with the treatment of ocular conditions. One of the major issues with topical administration of any drug designed for treating DED is the requirement that the drug have adequate drug ‘residence’ time at the ocular site to afford a pharmacologic benefit before being washed out through natural processes of tear enhancement and lacrimal tear drainage. The drug candidates we have developed are designed to combat washout by including a lipid ‘anchor’ within the candidate drug molecule to enhance the residence time of the drug in the eye. We refer to our candidates for DED as “lipidated-chemerin” analogues to highlight this pharmacologic characteristic. Figure 3 shows the significance of including a lipid anchor in the “chemerin” molecule on drug potency and wash resistance conducted in a series of *in vitro* studies.

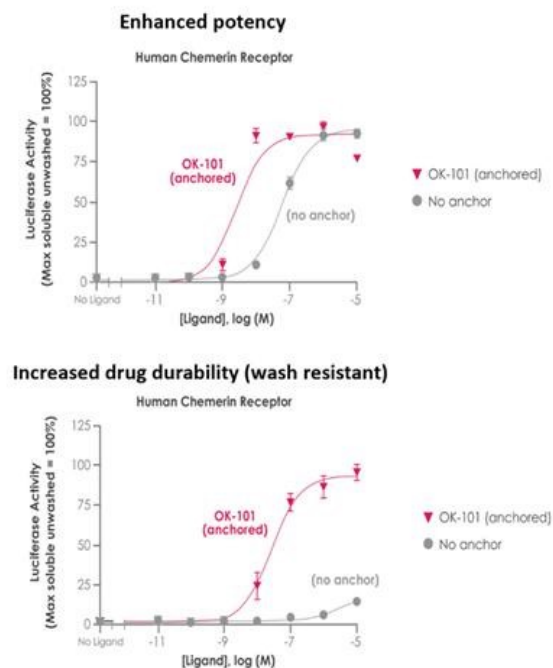


Figure 3 shows the significance of including a lipid anchor in the “chemerin” molecule on drug potency and wash resistance conducted in a series of *in vitro* studies. HEK293 cells were transiently transfected with cDNAs encoding human chemerin receptor CMKLR1. Twenty-four hours after transfection, cells were stimulated with increasing concentrations of OK-101 for 15 min and luciferase activity was determined as described (Doyle *J et al, J. Biol. Chem. 2014*). Data points represent the mean S.E. from at least three independent experiments, each performed in triplicate. A lipidated stable chemerin analog showed higher potency against human chemerin receptor than the corresponding non-lipidated peptide (Figure 3 top panel). Signaling of lipidated stable chemerin analog persisted despite serial washes, whereas activity of the non-lipidated peptide was markedly diminished (Figure 3 bottom panel).

The potency of OK-101 was first determined in a cell-based PathHunter® β -Arrestin assay. This assay monitors the activation of a GPCR in a homogenous, non-imaging assay format using a technology developed by DiscoverX called Enzyme Fragment Complementation (EFC) with β -galactosidase (β -Gal) as the functional reporter. The enzyme is split into two inactive complementary portions (EA for Enzyme Acceptor and PK for ProLink) expressed as fusion proteins in the cells. EA is fused to β -Arrestin and PK is fused to human Chemokine-like receptor 1, CMKLR1. Activation of CMKLR1-PK induces β -Arrestin-EA recruitment, forcing complementation of the two β -galactosidase enzyme fragments (EA and PK). The resulting functional enzyme hydrolyzes substrate to generate a chemiluminescent signal, which is measured using chemiluminescent PathHunter® Detection Reagents.

Assay Design: PathHunter cell lines co-expressing the ProLink™ (PK) tagged GPCR (human Chemokine-like receptor 1, CMKLR1) and the Enzyme Acceptor (EA) tagged β -Arrestin were expanded from freezer stocks according to standard procedures. Cells were seeded in a total volume of 20 μ L into white walled, 384-well microplates and incubated at 37°C for the appropriate time prior to testing. For agonist potency determination, cells were treated with various concentrations of peptide to induce response and incubated at 37°C for 90 minutes. Assay signal was generated through a single addition of 12.5 or 15 μ L (50% v/v) of PathHunter Detection reagent cocktail, followed by a one-hour incubation at room temperature. Microplates were read following signal generation with a PerkinElmer Envision™ instrument for chemiluminescent signal detection. Compound activity was analyzed using CBIS data analysis suite (ChemInnovation, CA). Figure 4 below shows the agonist activity of OK-101 against human chemerin receptor CMKLR1 determined using PathHunter® β -Arrestin assay. OK-101 was shown to have a sub-nanomolar EC50 potency.

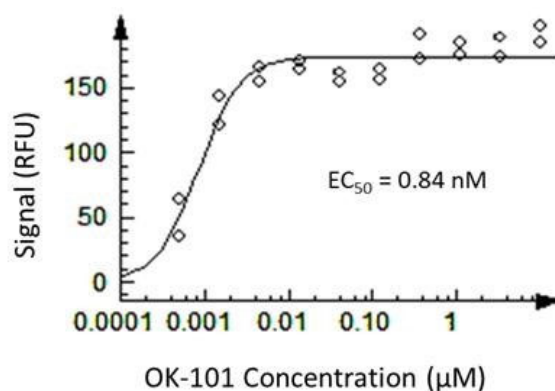


Figure 4. Agonist activity of OK-101 using PathHunter® β-Arrestin assay

To further characterize the potential efficacy of OK-101 to treat DED, OK-101 was tested in a mouse model of acute DED. Animals were divided into five separate cohorts that included: 1) non-stressed control animals untreated throughout the study, 2) animals treated with scopolamine to induce acute DED, 3) animals treated with scopolamine to induce acute DED and treated with 0.1% cyclosporine as a positive control, 4) animals treated with scopolamine to induce acute DED and treated with phosphate buffer solution (the vehicle used for OK-101 delivery), and 5) animals treated with scopolamine to induce acute DED and treated with OK-101 in phosphate buffered solution.

Animals in cohorts 1) and 2) were left untreated with test agents throughout the 5-day period, whereas animals in cohorts 3), 4) and 5) were treated with either cyclosporine, or CS, vehicle or OK-101, respectively, twice a day during the 5-day period *via* bilateral topical administration of the respective agents. On the fifth day, all of the animals were assessed for efficacy by evaluating corneal permeability, a measure of dry-eye effectiveness, in live animals, as well as by exploring the impact of respective treatments on immune response.

Figure 5 shows the results from this animal study. Animals induced with scopolamine to generate acute DED showed a dramatic, statistically significant increase in corneal permeability relative to naïve non-stressed animals. The addition of cyclosporine to scopolamine-induced DED animals showed a statistically significant reduction of permeability ($p \leq 0.001$). Notably, OK-101 demonstrated a dramatic reduction of DED-induced corneal permeability as well ($p \leq 0.001$). OK-101's effect in reducing DED-induced corneal permeability was virtually identical to that of the cyclosporine positive control and close to the baseline corneal permeability observed in non-stressed control animals.

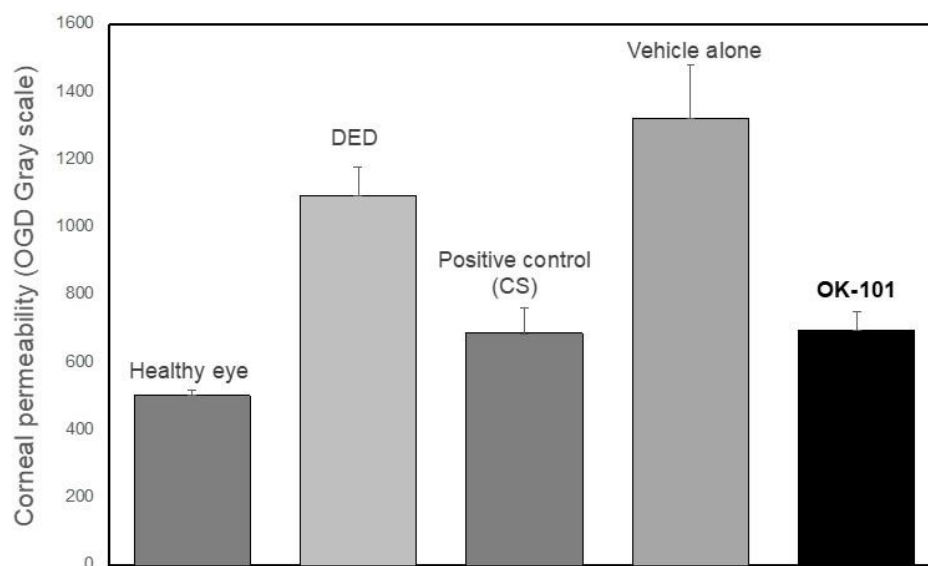


Figure 5. Effect of various treatments on mouse corneal permeability. Corneal permeability was measured using Oregon Green Dextran (OGD) staining followed by imaging. CS was positive control.

Following the in-life portion of the study, immunohistochemistry was performed on frozen sections of enucleated mouse eyes to measure CD4+ T-cell infiltration into the conjunctival epithelium of the eye (Figure 6). Animals induced to develop acute DED and not treated with drug (Vehicle animals) showed significant infiltration of CD4+ T cells within the conjunctival epithelium, whereas OK-101 demonstrated a statistically significant ($p \leq 0.01$) reduction in dry-eye-induced enhancement of CD4+ T-cells. In fact, the level of CD4+ T cells observed in OK-101 treated animals was equivalent to the CD4+ T cell level observed in naïve untreated animals.

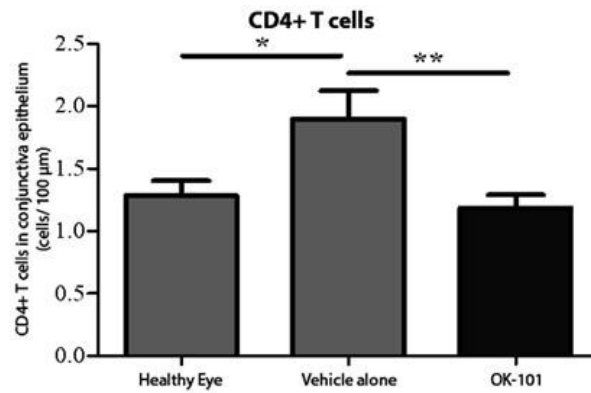


Figure 6. CD4+ T cells in the conjunctival epithelium after acute DED induction.

Immunohistochemistry was also performed on enucleated intact conjunctiva of mouse eyes fixed in 10% formalin, embedded in paraffin, and sectioned and stained. DED typically leads to a loss of goblet cell density as was observed following induction of DED in the mice administered Vehicle (Figure 7). Whereas administration of OK-101 significantly rescued the DED-induced loss of Goblet Cells.

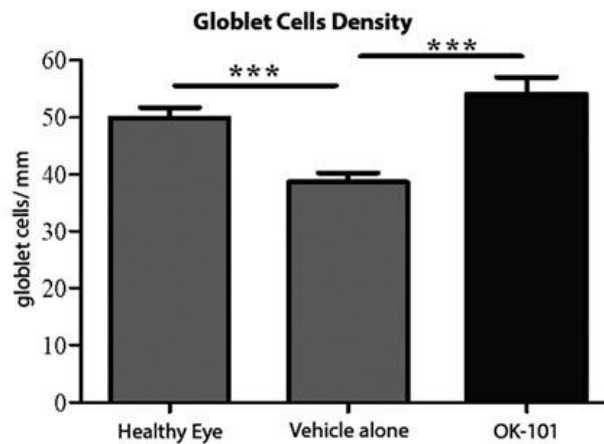


Figure 7. Goblet Cell density following acute DED induction.

DED is a multifactorial disease for which the exact pathophysiological mechanism remains unknown. The combination of a compromised tear film, ocular surface inflammation, and neurosensory abnormalities is considered the main causes of DED. Nerves of the ocular surface have both a sensory function and a physiological function. Sensory function involves the nociceptive system that provides awareness of surrounding environment as well as internal stimuli to the central nervous system so that appropriate action can be initiated, if needed, to prevent tissue damage. In addition, ocular surface nerves have a large impact on the tear film health and can impact both the progression and treatment of DED.

Neuropathic ocular pain in DED has remained a challenging condition to treat since there are no approved topical drugs available. Current treatments for neuropathic ocular pain are limited to short term NSAIDs, steroids, gabapentin, and opioids in severe cases. Neuropathic pain occurs through changes in both peripheral and central neurons leading to allodynia and hyperalgesia. Peripheral sensitization from the inflammatory cytokines during and after ocular surface injury alters responsiveness of peripheral sensory neurons, which initiates complex neuroinflammatory and electrophysiological signaling in the central nervous system that amplify the pain signaling.

In a separate set of animal model experiments, we evaluated the pain-reducing activity of OK-101 in a ciliary nerve ligation mouse model of corneal neuropathic pain. In collaboration with Pedram Hamrah, MD, Professor of Ophthalmology, an internationally recognized cornea specialist, and clinician-scientist at Tufts Medical Center, Boston, we demonstrated that OK-101 suppresses corneal neuropathic pain in a mouse model of ciliary nerve ligation developed in Dr. Hamrah's laboratory. OK-101 was topically administered to mice in comparison to the positive control gabapentin which was administered via intraperitoneal injection. Pain relief was evaluated by an eye-wipe count, and OK-101 was shown to reduce corneal pain similar to that of gabapentin (Figure 8), a commonly used anticonvulsant oral drug typically used to treat neuropathic pain for conditions such as shingles and other systemic nerve pain disorders. Notably, the drug concentration of OK-101 used in this study was identical to that used in mouse models of DED that demonstrated ocular anti-inflammatory activity. OK-101 had no neurotoxic effect and did not affect the corneal epithelial integrity.

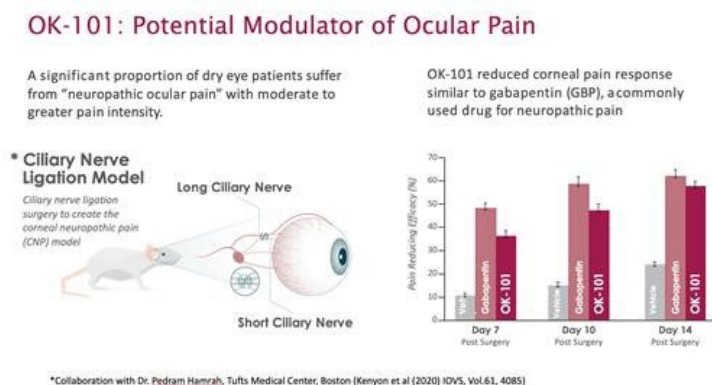


Figure 8. *OK-101 ameliorates neuropathic corneal pain in a mouse model of ciliary nerve ligation*

Corneal neuropathic pain when observed in DED patients typically makes their condition even more resistant to topical anti-inflammatory therapy. Such patients would benefit from a drug with the potential to treat both the ocular surface through its anti-inflammatory activity and the ocular sensory dysfunction with neuropathic pain-reducing activity. The chemerin receptor (ChemR23), that OK-101 targets is expressed on select populations of immune cells, as well as on neurons and glial cells in the dorsal root ganglion, spinal cord, and retina. We believe OK-101 has the potential to address both the increased inflammatory cytokines resulting from tear film imbalance as well as heightened neuro sensory abnormalities through peripheral corneal nerve damage as pictorially shown in Figure 9. We believe that OK-101 is a promising target for the treatment of both inflammatory and neuroinflammatory pain in DED patients.

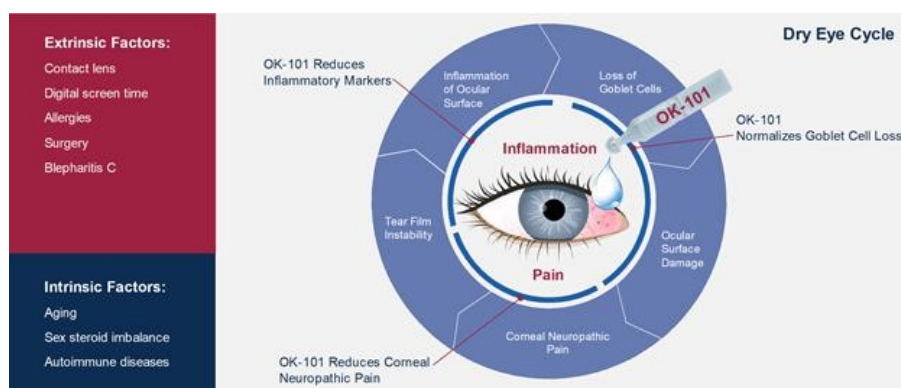


Figure 9. OK-101 Addresses Inflammation and Pain Components of Dry Eye

To evaluate the anticipated tolerance of humans to topical administration of OK-101, a separate series of experiments was also performed to evaluate ocular tolerance of OK-101 in rabbits *via* repeated ocular instillation followed by clinical ophthalmic observations. Rabbit ocular tolerance tests on OK-101 showed no adverse signs such as inflammation, chemosis or hyperemia and no signs of local irritation.

Based on the overall results from the DED animal model, the neuropathic corneal pain model, and the rabbit ocular tolerance studies, we moved forward over the past 18 months with plans to file an IND on OK-101 to treat DED to enable us to begin clinical trials soon thereafter. During the fourth quarter of 2021 we successfully manufactured a 200-gram batch of OK-101 drug substance needed for initiating the IND-enabling studies that were begun during the first quarter of 2022. In support of this work, we also had previously signed an agreement on April 13, 2021, with Ora, Inc., or Ora, a major CRO, specializing in ophthalmic drug development who have provided us with the following services over the past 18 months:

- Preparation of the OK-101 pre-IND briefing document used in the successful pre-IND meeting with FDA in February, 2022;
- Support with the OK-101 pre-IND meeting OKYO accomplished with FDA in February, 2022;
- Support for the planned regulatory publishing and submission of the OK-101 IND in electronic common technical document, or eCTD, format;
- Quality oversight for the recent successful development of the topical OK-101 formulation for future human studies;
- Quality oversight of the successful development and qualification of the drug stability analysis method for OK-101 along with successfully conducting stability studies to establish formulated drug product is stable for at least 90 days; and
- Support for the recently completed animal toxicology studies in rabbits and dogs

Outlook and Strategy for Development of OK-101 to Treat DED

The development of new drugs to treat DED has been particularly challenging due to the heterogeneous nature of the patient population suffering from DED, and due to the difficulties in demonstrating an improvement in both signs and symptoms of the disease in well-controlled clinical trials. The evidence from over 40 years of scientific literature, however, suggests inflammation as the most common underlying element of DED. Consequently, development of new therapeutic agents that target inflammatory pathways is looking to be an attractive approach in improving symptoms in DED patients. Moreover, large number of dry eye patients suffer from ocular neuropathic pain, making their condition more resistant to topical anti-inflammatory therapy, and a drug capable of targeting both of these aspects of DED would be a significant addition to the ocular-care practitioner's arsenal for the treatment of DED.

Over the past twelve months we accomplished the following:

- Completed topical formulation of the OK-101 drug product as well as initial stability studies
- Finalized the bioanalytical method development to support the OK-101 clinical program
- Completed batch manufacture of cGMP OK-101 for clinical trials
- Completed toxicokinetic method development
- Completed toxicology studies in rabbits and dogs
- Completed stability studies of formulated OK-101

We recently completed all final stages of this concerted effort to complete all IND enabling activities and filed with FDA the IND on OK-101 to treat DED on November 18, 2022. On December 22, 2022 we announced that we received clearance of the IND application from the FDA to enable us to initiate a Phase 2, first-in-human, clinical study of OK-101 for the treatment of DED.

Based on ongoing consultations with our clinical CRO, Ora Inc., we are planning to commence the first human study with OK-101 in the second quarter of 2023, and because the drug is designed to be administered topically, we plan to skip the standard Phase 1 studies typically expected with orally delivered or injectable drug candidates in non-life-threatening conditions. This first trial is planned to be a Phase 2 efficacy clinical trial in DED patients and is anticipated to be conducted in approximately 200 to 250 DED patients. The study is being designed in conjunction with, and will be managed and monitored by Ora Inc. The Phase 2 trial is expected to be completed in 6-9 months from enrollment of the first patient.

On February 15, 2022, we announced the successful completion of the pre-IND meeting facilitated by Ora with the FDA regarding development plans for OK-101 to treat DED. Both nonclinical and clinical development milestones were covered in the pre-IND meeting, with the FDA agreeing that our first human trial would be a Phase 2 safety and efficacy trial in DED patients. The FDA also provided guidance on the planned protocol for this trial in DED patients, concurring with our plan for the final protocol which is to prespecify primary and secondary efficacy endpoints covering both a sign and a symptom of DED in the clinical trial. Notably, the final decision to designate any efficacy endpoints as primary endpoints in this trial is highly significant as should this phase 2 trial then meet any prespecified primary endpoints, the trial should considerably affect the timeline to an NDA filing with the FDA for OK-101 to treat DED.

Additional Applicable Disease Indications for OK-101

Ophthalmic diseases

A second related ophthalmic disease indication that is the target of our chemerin-based technology is uveitis. Uveitis is the third leading cause of blindness worldwide. The most common type of uveitis is an inflammation of the iris called iritis (anterior uveitis). Uveitis can damage vital eye tissue, leading to permanent vision loss. Uveitis is currently treated with corticosteroid eyedrops and injections that reduce inflammation, however, the long-term use of corticosteroids causes increased risk of cataracts and glaucoma, requiring close monitoring for the drug's potential side effects.

Once we are in the clinic evaluating OK-101 to treat dry eye, we will also undertake the clinical plan to explore the drug candidate's potential to suppress the inflammation associated with uveitis. In support of this plan, we will also be exploring preclinical development of OK-101 for the uveitis indication by first establishing 'proof-of-concept' for this indication utilizing animal model studies of anterior uveitis to evaluate the potential of OK-101 to suppress the inflammation associated with uveitis.

A third related ophthalmic disease indication that is the target of our chemerin-based technology is allergic conjunctivitis. Allergic conjunctivitis is inflammation of the conjunctiva caused by an allergic reaction that affects about 20% of the global population and is typically treated with antihistamines, mast cell stabilizers and corticosteroids. Although there are effective drugs for the treatment of ocular allergies, about one third patients do not respond adequately to the currently marketed drugs. Further, patients who display poor response to antihistamines appear to suffer from chronic and seasonal allergies. There is a lack of an optimal treatment for the perennial and severe forms of ocular allergies. We plan on conducting 'proof-of-concept' studies using OK-101 for the treatment of chronic and seasonal allergic conjunctivitis using a conjunctival allergen challenge animal model to investigate the potential of OK-101 to suppress the inflammation associated with allergic conjunctivitis.

OK-201

On May 1, 2018, we obtained a license agreement from Tufts Medical Center for the right to exploit all the intellectual property claimed in patent application PCT/US2016/0611101 'Lipidated BAM8-22 and methods of using same' including claims covering composition-of-matter and methodology for treating symptoms of neuropathic chronic pain, ocular pain and uveitis-associated pain. OKYO began an effort to explore BAM8-22 analogs that have potential to ameliorate inflammation and neuropathic pain. OK-201 is the lead compound from the license agreement with Tufts Medical Center and was the focus of the Company's initial efforts to develop a lipidated BAM8-22 analogue to treat neuropathic pain.

On August 6, 2019, we signed a collaborative agreement with Tufts Medical Center, Boston and Pedram Hamrah, MD, Professor of Ophthalmology at Tufts University School of Medicine, Boston, MA to evaluate OKYO's BAM8-22 analogues, including OK-201, as non-opioid analgesics to suppress corneal neuropathic pain using a mouse ocular pain model developed in Dr. Hamrah's laboratory.

On April 28, 2021, we announced positive results of OK-201, a non-opioid analgesic drug candidate delivered topically in Dr. Hamrah's mouse neuropathic corneal pain model, as a potential drug to treat acute and chronic ocular pain. Importantly, OK-201 demonstrated a reduced corneal pain response equivalent to that of gabapentin, a commonly used oral drug for neuropathic pain. These observations demonstrated preclinical 'proof-of-concept' for the topical administration of OK-201 as a potential non-opioid analgesic for ocular pain. Current treatments for corneal pain are limited to short term NSAIDs, steroids, and oral gabapentin and opioids in severe cases.

Although the results with OK-201 were encouraging, due to subsequent success obtained with OK-101 (see section on OK-101) in follow-on animal model studies utilizing the same mouse neuropathic corneal pain model as for OK-201, we have decided to maintain this drug candidate at the exploratory level while we focus our primary energy on the OK-101 program to treat DED, based on OK-101's combination of anti-inflammatory and ocular pain-reducing activities in animal models of these conditions.

Intellectual Property

We consider the protection of our proprietary technologies and products, as well as our ability to maintain patent protection that covers the composition of matter of our product candidates, their methods of use, and other related technologies and inventions, to be a critical element in the success of our business. As of December 7, 2022, our owned and licensed intellectual property included 8 issued patents and 15 pending patent applications in the U.S. and abroad.

Issued United States patent directed to lipidated chemerin fragments or analogs has a statutory expiration date of March 13, 2034, with potential patent term extension available until 2039, following the grant of marketing authorization. Issued United States patent directed to methods of using lipidated chemerin fragments or analogs for treating neuropathic pain has a statutory expiration date of March 13, 2034 (plus 187 days of patent term adjustment, or PTA), with potential patent term extension available until 2039, following the grant of marketing authorization. Issued United States patent directed to methods of using lipidated chemerin fragments or analogs for treating DED has a statutory expiration date of January 23, 2037, with potential patent term extension available until 2041, following the grant of marketing authorization. We have pending patent applications for lipidated chemerin fragments or analogs and methods of use thereof that, if issued, would be expected to expire in the United States and in countries outside of the United States between 2034 and 2043, excluding any patent term adjustment that might be available following the grant of the patent and any patent term extensions that might be available following the grant of marketing authorizations.

Issued United States patent directed to lipidated BAM8-22 peptides or analogs and methods of use thereof has a statutory expiration date of November 9, 2036 (plus 70 days of PTA), with potential patent term extension available until 2042, following the grant of marketing authorization. We have pending patent applications for lipidated BAM8-22 peptides or analogs and methods of use thereof that, if issued, would be expected to expire in the United States and in countries outside of the United States between 2036 and 2040, excluding any patent term adjustment that might be available following the grant of the patent and any patent term extensions that might be available following the grant of marketing authorizations.

We plan to protect our intellectual property position by, among other things, licensing or filing our own U.S. and foreign patent applications related to our proprietary technologies and products, and any inventions or improvements that are important to the development and implementation of our business. We also may seek patent protection, if available, with respect to biomarkers and diagnostic methods that may be used to determine optimal patient populations for use of our product candidates.

Wherever possible, we seek to protect our inventions by filing U.S. patent applications as well as foreign counterpart applications in select countries. Because patent applications in the U.S. are maintained in secrecy for at least 18 months after the applications are filed, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first to make the inventions covered by each of our issued or pending patent applications, or that we were the first to file for protection of inventions set forth in such patent applications. Our planned or potential products may be covered by third-party patents or other intellectual property rights, in which case continued development and marketing of our products would require a license. Required licenses may not be available to us on commercially acceptable terms, if at all. If we do not obtain these licenses, we could encounter delays in product introductions while we attempt to design around the patents, or we could find that the development, manufacture or sale of products requiring such licenses are not possible.

In addition to patent protection, we also rely on know-how, trade secrets and the careful monitoring of proprietary information, all of which can be difficult to protect. We seek to protect some of our proprietary technologies and processes by entering into confidentiality agreements with our employees, consultants, and contractors. These agreements may be breached, we may not have adequate remedies for any breach and our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees or our consultants or contractors use intellectual property owned by others in their work for us, disputes may also arise as to the rights in related or resulting know-how and inventions.

License Agreement for OK-101

OTT and TMC entered into a license agreement on April 3, 2017, or the Master License, pursuant to which OTT licensed exclusive rights to certain patent applications that describe and claim lipidated chemerin peptides and their uses in DED, or Chemerin. The Master License remains in effect until the royalty term has expired with respect to all licensed products in all countries. The Master License may be terminated by either party in the event of a material breach and in addition, OTT may terminate the Master License at any time upon 90 days' notice.

On May 22, 2017, OTT entered into a license and sublicense agreement with Panetta Partners Limited, one of our principal stockholders, relating to Chemerin, or the Chemerin License Agreement, which was licensed from OTT and sublicensed from TMC. On May 1, 2018, we entered into an assignment of the Sublicense with Panetta Partners Limited. Under the terms of the Chemerin License Agreement, we have exclusive rights to Chemerin. Specifically, we have the benefit of the exclusive worldwide rights to a U.S. patent application (which if issued would expire in 2036). In addition, we have exclusive worldwide rights to a Patent Cooperation Treaty, or PCT, patent which has been nationalized in the U.S., Europe, Japan, Australia and Canada and if issued it would expire in 2037. The Chemerin License Agreement provides for the payment by us of up to \$4.9 million in development milestone payments and up to \$37 million in sales milestones as follows:

Development milestone payments being:

- \$300,000 upon first patient enrolled in a Phase I clinical trial;
- \$600,000 upon first patient enrolled in a Phase II clinical trial;
- \$1,500,000 upon first patient enrolled in a Phase III clinical trial; and
- \$2,500,000 upon first commercial sale of a licensed product.

Sales milestones payments as follows:

- \$2,000,000 on first achievement of annual net sales of \$50,000,000;
- \$4,000,000 on first achievement of annual net sales of \$100,000,000;
- \$6,000,000 on first achievement of annual net sales of \$250,000,000;
- \$10,000,000 on first achievement of annual net sales of \$500,000,000; and
- \$15,000,000 on first achievement of annual net sales of \$1,000,000,000.

The above payments equate to low and declining single digit percentage royalties on net sales.

We believe that we have novel composition-of-matter coverage on the lipidated chemerin peptide lead analogues and novel method-of-use claims in treating DED and other ophthalmic diseases. Each patent office has different patentability requirements, but we believe that the license patent applications 16/070,467 (U.S. patent application entitled “Compounds and methods for treating inflammation”; applicant: Tufts Medical Center / Trustees of Tufts College) and PCT/US2017/014605 (U.S. patent application entitled “Compounds and methods for treating inflammation”; applicant Tufts Medical Center / Trustees of Tufts College) contain patentable subject matter. The process for issuance of a patent involves a correspondence with each local patent office in the jurisdictions in which the patent application is filed. That process, patent prosecution, involves a discussion of any relevant prior art and typically a discussion of the scope of the claims. The patent prosecution process can take several years depending on the jurisdiction and is not in the control of the patent owner, but in the control of the local patent office.

The subject matter of the licensed IP may have been developed with government financial assistance and are subject to certain federal regulations under the Bayh-Dole Act of 1980. In particular, the federal government retains a “nonexclusive, nontransferable, irrevocable, paid-up license” for its own benefit to inventions produced with its financial assistance. The Bayh-Dole Act also provides federal agencies with “march-in rights” and allows the government certain rights to require products to be manufactured in the United States. March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a “nonexclusive, partially exclusive, or exclusive license” to a “responsible applicant or applicants.” If the patent owner refuses to do so, the government may grant the license itself.

OK-201

We entered into a license agreement with TMC on May 1, 2018 relating to intellectual property and proprietary technology for the use of certain lipidated BAM peptides in the treatment of neuropathic pain. Under the terms of the license agreement, we have acquired an exclusive license to certain patents (pending and issued), inventions (including future patent filings on lipidated BAM molecules related to the licensed patents. The license agreement requires an upfront license fee of \$15,000 (£11,000), which has been paid by us and annual maintenance fees of \$15,000 (£11,000) commencing on the first anniversary of the license agreement. The maintenance fees decrease to \$10,000 after the three-year anniversary until the first commercial sale. The license agreement also provides for further development and sales milestone payments and royalties.

On February 23, 2021, we announced that patent No. 10,899,796 entitled “Compounds and Methods for Treating Pain” was issued by the United States Patent and Trademark Office. The patent is directed to a class of BAM peptides linked to specific lipids that demonstrate potential for treating symptoms of neuropathic pain, ocular pain, ocular inflammation and/or DED. The work recited in this patent lays out the potential of this class of lipidated BAM analogues as non-opioid analgesics for ocular pain management without the side effects and potential abuse associated with opioid medications and is the foundation of our OK-201 program. In addition to the license from TMC we have a collaboration agreement with TMC pursuant to which TMC has agreed to make available the services of Dr Pedram Hamrah M.D. as principal investigator and nominated reach associate to carry out investigative and research studies in furtherance of our OK-201 corneal neuropathic pain program. The patent will expire in early 2036.

Government Regulation

Overview

Government authorities in most jurisdictions extensively regulate the research, development, clinical testing, manufacture, distribution and marketing of pharmaceutical products such as those that the company is developing. Obtaining regulatory approvals and ensuring subsequent compliance with applicable laws and regulations requires the expenditure of substantial time and financial and managerial resources. Regulatory requirements in different jurisdictions vary, and the timing and success of efforts to obtain regulatory approvals can be highly uncertain. Development of a successful drug candidate, from identification of a candidate drug compound, through preclinical and clinical testing, to filing of a marketing approval application, to registration, typically takes more than ten years.

Drug development is a highly structured process divided into two major stages, preclinical and clinical. In the preclinical stage, the toxicology and mode of action of an active compound is evaluated. The clinical stage is designed to prove the safety of any new pharmaceutical, determine dosage requirements and, predominantly in the later phases, prove its therapeutic utility. This stage is carried out in three phases, which, as a developer moves through the phases, require increasingly large, complex, expensive and time-consuming clinical studies. During Phase 1, the product candidate is initially given to a small number of healthy human subjects or patients and tested for safety, tolerance, absorption, metabolism, distribution and excretion. During Phase 2, additional trials are conducted in a larger, but still relatively limited, patient population to verify that the product candidate has the desired effect and to identify optimal dosage levels. Furthermore, possible adverse effects and safety risks are identified. The therapeutic utility of the product candidate for specific targeted diseases is also studied in more depth. During Phase 3, trials are undertaken to further evaluate dosage, to provide statistically significant evidence of clinical effectiveness and to further study the safety in an expanded patient population at multiple clinical trial sites. Phase 3 trials may require several hundreds or thousands of patients and are therefore the most expensive and time-consuming to conduct. At any time during one of the phases, a trial may produce a negative result, in which case the developer may choose to end the development project or a regulator could force clinical trials to terminate.

Following completion of the Phase 3 trials, the developer submits all the preclinical and clinical trial documentation as well as extensive data characterizing the manufacturing process to the regulator to seek regulatory approval to market the formulation as a pharmaceutical product. The regulator reviews all the information related to the safety of the active compound, and whether the pharmacological effect claimed by the developer on the proposed label can be substantiated by the results of the clinical trials. The regulator has the option to decide to approve the application as requested, ask for changes to the claims made by the developer, ask for more information, require that further clinical trials are undertaken, or refuse to approve the formulation for sale.

Even after initial regulatory approval has been obtained, further studies, including Phase 4 post-approval safety studies, may be required to provide additional data on safety and will be required to gain approval for the use of a product as a treatment for clinical indications other than those for which the product was initially tested. There are also continuing annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data. In addition, regulatory authorities require post-marketing reporting to monitor the adverse effects of the product. Results of post-approval programs may limit or expand the further marketing of the products. Further, if there are any modifications to the product, including changes in indication, manufacturing process or labeling, or a change in the manufacturing facility, an application seeking approval of such changes or, as the case may be, notification, must be submitted to the relevant regulatory authorities before the modified product can be commercialized. Moreover, an approved drug product may be subject to a REMS, which could impose a number of post-approval obligations, including (among other things) a communication plan for physicians regarding safe use of the drug, distribution and use restrictions, and/or periodic assessments of the effectiveness of the REMS. Finally, studies may be required as a contingency of regulatory approval (post-approval commitments), and completion of these studies within a regulator mandated time frame may be required.

European Union

The development, marketing and sale of medicinal products in the EU is subject to extensive pre- and post- marketing regulation by regulatory authorities at both the EU and national levels. The requirements, regulatory approvals and processes governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country, although there is some degree of EU wide harmonization.

Clinical Trials

Clinical trials of medicinal products in the EU must be conducted in accordance with EU and national regulations, focusing, in particular on traceability, apply to clinical trials of advanced therapy medicinal products. If the sponsor of the clinical trial is not established within the EU, it must appoint an entity within the EU to act as its legal representative. The sponsor must take out a clinical trial insurance policy and, in most EU countries, the sponsor is liable to provide 'no fault' compensation to any study subject injured in the clinical trial.

Prior to commencing a clinical trial, the sponsor must obtain a clinical trial authorization from the relevant regulatory authority, and a positive opinion from an independent ethics committee. The application for a clinical trial authorization must include, among other things, a copy of the trial protocol and an investigational medicinal product dossier containing information about the manufacture and quality of the medicinal product under investigation. Currently, clinical trial authorization applications must be submitted to the regulatory authority in each Member State in which the trial will be conducted. Under the new Regulation on Clinical Trials, which took effect on January 31, 2022, there is a centralized application procedure where one national authority takes the lead in reviewing the application and the other national authorities have only a limited involvement. Any substantial changes to the trial protocol or other information submitted with the clinical trial applications must be notified to or approved by the relevant competent authorities and ethics committees. Medicines used in clinical trials must be manufactured in accordance with cGMP.

Marketing Approval

In the EU medicinal products can only be commercialized after obtaining marketing authorization, or MA. There are three procedures for obtaining marketing approvals: the centralized procedure, the decentralized procedure and the mutual recognition procedure/national procedure.

The Community marketing authorization, which is issued by the European Commission through the centralized procedure, based on the opinion of the CHMP of the EMA, is valid throughout the entire territory of the EU. The centralized procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune and viral diseases. The centralized procedure is optional for products containing a new active substance not yet authorized in the EU, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU.

Marketing approvals obtained using the decentralized procedure are available for products not falling within the mandatory scope of the Centralized Procedure. An identical dossier is submitted to the regulatory authorities of each of the Member States in which the marketing approval is sought, one of which is selected by the applicant as the Reference Member State, or RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics and a draft of the labeling and package leaflet, which are sent to the other the concerned Member States, or CMSs, for their approval. A CMS can raise an objection, based on the assessment report, the summary of product characteristics, the labeling and the package leaflet on the grounds of potential serious risk to public health. If no such objections are raised the product will be granted a national marketing authorization in the RMS and all of the selected CMSs. Where a product has already been authorized for marketing in a Member State, this decentralized procedure approval can be recognized in other Member States through the mutual recognition procedure.

Marketing approvals obtained using the national procedure are issued by a single regulatory authority of one of the Member States and only apply to the territory covered by the relevant regulatory authority. They are available for products not falling within the mandatory scope of the centralized procedure. Once a product has been authorized for marketing in a Member State through the national procedure, any application in another Member State must be by the mutual recognition procedure whereby the marketing approval can also be recognized in other Member States through the mutual recognition procedure.

Under the procedures described above, before granting the MA, the EMA or the relevant regulatory authority of the Member States of the EU makes an assessment of the risk-benefit balance of the product on the basis of scientific criteria concerning its quality, safety and therapeutic utility.

The holder of a marketing authorization in any Member State of the EU is subject to various obligations under applicable EU regulations, such as pharmacovigilance obligations, requiring it to, among other things, report and maintain detailed records of adverse reactions, and to submit periodic safety update reports to the regulatory authorities. The holder must also ensure that the manufacturing and batch release of its product is in compliance with the applicable requirements. The marketing approval holder is further obligated to ensure that the advertising and promotion of its products complies with applicable laws, which can differ from Member State to Member State of the EU.

Data Exclusivity

MAAs for generic medicinal products in the EU do not need to include the results of preclinical and clinical trials, but instead can refer to the data included in the marketing approval of a reference product for which regulatory data exclusivity has expired. If a marketing approval is granted for a medicinal product containing a new active substance, that product benefits from eight years of data exclusivity, during which generic MAAs referring to the data of that product may not be accepted by the regulatory authorities, and a further two years of market exclusivity, during which such generic products may not be placed on the market. The two-year period may be extended to three years if during the first eight years a new therapeutic indication with significant clinical benefit over existing therapies is approved.

There is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product, for example, because of differences in raw materials or manufacturing processes. For such products, the results of appropriate preclinical or clinical trials must be provided, and guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product. There are no such guidelines for complex biological products, such as gene or cell therapy medicinal products, and so it is unlikely that biosimilars of those products will currently be approved in the EU. However, guidance from the EMA states that they will be considered in the future in light of the scientific knowledge and regulatory experience gained at the time.

Orphan Medicinal Products

The EMA's Committee for Orphan Medicinal Products, or COMP, may recommend orphan medicinal product designation to promote the development of products that are intended for the diagnosis, prevention or treatment of life-threatening or chronically debilitating conditions affecting not more than five in 10,000 persons in the EU. Additionally, designation is granted for products intended for the diagnosis, prevention or treatment of a life-threatening, seriously debilitating or serious and chronic condition and when, without incentives, it is unlikely that sales of the product in the EU would be sufficient to justify the necessary investment in developing the medicinal product. The COMP may only recommend orphan medicinal product designation when the product in question offers a significant clinical benefit over existing approved products for the relevant indication. Following a positive opinion by the COMP, the European Commission should adopt a decision granting orphan status. The COMP will reassess orphan status in parallel with EMA review of a marketing authorization application and orphan status may be withdrawn at that stage if it no longer fulfills the orphan criteria (for instance because in the meantime a new product was approved for the indication and no convincing data are available to demonstrate a significant benefit over that product). Orphan medicinal product designation entitles a party to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following marketing authorization. During this period, the competent authorities may not accept or approve any similar medicinal product, unless it offers a significant clinical benefit. This period may be reduced to six years if the orphan medicinal product designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of market exclusivity.

United States

Standard Procedure

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act of 1938 and its implementing regulations. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval, may subject an applicant to a variety of administrative or judicial sanctions, such as the FDA's refusal to approve pending NDAs or BLAs, withdrawal of an approval, imposition of a clinical hold, issuance of warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement or civil or criminal penalties.

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

- completion of preclinical laboratory studies, animal studies and formulation studies in compliance with the FDA's good laboratory practice regulations;
- submission to the FDA of an IND, which the FDA must approve before human clinical trials may begin;
- approval of the human clinical trial by the institutional review board, or IRB, at each clinical site before each trial may be initiated;
- performance of adequate and well-controlled human clinical trials in accordance with applicable IND and other clinical trial-related regulations, sometimes referred to as GCPs to establish the safety and clinical utility of the proposed product candidate for its proposed indication;
- submission to the FDA of a BLA or NDA;
- satisfactory completion of an FDA pre-approval inspection of the production facility or facilities where the product is produced to assess compliance with the FDA's cGMP requirements to assure that the facilities, methods and controls are adequate to preserve the product's identity, strength, quality, purity and potency;
- potential FDA audit of the preclinical and/or clinical trial sites that generated the data in support of the NDA; and
- FDA review and approval of the BLA or NDA prior to any commercial marketing or sale of the product in the United States.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Other potential consequences include, among other things:

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

Clinical Trials

Clinical trials involve the administration of the IND to human patients under the supervision of qualified investigators in accordance with GCP requirements, which include the requirement that all research patients provide their informed consent in writing for their participation in any clinical trial. Clinical trials are conducted under protocols detailing, among other things, the objectives of the trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. A protocol for each clinical trial and any subsequent protocol amendments must be submitted to the FDA as part of the IND. In addition, an IRB at each institution participating in the clinical trial must review and approve the plan for any clinical trial before it commences at that institution. Information about certain clinical trials must be submitted within specific timeframes to the National Institutes of Health for public dissemination on their website. Regulatory authorities, IRBs or the sponsor may suspend or terminate a clinical trial at any time on various grounds, including a finding that the research patients are being exposed to an unacceptable health risk.

Marketing Approval

Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls, or CMC, and proposed labeling, among other things, are submitted to the FDA as part of an NDA or BLA requesting approval to market the product for one or more indications. In most cases, the submission of an NDA or BLA is subject to a substantial application user fee. Under the Prescription Drug User Fee Act guidelines that are currently in effect, the FDA has a goal of 10 months from the date of filing of a standard NDA for a new molecular entity to review and act on the submission. This review typically takes 12 months from the date the NDA is submitted to the FDA because the FDA has approximately two months to make a filing decision.

In addition, under the Pediatric Research Equity Act of 2003, certain NDAs or supplements to an NDA must contain data that are adequate to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations, and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The FDA may, on its own initiative or at the request of the applicant, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adults, or full or partial waivers from the pediatric data requirements.

The FDA conducts a preliminary review of all NDAs within the first 60 days after submission, before accepting them for filing, to determine whether they are sufficiently complete to permit substantive review. The FDA may request additional information rather than accept an NDA for filing. In this event, the application must be resubmitted with the additional information included. The resubmitted application is also subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review. The FDA reviews an NDA to determine, among other things, whether the drug is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued safety, quality and purity.

The FDA may refer an application for a novel drug to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, that reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving a BLA or NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP requirements.

After evaluating the NDA or BLA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter, or, in some cases, a complete response letter (which generally contains a statement of specific conditions that must be met in order to secure final approval of the NDA and may require additional clinical or preclinical testing in order for the FDA to reconsider the application). Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications.

Even if the FDA approves a product, it may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a drug's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Orphan Drug Designation

Under the Orphan Drug Act of 1983, the FDA may designate a biologic product as an "orphan drug" if it is intended to treat a rare disease or condition (generally meaning that it affects fewer than 200,000 individuals in the United States, or more in cases in which there is no reasonable expectation that the cost of developing and making a biologic product available in the United States for treatment of the disease or condition will be recovered from sales of the product).

If a product with orphan status receives the first FDA approval for the disease or condition for which it has such designation, the product is entitled to orphan product exclusivity, meaning that the FDA may not approve any other applications to market the same drug or biologic product for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or if the party holding the exclusivity fails to assure the availability of sufficient quantities of the drug to meet the needs of patients with the disease or condition for which the drug was designated. 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 for which the orphan product has exclusivity.

Post-Approval Requirements for the EU and United States

The FDA and the relevant regulatory authorities in the EU strictly regulate marketing, labeling, advertising and promotion of products that are placed on the market in their respective territories. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved label. The regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses, and a company that is found to have improperly promoted off-label uses may be subject to significant liability.

In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the relevant regulatory authorities and are subject to periodic unannounced inspections by them to confirm compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior approval of the relevant regulatory authorities before being implemented. Regulations laid down by the FDA and the regulatory authorities in the EU also require investigation and correction of any deviations from the requirements of cGMP and impose reporting and documentation requirements upon the marketing approval holder and any third-party manufacturers that the marketing approval holder may decide to use.

Other Healthcare Laws in the EU and United States

The company will also be subject to healthcare regulation and enforcement by the U.S. federal government and the states and governments in the EU and any other countries in which the company conducts its business, including its research, and the marketing and distribution of its product candidates and products once they have obtained marketing approval. Failure to comply with these laws, where applicable, can result in the imposition of significant civil penalties, criminal penalties, exclusion from participating in health care programs, additional reporting requirements and oversight if the company becomes subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws and other sanctions. The healthcare laws and regulations that may affect the Company's ability to operate in the United States include: the federal fraud and abuse laws, including the federal anti-kickback and false claims laws; federal data privacy and security laws; and federal transparency laws related to payments and/or other transfers of value made to physicians and other healthcare professionals and teaching hospitals. Many US states have similar laws and regulations that may differ from each other and federal law in significant ways. Moreover, several US states have enacted legislation requiring pharmaceutical manufacturers to, among other things, establish marketing compliance programs, file periodic reports with the state, and make periodic public disclosures on sales and marketing activities, and prohibiting certain other sales and marketing practices. Rules and legislation covering more or less the same subject matter as those in the United States apply to in countries in the EU and to other countries. These can differ between jurisdictions and can sometimes result in lower or higher exposure in those countries than in the United States. Where a product is sold in a number of countries compliance efforts can therefore be complicated.

Coverage and Reimbursement in the EU and United States

Sales of products developed from the Company's product candidates, if approved, will depend, in part, on the extent to which such products will be covered by third party payors, such as government health care authorities, government health care programs, commercial insurance and managed healthcare organizations. These third-party payors are increasingly limiting coverage or reducing reimbursements for medical products and services. In the United States, no uniform policy of coverage and reimbursement for products exists among third party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products.

Governments influence the price of medicinal products in the EU through their pricing and reimbursement rules and control of national healthcare systems that fund a large part of the cost of those products to consumers. Some jurisdictions operate positive and negative list systems under which products may only be marketed once a reimbursement price has been agreed. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost-effectiveness of a particular product candidate to currently available therapies. 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 in the EU governments influence the price of medicinal products through their pricing and reimbursement.

The adoption of price controls and cost-containment measures, and the adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit the Company's net revenue and results. Decreases in third party reimbursement for the Company's product candidates or a decision by a third-party payor to not cover the Company's product candidates could reduce physician usage of the Company's product candidates, once approved, and have a material adverse effect on the Company's sales, results of operations and financial condition.

Privacy and Data Protection Laws in Europe

We are subject to European laws relating to our and our suppliers', partners' and subcontractors' collection, control, processing and other use of personal data (i.e., any data relating to an identifiable living individual, whether that individual can be identified directly or indirectly). We are subject to the supervision of local data protection authorities in those jurisdictions where we are established, where we offer goods or services to EU residents and where we monitor the behavior of individuals in the EU (i.e., undertaking clinical trials). We and our suppliers, partners and subcontractors process personal data including in relation to our employees, employees of customers, clinical trial patients, healthcare professionals and employees of suppliers including health and medical information. The data privacy regime in the EU includes the General Data Protection Regulation, or GDPR, the e-Privacy Directive (2002/58/EC) and the e-Privacy Regulation (once in force) and the national laws and regulations implementing or supplementing each of them.

The GDPR requires that personal data is only collected for specified, explicit and legal purposes as set out in the GDPR or local laws, and the data may then only be processed in a manner consistent with those purposes. The personal data collected and processed must be adequate, relevant and not excessive in relation to the purposes for which it is collected and processed, it must be held securely, not transferred outside of the EEA, (unless certain steps are taken to ensure an adequate level of protection) and must not be retained for longer than necessary for the purposes for which it was collected. In addition, the GDPR requires companies processing personal data to take certain organizational steps to ensure that they have adequate records, policies, security, training and governance frameworks in place to ensure the protection of data subject rights, including as required to respond to complaints and requests from data subjects. For example, the GDPR requires us to make more detailed disclosures to data subjects, requires disclosure of the legal basis on which we can process personal data, makes it harder for us to obtain valid consent for processing, will require the appointment of a data protection officer where sensitive personal data (i.e., health data) is processed on a large scale, introduces mandatory data breach notification throughout the EU and imposes additional obligations on us when we are contracting with service providers.

In addition, to the extent a company processes, controls or otherwise uses “special category” personal data (including patients’ health or medical information, genetic information and biometric information), more stringent rules apply, further limiting the circumstances and the manner in which a company is legally permitted to process that data. Finally, the GDPR provides a broad right for Member State to create supplemental national laws which may result in divergence across Europe making it harder to maintain a consistent operating model or standard operating procedures. Such laws, for example, may relate to the processing of health, genetic and biometric data, which could further limit our ability to use and share such data or could cause our costs to increase, and harm our business and financial condition.

We depend on a number of third parties in relation to the provision of our services, a number of which process personal data on our behalf. With each such provider, we enter into contractual arrangements to ensure that they only process personal data according to our instructions, and that they have sufficient technical and organizational security measures in place. In the case where we transfer personal data outside the EU, we do so in compliance with the relevant data export requirements from time to time. We take our data protection obligations seriously, as any improper, unlawful or accidental disclosure, loss, alteration or access to, personal data, particularly sensitive personal data (i.e., special category), could negatively impact our business and/or our reputation.

We are also subject to EU laws on personal data export, as we may transfer personal data from the EU to other jurisdictions which are not considered by the European Commission to offer adequate protection of personal data. Such transfers need to be legitimized by a valid transfer mechanism under the GDPR. There is currently ongoing litigation challenging the commonly used transfer mechanisms, the EU Commission approved model clauses. In addition, the U.S. Privacy Shield is currently under review by the European Commission. As such, it is uncertain whether the Privacy Shield framework and/or model clauses will be invalidated in the near future. These changes may require us to find alternative bases for the compliant transfer of personal data from the EU to the United States and we are monitoring developments in this area. Invalidation of any mechanism on which we rely could require operational changes and increased costs and may lead to governmental enforcement actions, litigation, fines and penalties or adverse publicity that could have an adverse effect on our business.

The EU is in the process of replacing the e-Privacy Directive with a new set of rules taking the form of a regulation, which will be directly implemented in the laws of each Member State, without the need for further enactment. The draft e-Privacy Regulation imposes strict opt-in marketing rules with limited exceptions for business-to-business communications and alters rules on third-party cookies, web beacons and similar technology. Regulation of cookies and web beacons may lead to broader restrictions on online research activities, including efforts to understand users’ internet usage. The current draft also significantly increases fining powers to the same levels as GDPR (i.e., the greater of 20 million Euros or 4% of total global annual revenue). While this e-Privacy Regulation was originally intended to be adopted on May 25, 2018, it is still going through the European legislative process and the timing of its adoption remains unclear.

There are costs and administrative burdens associated with compliance with the GDPR and the resultant changes in the EU and EEA member states' national laws and the introduction of the e-Privacy Regulation once it takes effect. Any failure or perceived failure to comply with global privacy laws carries with it the risk of significant penalties and sanctions of up to €20 million or 4% of global turnover. These laws or new interpretations, enactments or supplementary forms of these laws, could create liability for us, could impose additional operational requirements on our business, could affect the manner in which we use and transmit patient information and could increase our cost of doing business. Claims of violations of privacy rights or contractual breaches, even if we are not found liable, could be expensive and time-consuming to defend and could result in adverse publicity that could harm our business.

Organizational Structure

The following table sets out details of our significant subsidiaries:

Name	Principal activity	Registered address	Percentage shareholding	Country of incorporation
OKYO Pharma US Inc.	Clinical stage biotechnology company	420 Lexington Avenue Suite 1402 New York, NY 10170	100%	USA

Property, Plant and Equipment

The below table contains information regarding existing or planned material tangible fixed assets owned or leased by us and our subsidiary. We believe that suitable additional or substitute space will be available as needed to accommodate any future expansion of our operations.

Location	Tenure	Principal use
420 Lexington Ave New York NY 10170	Monthly	CEO Office

MANAGEMENT

DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

The following table sets forth information regarding our directors and senior management as of the date of this prospectus. The business address of all persons identified below is Martello Court, Admiral Park, St. Peter Port, Guernsey GY1.

Name	Age	Position
Gabriele Cerrone	51	Non-Executive Chairman
Dr. Gary S. Jacob	75	CEO and Director
Dr. Raj Patil	64	Chief Scientific Officer
Keeren Shah	46	Chief Financial Officer
Willy Simon (1)(2)(3)	70	Non-Executive Director
John Brancaccio (1)(2)(3)	74	Non-Executive Director
Bernard Denoyer (1)(2)(3)	74	Non-Executive Director

(1) Remuneration Committee member

(2) Nominating Committee member

(3) Audit Committee member

Gabriele Cerrone

Gabriele Cerrone has been the Non-Executive Chairman of our company since January 2021. Mr. Cerrone is the Founder of Tiziana Life Sciences Limited and has been its Executive Chairman since April 2014. Mr. Cerrone has founded 10 biotechnology companies in oncology, infectious diseases and molecular diagnostics, and has listed seven of these companies on Nasdaq, two to the Main Market and AIM Market in London. Mr. Cerrone co-founded Cardiff Oncology, Inc., an oncology company and served as its Co-Chairman; he was a co-founder and served as Chairman of both Synergy Pharmaceuticals, Inc. and Callisto Pharmaceuticals, Inc. and was a Director of and led the restructuring of Siga Technologies, Inc. Mr. Cerrone also co-founded FermaVir Pharmaceuticals, Inc. and served as Chairman of the Board until its merger in September 2007 with Inhibitex, Inc. Mr. Cerrone served as a director of Inhibitex, Inc. until its US\$2.5bn sale to Bristol Myers Squibb Co in 2012. Mr. Cerrone is the Executive Chairman and Founder of Nasdaq-listed Tiziana Life Sciences Limited, an oncology focused therapeutics company; Co-Founder of Rasna Therapeutics Inc., a company focused on the development of therapeutics for leukaemias; Co-Founder of Hepion Pharmaceuticals, Inc.; Executive Chairman and Co-Founder of Gensignia Life Sciences, Inc., a molecular diagnostics company focused on oncology using microRNA technology; Non-Executive Chairman and Founder of Accustem Sciences Limited; and founder of BioVitas Capital Ltd. Mr. Cerrone graduated from New York University's Stern School of Business with a master's degree in business administration (MBA).

Dr. Gary S. Jacob

Dr. Gary S. Jacob has served as Chief Executive Officer and a director of our company since January 2021. From November 2018 to March 2020, Dr. Jacob was the Chief Executive Officer of Immuron Limited, an Australian microbiome biopharmaceutical company. From July 2008 until December 2017, Dr. Jacob was President and Chief Executive Officer of Synergy Pharmaceuticals Inc., a biopharmaceutical company, where he held various positions from July 2008 to November 2018 and served as its Chairman from September 2013 to November 2018. Dr. Jacob is the co-inventor of the FDA-approved drug Trulance[®] which is currently marketed in the U.S. by Bausch Health Companies, Inc. to treat functional GI disorders. On December 12, 2018, Synergy Pharmaceuticals Inc. filed a petition for relief under Chapter 11 of the U.S. Bankruptcy Code. Since March 19, 2014, Dr. Jacob has been Chairman of the Board of Hepion Pharmaceuticals, Inc., a biotechnology company, and earlier served as its Chief Executive Officer from May 15, 2013 until March 19, 2014. Dr. Jacob served as Chief Executive Officer of Callisto Pharmaceuticals, Inc. from May 2003 until January 2013 and a director from October 2004 until January 2013. Dr. Jacob also serves as a director of Rasna Therapeutics, Inc., and is a past director of Cardiff Oncology, Inc. Dr. Jacob has over 35 years of experience in the pharmaceutical and biotechnology industries across multiple disciplines including research & development, operations and business development. Prior to 1999, Dr. Jacob served as a Monsanto Science Fellow, specializing in the field of glycobiology, and from 1997 to 1998 Dr. Jacob was Director of Functional Genomics, Corporate Science & Technology, at Monsanto Company. Dr. Jacob also served from 1990 to 1997 as Director of Glycobiology at G.D. Searle Pharmaceuticals Inc. During the period of 1986 to 1990, he was Manager of the G.D. Searle Glycobiology Group at Oxford University, England.

Dr. Raj Patil

Dr. Raj Patil has served as Chief Scientific Officer of our company since March 2021. Dr. Patil has over 15 years of ophthalmic drug development experience, including research & development, operations and business development. Dr. Patil previously worked with Ora, as Vice President of Research & Development, where he was responsible for driving all anterior and posterior segment ocular research of Ora's R&D Institute. From 2013 until 2018, Dr. Patil worked at iVeena Delivery Systems as Vice President of Advanced Ocular Delivery Systems. Dr. Patil's tenure at iVeena included a two-year sabbatical in Singapore, where he served as an Associate Professor of Ophthalmology at DUKE/NUS Medical School, and Principal Investigator at Singapore Eye Research Institute. From 2004 until 2013, Dr. Patil also held a number of leadership roles at Alcon/Novartis Institute of Biomedical Research, including Associate Director of Research and Head of Molecular Pharmacology - glaucoma and retina research. Prior to 2004, Dr. Patil served as an Associate Professor of Ophthalmology, Cell Biology & Genetics at the University of Nebraska Medical Centre in Omaha from 2001 until 2004, and as an Assistant Professor of Ophthalmology, Molecular Biology & Pharmacology at Washington University in St. Louis from 1992 until 2000. Dr. Patil received his PhD in Biochemistry from National Chemical Laboratory/University of Pune, India, and completed his postdoctoral training in Biochemistry and Molecular Biology at the University of Michigan, Ann Arbor, MI. He is the recipient of the Olga Keith Weiss Special Scholar Award from the Research to Prevent Blindness Foundation, and NIH Director's New Innovator Award. Dr. Patil has authored over 50 peer-reviewed research articles, serves as reviewer and editorial board member for numerous journals, and is frequently invited to lecture at academic and industry events.

Keeren Shah

Keeren Shah has served as our Chief Financial Officer since August 2020. Ms. Shah currently also serves as the Chief Financial Officer of Tiziana Life Sciences Limited, Accustem Sciences Limited and Rasna Therapeutics Inc., having previously served as the Group Financial Controller for all businesses from June 2016 to July 2020. Prior to joining us, Ms. Shah spent 10 years at Visa, Inc. as a Senior Leader in its finance team where she was responsible for key financial controller activities, financial planning and analysis, and core processes as well as leading and participating in key transformation programmes and Visa Inc.'s initial public offering. Before joining Visa, Ms. Shah also held a variety of finance positions at other leading companies including Arthur Andersen and BBC Worldwide. She holds a Bachelor of arts with honours in Economics and is a member of the Chartered Institute of Management Accountants.

Willy Simon

Willy Jules Simon has been a director of our company since November 2015. He is a banker and worked at Kredietbank N.V. and Citibank London before serving as an executive member of the Board of Generale Bank NL from 1997 to 1999 and as the chief executive of Fortis Investment Management from 1999 to 2002. He acted as chairman of Bank Oyens & van Eeghen from 2002 to 2004. He was chairman of AIM-traded Velox3 plc (formerly 24/7 Gaming Group Holdings plc) until 2014 and had been a director of Playlogic Entertainment Inc., a Nasdaq OTC listed company. Willy Simon has been the chairman of Bever Holdings, a company listed in Amsterdam, since 2006 and Chairman of Ducat Maritime since 2015. He is also a non-executive director of Tiziana Life Sciences Limited.

John Brancaccio

John Brancaccio, a retired CPA, has served as a director of our company since June 2020. From April 2004 until May 2017, Mr. Brancaccio was the Chief Financial Officer of Accelerated Technologies, Inc., an incubator for medical device companies. Mr. Brancaccio served as a director of Callisto Pharmaceuticals, Inc. from April 2004 until its merger with Synergy Pharmaceuticals, Inc. in January 2013 and has been a director of Tamir Biotechnology, Inc. (formerly Alfacell Corporation) since April 2004, as well as a director of Hepion Pharmaceuticals, Inc. since December 2013, Rasna Therapeutics, Inc. since September 2016, and Tiziana Life Sciences Limited since July 2020. Mr. Brancaccio served as a director of Synergy from July 2008 until April 2019.

Bernard Denoyer

Bernard F. Denoyer has served as a director of our company since December 2021. Mr. Denoyer served as Senior Vice President, Finance and Secretary of Synergy Pharmaceuticals, Inc. from July 2008 until his retirement in June 2017. Between 2004 and January 2013 Mr. Denoyer concurrently served as Principal Financial Officer of Synergy's former parent company, Callisto Pharmaceuticals, Inc. From October 2000 to December 2003, Mr. Denoyer was an independent consultant. Prior to this, Mr. Denoyer served as Chief Financial Officer and Senior Vice President of META Group, Inc.

Scientific Advisory Board

Our board of directors is assisted in its approach to its scientific strategy. Members of the Scientific Advisory Board are:

Professor Napoleone Ferrara, MD - University of California's Moores Cancer Center in San Diego

Dr Ferrara is Senior Deputy Director for Basic Sciences at University of California's Moores Cancer Center in San Diego; and Distinguished Professor of Pathology at the University of California's School of Medicine, also in San Diego. Dr Ferrara's research led to the development of the anti-VEGF monoclonal antibody bevacizumab (Avastin®) which was initially approved for the treatment of colorectal cancer and is now one of the top ten selling global pharmaceutical products. Dr. Ferrara won the 2010 Lasker Award for his work on VEGF.

Professor Pedram Hamrah, MD, FRCS, FARVO – Tufts University School of Medicine, Boston, and Clinician-Scientist at Tufts Medical Center

Dr. Hamrah is an ophthalmologist and cornea specialist, with a focus on corneal immunology and neuroscience, ocular imaging (immuno-imaging), ocular surface diseases, and corneal neuropathic pain. He is currently on faculty at the departments of Ophthalmology and Bioengineering at Tufts University, where he is the director of clinical research and director of the Center for Translational Ocular Immunology. In addition, he is a faculty member at the immunology, neuroscience, and cell, molecular and developmental biology graduate programs at the Sackler School of Graduate Biomedical Sciences at Tufts. Throughout his career, he has focused on discovery, patient care and teaching. Dr. Hamrah currently serves on over a dozen editorial boards, is the associate editor for The Ocular Surface and TVST, section editor for Eye, and assistant editor at Ocular Immunology and Inflammation.

Foreign Private Issuer Exemption

We are an FPI as defined by the SEC. As a result, in accordance with Nasdaq listing requirements, we may rely on home country governance requirements and certain exemptions thereunder rather than complying with Nasdaq corporate governance standards. While we voluntarily follow most Nasdaq corporate governance rules, we may choose to take advantage of the following limited exemptions:

- Exemption from filing 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.
- Exemption from Section 16 rules requiring insiders to file public reports of their stock ownership and trading activities and liability for insiders who profit from trades in a short period of time, which will provide less data in this regard than shareholders of U.S. companies that are subject to the Exchange Act.
- Exemption from the Nasdaq requirement requiring disclosure of any waivers of the code of business conduct and ethics for directors and officers.
- Exemption from the requirement that our board of directors have a remuneration committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities.
- Exemption from the requirement to have independent director oversight of director nominations.

We intend to follow the laws of Guernsey and rules applicable to companies admitted to listing on the standard segment of the Official List of the FCA and to trading on the Main Market of the London Stock Exchange in lieu of Nasdaq corporate governance requirements as follows:

- We do not intend to follow Nasdaq Rule 5620(c) regarding quorum requirements applicable to meetings of shareholders. Such quorum requirements are not required under the laws of Guernsey. In accordance with generally accepted business practice, our Articles provide alternative quorum requirements that are generally applicable to meetings of shareholders.
- We do not intend to follow Nasdaq Rule 5605(b)(2), which requires that independent directors regularly meet in executive sessions where only independent directors are present. Our independent directors may choose to meet in executive sessions at their discretion.

Although we may rely on certain home country corporate governance practices, we must comply with Nasdaq's Notification of Noncompliance requirement (Nasdaq Rule 5625) and the Voting Rights requirement (Nasdaq Rule 5640). Further, we must have an audit committee that satisfies Nasdaq Rule 5605(c)(3), which addresses audit committee responsibilities and authority and requires that the audit committee consist of members who meet the independence requirements of Nasdaq Rule 5605(c)(2)(A)(ii).

We intend to take all actions necessary for us to maintain compliance as an FPI under the applicable corporate governance requirements of the Sarbanes-Oxley Act, the rules adopted by the SEC and Nasdaq listing rules. Accordingly, our shareholders will not have the same protections afforded to shareholders of companies that are subject to all of the corporate governance requirements of Nasdaq. For an overview of our corporate governance principles, see the section titled "Description of Share Capital and Memorandum and Articles of Incorporation—Differences in Corporate Law."

Code of Business Conduct and Ethics

Our Code of Business Conduct and Ethics is applicable to all of our employees, officers and directors and is available on our website at <https://www.okyopharma.com>. Our Code of Business Conduct and Ethics provides that our directors and officers are expected to avoid any action, position or interest that conflicts with the interests of our company or gives the appearance of a conflict. Our directors and officers have an obligation under our Code of Business Conduct and Ethics to advance our company's interests when the opportunity to do so arises. We expect that any amendment to this code, or any waivers of its requirements, will be disclosed on our website. Information contained on, or that can be accessed through, our website is not incorporated by reference into this registration statement, and you should not consider information on our website to be part of this registration statement.

Composition of Our Board of Directors

Our board of directors is currently composed of five members. Our board of directors has determined that, of our five directors, three of the directors, Mr. John Brancaccio, Mr. Bernard Denoyer and Mr. Simon, each do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under Nasdaq rules.

In accordance with our Articles, each of our directors for whom it is the third annual general meeting following the annual general meeting at which they were elected or last re-elected, or who was appointed by the board since the previous annual general meeting, shall retire from office but shall be eligible to stand for re-election. See "Description of Share Capital and Articles of Association—Articles of Association—Board of Directors."

The expiration of the current terms of the members of the Board of Directors and the period each member has served in that term are as follows:

Name	Year Current Term Began	Year Current Term Expires
Gabriele Cerrone	2022	2023
Dr. Gary S. Jacob	2022	2023
Willy Simon	2022	2023
John Brancaccio	2022	2023
Bernard Denoyer	2022	2023

The Company has adopted best practice for corporate governance in its country of incorporation so all directors will retire and stand for re-election at each annual general meeting (as opposed to reliance upon rotational reappointment).

Committees of Our Board of Directors

Our board of directors has three standing committees: an audit committee, a remuneration committee and a nominating committee.

Audit, Risk and Disclosure Committee

The audit, risk and disclosure committee, which consists of John Brancaccio, Bernard Denoyer and Willy Simon, assists the board of directors in overseeing our accounting and financial reporting processes. Mr. Brancaccio serves as chairman of the audit committee. The audit committee consists exclusively of members of our board who are financially literate, and Mr. Brancaccio is considered an "audit committee financial expert" as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable Nasdaq rules and regulations.

Our board has determined that all of the members of the audit committee satisfy the "independence" requirements set forth in Rule 10A-3 under the Exchange Act. The audit committee will be governed by a charter that complies with Nasdaq rules.

The audit committee's responsibilities include:

- recommending the appointment of the independent auditor to the general meeting of shareholders;
- the appointment, compensation, retention and oversight of any accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit services;
- pre-approving the audit services and non-audit services to be provided by our independent auditor before the auditor is engaged to render such services;
- evaluating the independent auditor's qualifications, performance and independence, and presenting its conclusions to the full board of directors on at least an annual basis;
- reviewing and discussing with management and our independent registered public accounting firm our financial statements and our financial reporting process;
- reviewing, approving or ratifying any related party transactions.

Remuneration Committee

The remuneration committee consists of Mr. Brancaccio, Mr. Denoyer and Mr. Simon. Mr. Simon serves as chairman of the remuneration committee. Under SEC and Nasdaq rules, there are heightened independence standards for members of the remuneration committee, including a prohibition against the receipt of any compensation from us other than standard board member fees.

The remuneration committee's responsibilities include:

- identifying, reviewing and proposing policies relevant to the compensation and benefits of our directors and executive officers;
- evaluating each executive officer's performance in light of such policies and reporting to the board; and
- overseeing and administering our employee share option scheme or equity incentive plans in operation from time to time.

Nominating Committee

The nominating committee consists of Mr. Denoyer and Mr. Simon. Mr. Denoyer serves as chairman of the nominating committee. The nominating committee's responsibilities include:

- drawing up selection criteria and appointment procedures for directors;
- recommending nominees for election to our board of directors and its corresponding committees;
- assessing the functioning of individual members of our board of directors and executive officers and reporting the results of such assessment to the board of directors; and
- developing corporate governance guidelines.

None of our non-employee directors have any service contracts with Tiziana Life Sciences PLC or any of our subsidiaries that provide for benefits upon termination of employment.

Compensation of Executive Officers and Directors

The table below sets the remuneration of the CEO and other Executive Directors for the financial year ended March 31, 2022.

Name	Position	Fees earned or paid in cash (\$000)	Bonus earned or paid in cash (\$000)	Options awarded (\$000) (1)	Total (\$000)
Dr. Gary S. Jacob	CEO	350	75	517	942
Dr. Kunwar Shailubhai (2)	Director	18	-	-	18

- (1) Represents the fair value of incentive stock options granted during the year to March 31, 2022 using an appropriate valuation model for computing stock-based compensation expense as of the date of grant.
- (2) Dr. Kunwar Shailubhai resigned as Director on 17 June 2021

Narrative Disclosure to the Compensation table

We entered into an employment agreement with Dr. Gary S. Jacob, our Chief Executive Officer, on December 21, 2020 and amended the agreement on January 19, 2021. Pursuant to the agreement, Dr. Jacob has an annual salary of \$350,000 and a cash bonus of up to 50% of his annual salary based on annual performance goals. In addition, Dr. Jacob was granted options to purchase 40,000,000 ordinary shares. The options will vest over 4 years in 4 equal tranches.

Dr. Jacob is also entitled to the same fringe benefits as we provide to our other executives from time to time and is eligible to receive employee share incentives. If Dr. Jacob's employment with the company is terminated without cause, or if he resigns for good reason, Dr. Jacob will also be entitled to receive severance equal to continuation of his base salary as then currently in effect for 12 months following his date of termination and will be eligible for a pro-rated bonus and for reimbursement for medical coverage premiums for 6 months following his date of termination. Dr. Jacob's severance benefits are conditioned on, amongst other things, his execution of our standard separation agreement and a general release of claims in our favor.

Employees

As of the date of this prospectus, we had four full time employees. Two of our employees were engaged in research and development and two employees were engaged in management, administration and finance. One is located in England and three are located in the United States. None of our employees are members of labor unions. None of our employees are covered by a collective bargaining agreement.

Insurance and Indemnification

To the extent permitted by the Guernsey Companies Law, we are empowered to indemnify our directors against any liability they incur by reason of their directorship. We maintain directors' and officers' insurance to insure such persons against certain liabilities. We expect to enter into a deed of indemnity with each of our directors and executive officers prior to, or as soon as practicable, following the filing of this registration statement.

In addition to such indemnification, we provide our directors and executive officers with directors' and officers' liability insurance.

Insofar as indemnification of liabilities arising under the Securities Act may be permitted to our board of directors, executive officers, or persons controlling us pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Compensation

Total Compensation for the Non-Executive Chairman and Non-Executive Directors for the year ending March 31, 2022:

Name	Position	Fees earned or paid in cash (\$000)	Bonus earned or paid in cash (\$000) (2)	Options awarded (\$000) (1)	Other (\$000)	Total (\$000)
Gabriele Cerrone	Non-Executive Chairman	164	-	-	-	164
Willy Simon	Non-Executive Director	44	-	-	-	44
John Brancaccio	Non-Executive Director	42	-	39	-	81
Bernard Denoyer	Non-Executive Director	15	-	35	-	50

- (1) The amounts have been translated into U.S. dollars from Pounds Sterling based upon the exchange rate as certified by the Federal Reserve Bank of New York for customs purposes as of March 31, 2022. These translations are merely for the convenience of the reader and should not be construed as representations that the Pounds Sterling amounts actually represent such U.S. dollar amounts or could be converted into U.S. dollars at the rate indicated.
- (2) Represents the fair value of incentive stock options granted during the year to March 31, 2022 using the Black-Scholes model for computing stock-based compensation expense as of the date of grant.

Narrative Disclosure to the Compensation table

Gabriele Cerrone

We entered into an appointment agreement with Mr. Gabriele Cerrone on January 6, 2021 to serve as our Non-Executive Chairman. This agreement entitles Mr. Cerrone to receive a consultancy fee of £120,000 per year. On April 28, 2021 we entered into an agreement with the Mr. Cerrone pursuant to which Mr. Cerrone was awarded a retrospective bonus of \$687,273 for the financial year ended March 31, 2020 and a further bonus of \$554,400 for the financial year ended March 31, 2021, in each case for services prior to his agreeing to become a director of the Company, on condition that Mr. Cerrone agreed that Panetta Partners Limited and Planwise Group Limited exercise a total of 147,969,396 warrants at exercise prices between \$0.006 and \$0.0189 (being all of the warrants held by Mr. Cerrone and his associated entities). Mr. Cerrone also agreed that his accrued but unpaid compensation from January 1, 2021 to May 4, 2021 and through to March 31, 2022, in the sum of \$210,000 be waived and offset against the costs of the exercise of certain of the warrants.

Non -Executive Director remuneration

The remuneration of our non-executive directors is determined by our board as a whole, based on a review of current practices in other companies. We intend to enter into service contracts with our directors for their services or amend and restate any prior service contracts in place prior to, or as soon as practicable, following the filing of this registration statement.

Employee Share Option Plan with Non-Employee Sub-Plan and US Sub-Plan

The main features of the Employee Share Option Plan are summarized below.

Eligibility

All executive directors and employees of the Company and any of its subsidiaries are eligible to participate in the Employee Share Option Plan. The Remuneration Committee selects the individuals to whom share options are to be granted from time to time.

Grant of options

Options may be granted at such time or times as the Remuneration Committee (or the Board, excluding any interested Director, until a Remuneration Committee is formally established) determines.

Exercise price and adjustments to options

While the Ordinary Shares are admitted to trading on the LSE, the exercise price per Ordinary Share may not be less than the average of the middle market quotations for an Ordinary Share for the five dealing days immediately prior to the date of grant. While the Ordinary Shares are not admitted to trading on the LSE, the exercise price will be the amount specified by the Remuneration Committee. If the Ordinary Shares are newly issued the exercise price may not, in any event, be less than the nominal value of an Ordinary Share. In the event of any variation in the share capital of the Company the exercise price and/or the number of Ordinary Shares comprised in each option may be adjusted as the Remuneration Committee determines. No adjustment may be made which will reduce the exercise price below the nominal value of an Ordinary Share.

Rights and restrictions

An option granted under the Employee Share Option Plan is not transferable. The option certificate will specify when the option will lapse, and such date may not be later than the tenth anniversary of its date of grant. Except in the circumstances referred to below, an option will only be exercisable on or after the date which is three years after the date of grant.

If the participant ceases to be employed by the Company by reason of injury, disability, ill-health or redundancy; or because the business or company that employs them is transferred out of the ultimate ownership of the Company, his option may be exercised within six months after such cessation or transfer provided that this limit may be further extended by the Remuneration Committee in the event that any exercise of the options would trigger any requirement upon the holder to make a general offer to shareholders under Rule 9 of the Takeover Code. In the event of the death of a participant, the personal representatives of a participant may exercise his option within six months after the date of death. The extent to which an option may be exercised in these circumstances will be determined by reference to any exercise conditions and time vesting provisions set out in the option certificate unless the Remuneration Committee decides otherwise and is satisfied that any waiver of such provisions does not constitute a reward for failure.

On cessation of employment for any other reason (or when a participant serves or has been served with, notice of termination of such employment), the option will lapse unless the Remuneration Committee exercises its discretion to allow the exercise of the option for a period not exceeding 6 months from the date of such cessation or notice. In such circumstances and where exercise is permitted, the extent to which an option may be exercised will be determined by reference to any exercise conditions and time vesting provisions set out in the option certificate unless the Remuneration Committee decides otherwise and is satisfied that any waiver of such provisions does not constitute a reward for failure.

Corporate events

Options, to the extent not already exercisable, will become exercisable immediately prior to a change in control of the Company, in the event of a takeover of the Company, in the event that an officer becomes entitled or bound to acquire Ordinary Shares or in the event that the court sanctions a compromise or arrangement for the reconstruction of the Company or its amalgamation with any other company. In such event, all share options may be exercised for a limited period and will lapse to the extent not exercised. Options, to the extent not already exercisable, will become exercisable in the event that the Company is proposed to be voluntarily wound up and all share options may be exercised within a limited period in connection with the winding up, failing which they will lapse. In such circumstances and where exercise is permitted, the extent to which an option may be exercised will be determined by reference to any exercise conditions set out in the option certificate unless the Remuneration Committee decides otherwise and is satisfied that any waiver of such provisions does not constitute a reward for failure.

Performance conditions

The exercise of share options may be subject to the satisfaction of such performance conditions, if any, as may be specified and subsequently varied and/or waived by the Remuneration Committee.

Issuance of Ordinary Shares

The Ordinary Shares issued upon the exercise of share options granted under the Employee Share Option Plan will rank *pari passu* with the Company's issued Ordinary Shares on the date of exercise, save as regards any rights arising by reference to a record date prior to the date of such exercise.

Plan limit

Options may not be granted under the Employee Share Option Plan if such grant would result in the total number of "Dilutive Shares" exceeding 15% of the Company's issued share capital from time to time. "Dilutive Shares" means, on any date, all shares of the Company which (a) have been issued, or transferred out of treasury, on the exercise of share options granted, or in satisfaction of any other awards made, under any share incentive scheme (including the Employee Share Option Plan) in the shorter of the five years ending on (and including) that date and the period since Admission; and (b) remain capable of issue, or transfer out of treasury, under any subsisting share options granted by the Company.

Alternative settlement on exercise

Instead of delivering the number of Ordinary Shares specified in the exercise notice, the Remuneration Committee may make a cash payment with the option holder's consent or deliver Ordinary Shares equal to the value of the Ordinary Shares over which the option is exercised, less the relevant exercise price, or may deliver a combination of the above two.

Alteration

The Remuneration Committee may alter the Employee Share Option Plan except that (apart from minor amendments to benefit the administration of the Employee Share Option Plan, to correct typographical or other errors, to take account of a change in legislation or to obtain or maintain favorable tax, exchange control or regulatory treatment for participants or the Company) no alteration to the advantage of participants or to the Employee Share Option Plan limit described above can be made without the prior approval of Shareholders in general meeting.

No amendment may have a materially adverse effect on share options granted before the amendment without the relevant option holder's consent.

Termination and Plan period

The Remuneration Committee may terminate or suspend the operation of the Employee Share Option Plan at any time, whereupon no further share options shall be granted but in all other respects the provisions of the Employee Share Option Plan shall remain in force. In any event, no share options may be granted after the date which is five years after the date the Employee Share Option Plan is adopted.

RELATED PARTY TRANSACTIONS

The following is a description of related party transactions we have entered into with the beneficial owners of 3% or more of our ordinary shares, which are our only voting securities, and senior management and members of our board of directors, for the two-year period ended March 31, 2022.

Tiziana Life Sciences Ltd

Tiziana Life Sciences Ltd is a related party as the entity is controlled by a person that has significant influence over the Group. On January 1, 2018, we entered into a Shared Services Agreement with Tiziana Life Sciences Limited, or Tiziana, pursuant to which we share premises and other resources. The agreement is renewed for successive three (3) month periods. As of March 31, 2022, we had incurred \$107,132 (2021: \$86,567) worth of costs in relation to this agreement and \$47,041 was due to Tiziana Life Sciences Ltd. At March 31, 2021, \$27,664 was receivable from Tiziana Life Sciences Ltd. We share common officers and directors with Tiziana, namely Gabriele Cerrone, Willy Simon and John Brancaccio.

Letter of Appointment

We entered into an appointment agreement with Mr. Gabriele Cerrone on January 6, 2021 to serve as our Non-Executive Chairman. This agreement entitles Mr. Cerrone to receive a consultancy fee of £120,000 per year. On April 28, 2021 we entered into an agreement with the Mr. Cerrone pursuant to which Mr. Cerrone was awarded a retrospective bonus of \$687,273 for the financial year ended March 31, 2020 and a further bonus of \$554,400 for the financial year ended March 31, 2021, in each case for services prior to his agreeing to become a director of the Company, on condition that Mr. Cerrone agreed that Panetta Partners Limited and Planwise Group Limited exercise a total of 147,969,396 warrants at exercise prices between \$0.006 and \$0.0189 (being all of the warrants held by Mr. Cerrone and his associated entities). Mr. Cerrone also agreed that his accrued but unpaid compensation from January 1, 2021 to May 4, 2021 and through to March 31, 2022, in the sum of \$210,000 be waived and offset against the costs of the exercise of certain of the warrants.

Indemnity Agreements

We have entered into deeds of indemnity with each of our directors and officers. See “Management—Insurance and Indemnification.”

Related Person Transaction Policy

Our board of directors has adopted a written related person transaction policy, to be effective immediately upon the effectiveness of the registration statement of which this prospectus forms a part, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover, any transaction or proposed transactions between us and a related person that are material to us or the related person, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit and risk committee is tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm’s length transaction and the extent of the related person’s interest in the transaction. All of the transactions described in this section occurred prior to the adoption of this policy.

PRINCIPAL SHAREHOLDERS

The following table sets forth information relating to the beneficial ownership of our ordinary shares as of March 10, 2023 by:

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

The number of ordinary shares beneficially owned by each entity, person, board member, or executive officer is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any ordinary shares over which the individual has sole or shared voting power or investment power as well as any ordinary shares that the individual has the right to acquire within 60 days of March 10, 2023 through the exercise of any option, warrant or other right. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all ordinary shares held by that person.

Name and address of beneficial owner	Number of Ordinary Shares Beneficially Owned	
	Shares	%
5% or Greater Shareholders:		
Gabriele Cerrone ⁽¹⁾	553,043,715	39.08
Executive Officers and Directors:		
Gabriele Cerrone ⁽¹⁾	553,043,715	39.08
Willy Simon ⁽²⁾	2,307,100	*
Gary S. Jacob ⁽³⁾	23,250,000	1.62
John Brancaccio ⁽⁴⁾	483,333	*
Bernard Denoyer ⁽⁵⁾	333,333	*
All directors and executive officers as a group (5 persons) ⁽⁶⁾	579,417,481	40.21

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

⁽¹⁾ Mr. Gabriele Cerrone is the ultimate beneficial owner of ordinary shares through Planwise Group Limited and Panetta Partners Limited.

⁽²⁾ Consists of 2,000,000 stock options which are currently exercisable or exercisable within 60 days of March 10, 2023

⁽³⁾ Consists of 23,250,000 stock options which are currently exercisable or exercisable within 60 days of March 10, 2023

⁽⁴⁾ Consists of 483,333 stock options which are currently exercisable or exercisable within 60 days of March 10, 2023

⁽⁵⁾ Consists of 333,333 stock options which are currently exercisable or exercisable within 60 days of March 10, 2023

⁽⁶⁾ Includes 26,066,666 stock options which are currently exercisable or exercisable within 60 days of March 10, 2023

DESCRIPTION OF SHARE CAPITAL AND MEMORANDUM AND ARTICLES OF INCORPORATION

We were originally incorporated in the British Virgin Islands as a British Virgin Islands Business Company on 4 July 2007 under the BVI Business Companies Act 2004 with company number 1415559 under the name Jellon Enterprises, Inc. Our legal and commercial name was changed to Minor Metals & Mining, Inc. on October 24, 2007, to Emerging Metals Limited on November 28, 2007, to West African Minerals Corporation on December 9, 2011, and to OKYO Pharma Corporation on January 10, 2018. On March 9, 2018, shareholders approved the cancellation of the Company's AIM listing and migration to Guernsey. On July 3, 2018, following the approval of the Guernsey Companies Registry, the Company was registered under the Guernsey Companies Law under the name OKYO Pharma Limited, as a Guernsey company with limited liability, an indefinite life and company number 65220. The Company is domiciled in Guernsey.

Our registered office is located at Martello Court, Admiral Park, St. Peter Port, Guernsey, GY1 3HB and our telephone number is +44 (0) 20 7495 2379. Our website address is www.okyopharma.com. The reference to our website is an inactive textual reference only and the information contained in, or that can be accessed through, our website is not a part of this registration statement.

Current authorized share capital

Not applicable.

Current issued share capital

As of March 10, 2023, our issued share capital was 1,415,217,968 ordinary shares, no par value. Each issued ordinary share is fully paid.

Options

As of March 10, 2023, there were vested options to purchase 35,155,667 ordinary shares outstanding with a weighted average exercise price of \$0.066 per ordinary share. The remaining options to purchase 46,664,333 ordinary shares vest between January 31, 2023 and August 31, 2025.

Warrants

As of March 10, 2023, there were warrants to purchase 35,909,090 ordinary shares outstanding as follows:

No. outstanding		Exercise Price		Exercise Price	Final Exercise Date
35,000,000	\$	0.054	£	0.045	07/17/2023
909,090	\$	0.033	£	0.0275	05/21/2023

Warrants to purchase 909,090 ordinary shares are exercisable immediately until the final exercise date. Warrants to purchase the remaining 35,000,000 ordinary shares are exercisable based on the achievement of milestones, with a final exercise date of July 17, 2023.

Information about the Ordinary Shares

In accordance with our Articles, the following summarizes the rights of holders of our ordinary shares:

- each holder of our ordinary shares is entitled to one vote per ordinary share on all matters to be voted on by shareholders generally;
- the holders of the ordinary shares shall be entitled to receive notice of, attend, speak and vote at our general meetings; and
- holders of our ordinary shares are entitled to receive such dividends as are recommended by our directors and declared by our shareholders.

Articles

We are incorporated in Guernsey as a non-cellular company limited by shares under company number 65220. We are governed by our Articles and the Guernsey Companies Law.

Our Articles were adopted by a special resolution of our shareholders at our annual general meeting held on September 25, 2020. The summary below is not a complete copy of the terms of the Articles.

The Articles contain no specific restrictions on our purpose and therefore our purpose is unrestricted.

The Articles contain, among other things, provisions to the following effect:

Share Capital

Our share capital currently consists of ordinary shares. Subject to the Guernsey Companies Law and to any rights attached to existing shares, we may issue shares with such rights or restrictions as may be determined by the board. In addition, shares which are to be redeemed, or are liable to be redeemed at our option or the holder of such shares may be issued with the board determining the terms and conditions of such redemption.

All of our issued and outstanding ordinary shares are fully paid. Holders of ordinary shares do not have conversion or redemption rights. There are no provisions in our Articles discriminating against a shareholder as a result of such shareholder's ownership of a particular number of shares.

Preferred Shares

Our board of directors may provide for other classes of shares, including series of preferred shares. If any preferred shares are issued, the rights, preferences and privileges of our ordinary shares will be subject to, and may be adversely affected by, the rights of holders of such preferred shares.

Voting

Subject to any rights or restrictions attached to any shares, on a show of hands every shareholder who is present in person or by proxy at a general meeting shall have one vote. On a poll, every shareholder present in person or by proxy at a general meeting shall have one vote for every ordinary share held by such shareholder. A proxy need not be a shareholder of ours.

A shareholder shall not be entitled, in respect of any shares held by such shareholder, to vote (either personally or by proxy) at any general meeting of ours unless all amounts payable by such shareholder in respect of that share in our capital have been paid or credited as having been paid, or where such shareholder is in default of the provisions in the Articles requiring disclosure of ownership of shares and we have served a direction notice on such shareholder advising such shareholder that such shares may not be voted.

Variation of Rights

All or any of the rights, privileges or conditions attached to any class of shares in issue may only be varied with the consent in writing of the holders of 75% in value of the issued shares of that class (excluding treasury shares) or with the sanction of a special resolution passed at a separate general meeting of the holders of the shares of that class. A quorum for the separate class meeting is two persons (in person or by proxy) holding one-third of the voting rights of the shares of that class or group.

Alteration of capital

We may by ordinary resolution:

- (a) consolidate and divide all or any of our share capital into shares of a larger amount than our existing shares;
- (b) sub-divide all or any of our shares into shares of a smaller amount than is fixed by our Articles or by ordinary resolution;
- (c) cancel any shares which, at the date of passing the resolution have not been taken up or agreed to be taken up;
- (d) convert the whole, or any particular class, of our shares into redeemable shares;
- (e) redesignate the whole, or any particular class, of our shares into shares of another class;
- (f) covert all or any of our shares into shares of a nominal amount of a different currency, at the exchange rate; and
- (g) where our shares were expressed in a particular currency, denominate or redenominate it.

Dividends

(a) Subject to the Guernsey Companies Law, our directors may authorize dividends and distributions to be paid to Shareholders. If any share is issued on terms providing that it shall rank for dividend or distribution as from a particular date, such share shall rank for dividend or distribution accordingly.

(b) Our directors may direct that any dividend or distribution shall be satisfied wholly or partly by the distribution of assets, and in particular of paid-up shares, debentures, or other securities of any other company.

- (c) No dividend or distribution payable shall bear interest against us.

(d) A transfer of shares shall not pass the right to any dividend or distribution declared thereon before the registration of the transfer.

(e) All dividends or distribution unclaimed for a period of one year from the date on which such dividend or distribution was declared may be invested or otherwise made use of by our directors for the benefit of until claimed.

(f) All dividends or distribution unclaimed for a period of six years from the date on which such dividend or distribution was declared shall, if our directors so resolve, be forfeited and shall revert to us.

(g) Subject to the Guernsey Companies Law or in the terms of issue of any share in our capital, for the purposes of making any distribution or paying any dividend, our directors may determine that those persons who are entered on the register of members at the close of business on a day determined by our directors shall be the persons who are entitled to receive such dividends or distributions.

(h) Payments of dividends or distributions may be made by electronic transfer in such manner as agreed between the member and us or by cheque or warrant.

Transfer of Ordinary Shares

A shareholder may transfer all or any of their shares (i) in the case of certificated shares by transfer in writing in any usual or common form or in any other form acceptable to our directors; and (ii) in the case of uncertificated shares, in the manner provided for in the rules and procedures of the operator of the “relevant system” (i.e., the CREST System) and in accordance with and subject to the CREST Regulations.

The instrument of transfer of a certified share shall be signed by or on behalf of the transferor and, if the share is not fully paid, by or on behalf of the transferee.

Our board of directors may, in its absolute discretion and without assigning any reason, decline to register any transfer of certificated share or uncertificated shares unless it is:

- (a) in respect of a share which is fully paid up;
- (b) in respect of a share in which we have no lien;
- (c) in respect of only one class of share;
- (d) in favor of a single transferee or not more than four joint transferees; and
- (e) in relation to a certificated share, delivered for registration to our registered office (or such other place as our board of directors may from time to time determine) accompanied by the relevant share certificate(s) and such other evidence as our board of directors may reasonably require, to show the right of the transferor to make the transfer.

Our board of directors shall not refuse to register any transfer or renunciation of partly paid shares which are listed on the Main Market of the London Stock Exchange on the grounds that they are partly paid shares in circumstances where that refusal would prevent dealings in any such shares from taking place on an open and proper basis.

Disclosure of Ownership

Our directors may by notice in writing require a shareholder to disclose to us the identity of any person other than such shareholder who has, or has had, at any time during the three years immediately preceding the date on which the notice is issued, any interest (whether direct or indirect) in the shares held by such shareholder.

If a shareholder, or any other person appearing to be interested in shares held by that shareholder, has been issued with such a notice and has failed in relation to any shares, or the Default Interests, to give the Company the information thereby required within the prescribed period from the service of the notice, our directors may in their discretion serve a direction notice on such shareholder which may direct that:

(a) the shareholder shall not be entitled in respect of the Default Interests to be present or to vote (either in person or by proxy) at any general meeting or at any separate meeting of the holders of any class of shares or on any poll or to exercise any other right conferred by membership in relation to any such meeting or poll; and

(b) where the Default Interests represent at least 0.25% of the number of shares in issue of the class concerned:

(i) any dividend, distribution or other money payable in respect of the shares shall be withheld by us, which shall not have any obligation to pay interest on it; and

(ii) no transfer of the Default Interests held by us shall be registered unless: (I) the shareholder is not himself in default as regards supplying the information requested; and (II) the shareholder proves to the satisfaction of our directors that no person in default as regards supplying such information is interested in any of the shares the subject of the transfer.

Requirement to disclose interests

Each shareholder shall be under an obligation to comply with the disclosure and notification requirements set out in Chapter 5 of the DTRs. If the Company determines that a shareholder, or the Defaulting Member, has not complied with the provisions of Chapter 5 of the DTRs with respect to some or all of such shares held by such Shareholder, or the Default Shares, we shall have the right by delivery of notice to the Defaulting Member, or a Default Notice, to:

(a) suspend the right of such Defaulting Member to vote on the Default Shares in person or by proxy at any meeting of ours; and/or

(b) (i) withhold, without any obligation to pay interest thereon, any dividend or other amount payable with respect to the Default Shares, (ii) render ineffective any election to receive our shares instead of cash in respect of any dividend or part thereof, and/or (iii) prohibit the transfer of any of our shares held by the Defaulting Member except with the consent of ours.

Pre-emptive Rights

Neither the laws of Guernsey nor the Articles provide shareholders with pre-emptive rights when new shares are issued by the Company.

Board of Directors

Unless otherwise determined by the company by ordinary resolution, the number of directors (other than any alternate directors) shall not be less than one, but there shall be no maximum number of directors.

The business and affairs of the Company shall be managed by, or under the direction or supervision of the our directors who may pay all expenses incurred in promoting and registering the Company, and may exercise all such powers necessary for managing, and for directing and supervising the management of, the our business and affairs as are not, by the Guernsey Companies Law or by the Articles, required to be exercised by us in a general meeting, subject to the Articles, to the provisions of the Guernsey Companies Law and to such regulations as may be prescribed by us by special resolution provided that such regulations are not inconsistent with the Articles or the provisions of the Guernsey Companies Law.

Subject to the Articles, our directors may meet together for the dispatch of business, adjourn and otherwise regulate their meetings as they think fit. The quorum necessary for the transaction of the business is two unless otherwise resolved by our directors. A meeting of our directors at which a quorum is present shall be competent to exercise all powers and discretions for the time being exercisable by our directors.

A director who is in any way, directly or indirectly, interested in a proposed transaction or arrangement with us, or in a transaction or arrangement that has been entered into by us, must declare the nature and extent of such director's interest to our directors. The declaration must be made at a meeting of our board of directors, or by written notice, or by general notice, in accordance with the Guernsey Companies Law and the Articles.

Our directors shall have power at any time and from time to time to appoint any person to be a director, either to fill a casual vacancy or as an addition to our existing directors.

Subject to the provisions of the Guernsey Companies Law and provided the director has disclosed their interest to our other directors, such director notwithstanding their office may:

- (a) be a party to, or otherwise interested in, any transaction or arrangement with us, or in which we are otherwise interested;
- (b) act by themselves or through their firm in a professional capacity for us be entitled to remuneration as if they were not a director;
- (c) be a director or officer of, or employed by, or a party to any transaction or arrangement with, a shareholder of or otherwise directly or indirectly interested in, any corporate entity promoted by us, or with which we have entered into any transaction with or are interested in; and
- (d) not by reason of his office, be accountable to us for any benefit which such director derives from any such office or employment or from any such transaction or arrangement or from any interest in any such body corporate and no such transaction or arrangement shall be liable to be avoided on the ground of any such interest or benefit.

A director shall be counted in the quorum at any meeting in relation to any resolution in respect of which such director has declared an interest and may vote thereon.

A person must not be appointed as a director unless such person has consented in writing and submitted their declaration that they are not ineligible to act as a director under the Guernsey Companies Law. A director need not be a shareholder but shall be entitled to receive notice of and attend all of our general meetings.

No person shall, unless recommended by our directors, be eligible for election to the office of director at any general meeting unless not less than three nor more than 21 days before the date appointed for the meeting there shall have been left at our registered office a notice in writing signed by a shareholder, their intention to propose such a person for election (this must be accompanied by that persons willingness to be elected and their signed declaration).

Our directors shall be paid such remuneration (by way of fee) for their services as may be determined by our directors in their absolute discretion. Our directors shall also be entitled to be repaid all travelling, hotel and other expenses of travelling to and from board meetings, committee meetings, general meetings, or otherwise incurred while engaged on our business.

Subject to the provisions of the Guernsey Companies Law, every director shall have the power to purchase and maintain insurance for or for the benefit of any persons who are or were at any time our directors, officers or employees (including any other company which is its holding company or in which we have any direct or indirect interest in) against any liability incurred by such persons in respect of any act or omission in the actual or purported execution and /or discharge of their duties or exercise or purported exercise of their powers in relation to or in connection with their duties, powers or offices in relation to us or any other such company or subsidiary.

Any director may at any time by writing appoint any person to be their alternate director and may in like manner at any time terminate such appointment.

The office of director shall, ipso facto, be vacated if such director:

- (a) resigns his office by writing under his hand and it is deposited at our registered office and we may agree to accept this at a later date than specified;
- (b) shall have absented themselves from meetings of the directors for six months in succession and all our other directors have resolved that such director should vacate their office;
- (c) becomes bankrupt, suspends payment or compounds with such director's creditors, or is adjudged insolvent or has his affairs declared en désastre;
- (d) dies;
- (e) becomes ineligible to act as a director under the Guernsey Companies Law;
- (f) is removed by resolution of our directors in writing signed by all of our other directors (being not less than two in number); or
- (g) if we shall by ordinary resolution declare that such person shall cease to be a director.

Indemnity

Our directors (including any alternate director), secretary and other officer or employee for the time being shall be indemnified out of the our assets to the fullest extent permitted by the Guernsey Companies Law from and against all actions, costs, charges, losses, damages and expenses in respect of which they may lawfully be indemnified which they or any of them shall or may incur or sustain by reason of any contract entered into or any act done, concurred in, or omitted, in or about the execution of their duty or supposed duty or in relation thereto.

Limitations on the Rights to Own Our Securities

We are not aware of any limitations on the rights to own our securities, including rights of non-resident or foreign shareholders to hold or exercise voting rights on our securities, imposed by foreign law or by our Articles.

General Meetings

An annual general meeting of ours shall be held in each calendar year (provided that no more than fifteen months may elapse between one annual general meeting and the next) at such time and place as may be determined by our directors.

Our directors may convene a general meeting whenever they think fit. General meetings shall also be convened by the directors within 21 days of a requisition by our shareholders as provided for by the Guernsey Companies Law.

Unless special notice is required in accordance with the Guernsey Companies Law, not less than fourteen days' notice in respect of all general meeting shall be given to all Shareholders (other than those who, under the provisions of the Articles or otherwise, are not entitled to receive notices from the Company).

Every notice shall specify the place, the date and the time of the meeting and the general nature of the business of the meeting. Any general meeting may be held in Guernsey, or elsewhere, as our directors may from time to time determine. There is no age limit at which a director is required to retire.

For the purpose of determining which persons are entitled to attend and vote at any general meeting and how many votes such persons may cast, the Company may specify in the relevant notice of general meeting a time, not more than forty eight hours (excluding any days which are not business days) before the time fixed for the meeting, by which a person must be entered on the register of members in order to have the right to attend and vote at the meeting.

No business shall be transacted unless the requisite quorum is present when the meeting proceeds to business. Two shareholders present in person or by proxy and entitled to vote shall be a quorum, save where we only have one shareholder.

If within half an hour from the time appointed for the general meeting a quorum is not present, if convened on the requisition of the shareholders the meeting shall be dissolved. In any other case the meeting shall be adjourned to the same day in the next week at the same time and place and no notice of such adjournment need be given. At any such adjourned meeting, those shareholders present in person or by proxy shall be a quorum. If no shareholders are present at the adjourned meeting, the meeting shall be dissolved.

Every question submitted to a general meeting shall be determined in the first instance by a show of hands of the shareholders present in person or by proxy or by attorney and entitled to vote, but a poll may be demanded by no fewer than five shareholders having the right to vote on the resolution, or one or more of the shareholders present in person or by proxy representing at least 10% of the total voting rights of all of the shareholders having the right to vote on the resolution.

Corporate representatives

Any corporation which is a shareholder may by resolution of its directors or other governing body authorize such person as it thinks fit to act as its representative at any meeting of ours or of any class of shareholders, and the person so authorized shall be entitled to exercise the same powers on behalf of the corporation which he represents as that corporation could exercise if it were an individual shareholder.

Borrowing Powers

Subject to the Articles and the Guernsey Companies Law, our board of directors may exercise all of the powers of the company to:

- (a) borrow money;
- (b) indemnify and guarantee;
- (c) mortgage or charge;
- (d) create and issue debentures and other securities; and
- (e) give security either outright or as collateral security for any debt, liability or obligation of the company or of any third party.

Uncertificated Shares

Subject to the Guernsey Companies Law, our board of directors may permit title to shares of any class to be issued or held otherwise than by a certificate and to be transferred by means of a "relevant system" (i.e., the CREST System) without a certificate.

Our board of directors may take such steps as it sees fit in relation to the evidencing of and transfer of title to uncertificated shares, any records relating to the holding of uncertificated shares and the conversion of uncertificated shares to certificated shares, or vice-versa.

Our board of directors may by notice to the holder of an uncertificated share, require that share to be converted into certificated form.

Our board of directors may take such other action that the board considers appropriate to achieve the sale, transfer, disposal, forfeiture, re-allotment or surrender of an uncertificated share or otherwise to enforce a lien in respect of it.

Winding up

Subject to any preferred, deferred or other special rights, or subject to such conditions or restrictions to which any shares in our capital may be issued, on a winding-up or other return of capital, the holders of our ordinary shares are entitled to share in any surplus assets *pro rata* to their holdings of such ordinary shares. A liquidator may, with the sanction of a special resolution of ours and any other sanction required by the Guernsey Companies Law, divide amongst our shareholders in specie or in kind the whole or any part of our assets (whether or not the assets shall consist of property of one kind or shall consist of property of different kinds), those assets to be set at such value as such liquidator deems fair. A liquidator may also vest the whole or any part of our assets in trustees on trusts for the benefit of the shareholders as the liquidator shall think fit.

Where the Company is proposed to be or is in the course of being wound up and the whole or part of its business or property is proposed to be transferred or sold to another company the liquidator may, with the sanction of an ordinary resolution, receive in compensation for the transfer or sale, shares, policies or other like interests in such other company for distribution among our shareholders or may enter into any other arrangement whereby our shareholders may, in lieu of receiving cash, shares, policies or other like interests, or in addition thereto, participate in the profits of or receive any other benefits from such company.

Issue of shares and share rights

Our directors may exercise the power of the company for an unlimited duration to issue an unlimited number of shares or grant rights to subscribe for, or to convert any security into shares.

We may issue shares which: (i) are redeemable shares; (ii) confer preferential rights to distribution of capital or income; (iii) do not entitle the holder to voting rights; and (iv) entitle the holder to restricted voting rights. Our directors may issue shares which have a nominal or par value, no par value, in any number they see fit and in fractions of a share. Subject to "Variation of Rights" above, we may convert all or any classes of our shares into redeemable shares.

Our directors may make arrangements on the issue of shares to distinguish between shareholders as to the amounts and the times of payments of calls on their shares and issue shares that provide for the payment of dividends and distributions in differing proportions.

Acquisition of own shares

Subject to the provisions of the Guernsey Companies Law and the rights of holders of any class of shares, we may purchase our own shares, including redeemable shares.

Liens, Calls on Shares and Forfeiture

In respect of any shares we issue that are not fully paid, we will have a first and paramount lien on every share (not being a fully paid share) for all moneys payable at a fixed time or called in respect of such share. Our board of directors may make calls upon shareholders for any amounts unpaid in respect of their shares, subject to the terms of allotment (whether in respect of nominal value or premium).

If a call remains unpaid after it has become due and payable, then, following notice by our board of directors requiring payment of the unpaid amount together with any accrued interest and expenses incurred, such share may be forfeited by a resolution of our board of directors.

A shareholder whose shares have been forfeited will cease to be a shareholder in respect of such share, but will, notwithstanding the forfeiture, remain liable to us for all moneys which at the date of forfeiture were presently payable together with interest. A forfeited share may be sold, re-allotted or otherwise disposed of as our board of directors sees fit.

Provisions that Would Delay, Defer or Prevent a Change of Control

There are no provisions in our Articles that would have the effect of delaying, deferring or preventing a change in control of us and that would operate only with respect to a merger, acquisition or corporate restructuring involving us or any of our subsidiaries.

Other Relevant Laws and Regulations

Mandatory Bid

The U.K. City Code on Takeovers and Mergers, or Takeover Code, applies to the company. Under the Takeover Code, where:

- (a) any person, together with persons acting in concert with them, acquires, whether by a series of transactions over a period of time or not, an interest in shares which (taken together with shares in which he is already interested, and in which persons acting in concert with them are interested) carry 30% or more of the voting rights of a company; or
- (b) any person who, together with persons acting in concert with them, is interested in shares which in the aggregate carry not less than 30% of the voting rights of a company but does not hold shares carrying more than 50% of such voting rights and such person, or any person acting in concert with them, acquires an interest in any other shares which increases the percentage of shares carrying voting rights in which he is interested, such person shall, except in limited circumstances, be obliged to extend offers, on the basis set out in Rules 9.3, 9.4 and 9.5 of the Takeover Code, to the holders of any class of equity share capital, whether voting or non-voting, and also to the holders of any other class of transferable securities carrying voting rights. Offers for different classes of equity share capital must be comparable; the U.K. Panel on Takeovers and Mergers, or Takeover Panel, should be consulted in advance in such cases.

An offer under Rule 9 of the Takeover Code must be in cash and at the highest price paid for any interest in the shares by the person required to make an offer or any person acting in concert with them during the 12 months prior to the announcement of the offer.

Under the Takeover Code, a “concert party” arises where persons acting together pursuant to an agreement or understanding (whether formal or informal and whether or not in writing) cooperate, through the acquisition by them of an interest in shares in a company, to obtain or consolidate control of the company. “Control” means holding, or aggregate holdings, of an interest in shares carrying 30% or more of the voting rights of the company, irrespective of whether the holding or holdings give *de facto* control.

Shareholder Notification and Disclosure Requirements

Shareholders are obliged to comply with the shareholding notification and disclosure requirements set out in Chapter 5 of the DTRs. As the company is classified as a “non-UK issuer” for the purposes of the DTRs, a shareholder is required pursuant to Rule 5 of the DTRs to notify the company if, as a result of an acquisition or disposal of shares or financial instruments, the shareholder’s percentage of voting rights of the company reaches, exceeds or falls below 5%, 10%, 15%, 20%, 25%, 30%, 50% and 75%.

The DTRs can be accessed and downloaded from the FCA’s website at <https://www.handbook.fca.org.uk/handbook/DTR/>.

Shareholders are urged to consider their notification and disclosure obligations carefully as a failure to make a required disclosure to the company may result in disenfranchisement.

Shareholder rights under Guernsey Law

The following is a summary of the rights of shareholders under the Guernsey Companies Law and other applicable laws in Guernsey. Prospective shareholders are advised that this is not a complete statement of the rights of Shareholders under applicable law in Guernsey or under the Articles.

(a) Company alterations

Under the Guernsey Companies Law, it is possible for a Guernsey company to merge with another Guernsey company or an overseas company with the approval by a special resolution of members, provided that there is a short form amalgamation process for amalgamations between a company and its wholly-owned subsidiary or between two or more wholly-owned subsidiaries of the same company which does not require a special resolution of the members of each company.

Under the Guernsey Companies Law, a compromise or arrangement is permitted between the company and its creditors or shareholders, or any class thereof, whether for the purpose of facilitating the company's reconstruction or its merger with another company, or otherwise. An application must be made to court which court will then order a meeting of the company's creditors or shareholders. It is necessary for 75% in value of the creditors or 75% of the voting rights of the shareholders, or class thereof, as the case may be, to agree to the compromise or arrangement and if such compromise or arrangement is sanctioned by the court, it will be binding on the creditors or shareholders, or class thereof, as appropriate.

The Guernsey Companies Law also requires the approval of the shareholders by special resolution for the removal of a company from the Guernsey Register of Companies for the purpose of becoming registered as a company under the law of a district, territory or place outside Guernsey.

Under the Guernsey Companies Law, amendments to a company's articles of incorporation so permitted may be authorized by way of a special resolution of the company's shareholders (provided that certain provisions within a company's articles of incorporation can be embedded with a higher voting threshold required for change).

(b) Rights of dissent and appraisal

The Guernsey Companies Law contains rights of dissent (the granting of which is discretionary on the part of the court), which are applicable where the company resolves to:

- (i) amalgamate with another corporation (other than vertical or horizontal short form amalgamations);
- (ii) transfer of its registration into another jurisdiction; or
- (iii) carry out a takeover transaction.

(c) Shareholder derivative actions

The laws of Guernsey permit derivative actions to be brought by a shareholder, or such person as the court directs who, in the discretion of the court, is a proper person to make an application to court to bring a derivative action. Under the laws of Guernsey, the complainant must obtain permission of the court to commence a derivative action.

(d) Sale of undertaking

The Companies Law does not contain provisions in relation to shareholder authority for the sale of a company's undertaking and, accordingly, the sale, lease or exchange of all or substantially all the property of the company will be governed by the articles of incorporation of a company.

(e) Unfair prejudice

A member of a company may apply to the court on the ground that the affairs of the company are conducted in a manner that is unfairly prejudicial to the interests of members generally or of some part of its members (including at least themselves), or an actual or proposed act or omission of the company is or would be so prejudicial.

If the court is satisfied that an application is well founded it may make such orders as it sees fit, which may include without limitation: (a) requiring the company to refrain from doing or continuing to do an act, or require it to do any act which the applicant has complained it has omitted to do; or (b) providing for the purchase of shares of any member of the company by other members of the company or by the company itself (and the reduction of the company's capital accordingly).

Differences in Corporate Law

As a non-cellular company limited by shares incorporated in Guernsey, we are governed by the Guernsey Companies Law. The applicable provisions of the Guernsey Companies Law differ from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of certain differences between the provisions of the Guernsey Companies Law applicable to us and the Delaware General Corporation Law relating to shareholders' rights and protections. This summary is not intended to be a complete discussion of the respective rights and it is qualified in its entirety by reference to the laws of Guernsey and Delaware law.

	Guernsey	Delaware
Shareholder Meetings	<ul style="list-style-type: none"> ● Unless a company's memorandum or articles of incorporation state otherwise, the directors are required to call a general meeting once the company receives requests to do so from shareholders who hold more than 10% of the capital of the company that carries the right of voting at general meetings (excluding any capital held as treasury shares). 	<ul style="list-style-type: none"> ● Shareholders generally do not have the right to call meetings of shareholders unless that right is granted in the certificate of incorporation or bylaws.
	<ul style="list-style-type: none"> ● Unless the shareholders pass a resolution exempting the company from holding an annual general meeting, a company must hold a general meeting of its members within a period of 18 months beginning on the date on which it was incorporated and thereafter at least once every calendar year (with no more than 15 months elapsing between one annual general meeting and the next). ● Subject to the articles of incorporation, a meeting may be held at any place in Guernsey or elsewhere. ● Notice: <ul style="list-style-type: none"> — A meeting must be called by at least 10 days' notice or such longer period as provided by the articles of incorporation. — A meeting may be called by shorter notice if all shareholders entitled to attend and vote so agree. — The notice shall specify the date, time and place of the meeting, the information of any resolutions to be passed at the meeting and such other information as is required by the articles of incorporation. 	<ul style="list-style-type: none"> ● May be held at such time or place as designated in the certificate of incorporation or the bylaws, or if not so designated, as determined by the board of directors ● May be held inside or outside Delaware ● Notice: <ul style="list-style-type: none"> — Whenever shareholders are required to take any action at a meeting, a written notice of the meeting shall be given which shall state the place, if any, date and hour of the meeting, and the means of remote communication, if any.
Shareholders' Voting Rights	<ul style="list-style-type: none"> ● Unless the memorandum or articles of incorporation provide otherwise, directors are appointed by ordinary resolution of the shareholders. ● Any shareholder may appoint another person or persons to be their proxy to exercise all or any of their rights to attend, speak and vote at a meeting. ● Subject to the articles of incorporation, the quorum shall be two shareholders holding 5% of the total voting rights of the company between them. ● Subject to certain limited exceptions, a provision of the articles of incorporation is void to the extent that it would have the effect of excluding or making ineffective a demand for a poll at general meeting. 	<ul style="list-style-type: none"> ● With limited exceptions, and unless the certificate of incorporation provides otherwise, shareholders may act by written consent to elect directors. ● Each stockholder entitled to vote may authorize another person or persons to act for such shareholder by proxy. ● The certificate of incorporation or bylaws may specify the number to constitute a quorum, but in no event shall a quorum consist of less than one-third of shares entitled to vote at a meeting. In the absence of such specifications, a majority of shares entitled to vote, present in person or represented by proxy, shall constitute a quorum. ● The certificate of incorporation may provide for cumulative voting.

	Guernsey	Delaware
Directors	<ul style="list-style-type: none"> • Subject to the articles of incorporation, the board of directors must consist of at least one director and is not subject to a maximum number of directors. • Subject to the articles of incorporation, the board of directors may determine the remuneration or other benefits given to a director. • A person will cease to be a director if such person: <ul style="list-style-type: none"> — provides written notice of their resignation to the company; — is removed in accordance with the memorandum and articles of incorporation; — becomes ineligible to be a director under the laws of Guernsey; — dies; or — otherwise vacates office in accordance with the memorandum and articles of incorporation. 	<ul style="list-style-type: none"> • The board of directors must consist of at least one director and is not subject to a maximum number of directors. • The number of directors shall be fixed by the bylaws, unless the certificate of incorporation fixes such number, in which case a change in the number shall be made only by amendment of the certificate of incorporation. • A classified board is permitted. • The board of directors has the authority to fix the compensation of directors, unless otherwise restricted by the certificate of incorporation or bylaws. • Removal <ul style="list-style-type: none"> — Any or all of the directors may be removed, with or without cause, by the holders of a majority of the shares entitled to vote unless the certificate of incorporation provides otherwise. — In the case of a classified board, shareholders may affect removal only for cause.
Interested Shareholders' Transactions	<ul style="list-style-type: none"> • The Guernsey Companies Law does not contain any specific prohibition on interested shareholder transactions. 	<ul style="list-style-type: none"> • The Delaware General Corporation Law contains a business combination statute applicable to corporations whereby, unless the corporation has specifically elected not to be governed by such statute, it is prohibited from engaging in certain business combinations with an "interested shareholder" for three years following the date that such shareholder becomes an interested shareholder. An interested shareholder generally is a person or a group that owns at least 15% of the corporation's outstanding voting stock.
Interested Director Transactions	<ul style="list-style-type: none"> • A director must, immediately after becoming aware of the fact that such director is interested in a transaction or proposed transaction with the company, disclose to the board the nature and extent of such director's interest. <p>Subject to the memorandum and articles of incorporation, a director who is interested in a transaction may vote, attend board meetings, sign documents and do any other thing in such director's capacity as a director in relation to a transaction in which such director is interested as if such director was not interested in the transaction provided that such director has made the necessary declarations.</p> <p>A transaction in which a director is interested is voidable by the company at any time within 3 months of the date after which the transaction is disclosed to the board unless:</p> <ul style="list-style-type: none"> — the director's interest was disclosed at the time the transaction was entered into or a disclosure was not required (for example, if the transaction is entered into in the ordinary course of business and on usual terms and conditions); — the transaction is ratified by the shareholders; or — the company received fair value for the transaction. 	<ul style="list-style-type: none"> • Interested director transactions are permissible and may not be legally voided if: <ul style="list-style-type: none"> — the material facts of the director's interest are disclosed and a majority of the disinterested directors approve the transaction; — the material facts of the director's interest are disclosed and a majority of the shareholders entitled to vote approve the transaction; or — the transaction is determined to have been fair to the corporation at the time it is authorized, approved or ratified by the board of directors, a committee thereof or the shareholders.

	Guernsey	Delaware
Dividends	<ul style="list-style-type: none"> • A company may pay a dividend if the board of directors is satisfied on reasonable grounds that the company will, immediately after payment of the dividend, satisfy the statutory solvency test contained in the Guernsey Companies Law as well as any other requirement of the memorandum or articles of incorporation. • A dividend may be of such amount, be paid at such time and be paid to such members as the board of directors thinks fit; <i>provided</i> that the directors must not authorize a dividend in respect of some but not all of the shares in a class or that is of a greater value per share in respect of some shares of a class than in respect of other shares of that class. • Subject to the articles of incorporation, there is no requirement for dividends to be paid out of a particular account or source. 	<ul style="list-style-type: none"> • The board of directors may declare and pay dividends, subject to any restrictions contained in the certificate of incorporation, upon the shares of the corporation's capital stock either: out of its surplus or, in case there is no surplus, out of its net profits for the fiscal year in which the dividend is declared or the preceding fiscal year.
Variation of Rights of Class of Shares	<ul style="list-style-type: none"> • A company may only vary the rights of a class of shareholders in accordance with the provisions of the articles of incorporation or, in the absence of such provisions, with the consent in writing from the holders of at least 75% in value of the issued shares of that class or by means of a special resolution passed by at least 75% in value of the issued shares of that class at a separate meeting of shareholders of that class. 	<ul style="list-style-type: none"> • A corporation may vary the rights of a class of shares with the approval of a majority of the outstanding shares of such class, unless the certificate of incorporation provides otherwise.
Mergers and Similar Arrangements	<p>Subject to the articles of incorporation, a merger, consolidation, sale, lease or transfer of all or substantially all of the assets of a company may be negotiated and approved by the board of directors. Depending on the structure of such a transaction, a separate shareholder approval may be required.</p> <p>If, within a period of four months after the date of an offer being made in respect of a transfer of shares, the offer is approved or accepted by the shareholders comprising not less than 90% in value of the shares affected, the offeree may, within two months immediately after the last day on which the offer can be approved or accepted, give notice to any dissenting shareholders of its desire to acquire the remaining shares. On the expiration of one month from the date of the notice to acquire, the offeror will be entitled to acquire the shares of the dissenting shareholder(s) by sending them a copy of the notice to acquire and by paying or transferring to them the consideration that such shareholder(s) are entitled to in respect of those shares, at which point the offeror shall be registered as the holder of those shares.</p>	<ul style="list-style-type: none"> • Under the Delaware General Corporation Law, with certain exceptions, a merger, consolidation, sale, lease or transfer of all or substantially all of the assets of a corporation must be approved by the board of directors and a majority of the outstanding shares entitled to vote thereon. • The Delaware General Corporation Law also provides that a parent corporation may, by resolution of its board of directors, merge with any subsidiary of which it owns at least 90% of each class of capital stock without a vote by the shareholders of such subsidiary.
Appraisal Rights	<ul style="list-style-type: none"> • The Guernsey Companies Law does not specifically provide for any appraisal rights of shareholders. The Guernsey Companies Law does, however, give the courts of Guernsey broad authority in respect of orders made pursuant to successful unfair prejudice claims under the Guernsey Companies Law. 	<ul style="list-style-type: none"> • A shareholder of a corporation participating in certain major transactions may, under certain circumstances, be entitled to appraisal rights under which the shareholder may receive cash in the amount of the fair value of the shares held by such shareholder in lieu of the transaction consideration.

	Guernsey	Delaware
Shareholder Suits	<ul style="list-style-type: none"> ● A shareholder may commence or continue a claim as a representative of those with the same interests in the claim. Unless the court directs otherwise, any judgment in which a party is acting as a representative will be binding on all persons represented. ● Derivative actions are also available to shareholders in respect of a cause of action arising from an actual or proposed act or omission involving: negligence, default, breach of duty and/or breach of trust by a director of the company. ● Costs are awarded by the court at its discretion. The normal order is for the winning party to recover its costs incurred in connection the action. 	<ul style="list-style-type: none"> ● Class actions and derivative actions generally are available to shareholders for, among other things, breach of fiduciary duty, corporate waste, and actions not taken in accordance with applicable law. In such actions, the court has discretion to permit the winning party to recover attorneys' fees incurred in connection with such action.
Limitations on Directors' Liability and Indemnification of Directors and Officers	<ul style="list-style-type: none"> ● A company may include in its articles of incorporation provisions limiting the liability of its directors (and officers or other persons); however, any provision that purports to exempt a director from any liability in connection with any negligence, default, breach of duty or breach of trust in relation to the company is void. ● Any provision by which a company directly or indirectly provides an indemnity for a director of the company, or any associated company, against any liability in connection with any negligence, default, breach of duty or breach of trust is void, except that: <ul style="list-style-type: none"> — a company is not prevented from purchasing and maintaining for a director of the company, or any associated company, insurance against any such liability; and — such restriction does not apply to a qualifying third-party indemnity provision, which is a provision for indemnity against liability incurred by a director to a person other than the company or an associated company that does not provide any indemnity against a prescribed list of liabilities, including certain fines and penalties and liabilities incurred in defending certain proceedings. 	<ul style="list-style-type: none"> ● A corporation may include in its certificate of incorporation provisions limiting the personal liability of its directors to the corporation or its shareholders for monetary damages for certain breaches of fiduciary duty. However, such provisions may not limit liability for any breach of the duty of loyalty, acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law, the authorization of unlawful dividends, stock purchases, or redemptions, or any transaction from which a director derived an improper personal benefit. ● A corporation may indemnify a director or officer of the corporation against expenses, judgments, fines and amounts paid in settlement actually and reasonably incurred in defense of any action, suit or proceeding by reason of such person's position if (i) the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and (ii) with respect to any criminal action or proceeding, the person had no reasonable cause to believe the conduct was unlawful.

Directors' Fiduciary Duties

Guernsey

● The duties of directors in Guernsey are generally owed to the company and its shareholders as a whole rather than to any other person or particular shareholders (subject to certain exceptions) and arise from customary laws, statutory laws and contractual obligations.

● Customary law duties of directors include:

— a duty to act in good faith, in the best interests of the company, and not for any collateral purpose;

— a duty to exercise powers for a proper purpose. Even if a director is acting in good faith and in the best interests of the company, such director must nevertheless use their powers for the proper purpose for which they were conferred;

— a duty to avoid and mitigate conflicts of interest; and

— a duty to account for profits. As a fiduciary, a director may not take a personal profit from opportunities arising from such director's office, even if the director is acting honestly and in the best interests of the company. Any such profit must be paid to the company. A director's entitlement to remuneration and payment of expenses will be governed by the company's articles of incorporation.

● Statutory duties of directors include:

— a general duty to manage the business and affairs of the company; and

— the directors are responsible for considering a solvency test in various circumstances, including in authorizing distributions by the company to its shareholders.

Delaware

● Directors of a Delaware corporation have a fiduciary duty to the corporation and its shareholders. This duty has two components: the duty of care and the duty of loyalty.

— The duty of care requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform themselves of, and disclose to shareholders, all material information reasonably available regarding a significant transaction.

— The duty of loyalty requires that a director act in a manner he or she reasonably believes to be in the best interests of the corporation. He or she must not use their corporate position for personal gain or advantage. This duty prohibits self-dealing by a director and mandates that the best interest of the corporation and its shareholders take precedence over any interest possessed by a director, officer or controlling shareholder and not shared by the shareholders generally.

● In general, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Should such evidence be presented concerning a transaction by a director, such director must prove the procedural fairness of the transaction, and that the transaction was of fair value to the corporation.

	Guernsey	Delaware
Inspection of Books and Records	<ul style="list-style-type: none"> • The register and index of members, register of directors, register of secretaries and copies of all resolutions of shareholders passed other than at general meetings and minutes of the proceedings of general meetings, in each case, in the last six years, must be open for the inspection by any shareholder of the company without charge during ordinary business hours. They must also be open to inspection by any other person upon payment of such fee as may be prescribed by the Guernsey Committee for Economic Development or such lesser fee as the company may request. • When a company receives a request to inspect its records, the company must comply with that request or apply to the Guernsey courts for a direction not to comply. 	<ul style="list-style-type: none"> • All shareholders have the right, upon written demand, to inspect or obtain copies of the corporation's shares ledger and its other books and records for any purpose reasonably related to such person's interest as a shareholder.
Amendments of Governing Documents	<ul style="list-style-type: none"> • Subject to certain exceptions, such as the alteration of the statement of the company's name, a company may only make or alter a provision of its memorandum of incorporation in accordance with the terms of the memorandum of incorporation or by unanimous resolution of all of its shareholders. • A company may alter its articles of incorporation by means of a special resolution passed by at least 75% of the shareholders. 	<p>Amendments to the certificate of incorporation require the affirmative vote of the holders of a majority of the outstanding shares entitled to vote thereon, unless the certificate of incorporation provides otherwise. Bylaws may be amended with the approval of a majority of the outstanding shares entitled to vote and may, if provided in the certificate of incorporation, also be amended by the board of directors.</p>
Dissolution and Winding Up	<ul style="list-style-type: none"> • A company may be dissolved by means of a compulsory or voluntary winding up or a compulsory or voluntary striking off. • An application for voluntary winding up requires a special resolution of the members passed by a majority of at least 75%. • An application for the voluntary striking off of a company must be made by the board of directors and be accompanied by a declaration of compliance confirming that all requirements of Guernsey law with respect to the striking off have been complied with. 	<p>Unless the board of directors approves the proposal to dissolve, dissolution must be approved by all of the shareholders. Only if the dissolution is initiated by the board of directors may it be approved by a simple majority of the corporation's outstanding shares.</p>

Other Guernsey Law Considerations

Registered Shares

We are required by the Guernsey Companies Law to keep a register of our shareholders. Under the laws of Guernsey, the ordinary shares are deemed to be issued when the name of the shareholder is entered in our share register. The share register therefore is prima facie evidence of the identity of our shareholders, and the shares that they hold. The share register generally provides limited, or no, information regarding the ultimate beneficial owners of our ordinary shares. Our share register is maintained by our registrar, Computershare Investor Services (Guernsey) Limited.

Potential future holders of our ADSs will not be treated as one of our shareholders and their names will therefore not be entered in our share register. The depositary, the custodian or their nominees will be the holder of the shares underlying our ADSs. Potential future holders of our ADSs have a right to receive the ordinary shares underlying their ADSs. For discussion on our ADSs and ADS holder rights, see “Description of the American Depositary Shares” in this prospectus.

We will perform all procedures necessary to update the share register to reflect any ordinary shares being sold in any potential offering, including updating the share register with the number of ordinary shares to be issued to the depositary upon the closing of any such offering in the future. We also are required by the Guernsey Companies Law to register a transfer of shares (or give the transferee notice of and reasons for refusal as the transferee may reasonably request) as soon as practicable and in any event within two months of receiving notice of the transfer.

We, any of our shareholders, or any other affected person may apply to the court for rectification of the share register if:

- the name of any person, without sufficient cause, is entered in or omitted from our register of members; or
- default is made or unnecessary delay takes place in entering on the register the fact of any person having ceased to be a member or on which we have a lien, provided that such delay does not prevent dealings in the shares taking place on an open and proper basis.

A shareholder may transfer all or any of his shares (i) in the case of certificated shares by transfer in writing in any usual or common form or in any other form acceptable to the Directors; and (ii) in the case of uncertificated shares, in the manner provided for in the rules and procedures of the operator of the relevant system and in accordance with and subject to the CREST Regulations.

The instrument of transfer of a certified share shall be signed by or on behalf of the transferor and, if the share is not fully paid, by or on behalf of the transferee.

The Board may, in its absolute discretion and without assigning any reason, decline to register any transfer of certificated share or uncertificated shares unless it is:

- (a) in respect of a share which is fully paid up;
- (b) in respect of a share in which the Company has no lien;
- (c) in respect of only one class of share;
- (d) in favor of a single transferee or not more than four joint transferees; and
- (e) in relation to a certificated share, delivered for registration to the registered office of the Company (or such other place as the Board may from time to time determine) accompanied by the relevant share certificate(s) and such other evidence as the Board may reasonably require to prove the right of the transferor to make the transfer.

The Board shall not refuse to register any transfer or renunciation of partly paid shares which are listed on the Main Market of the London Stock Exchange on the grounds that they are partly paid shares in circumstances where that refusal would prevent dealings in any such shares from taking place on an open and proper basis

Distributions and Dividends

(a) Subject to the Guernsey Companies Law, our directors may authorize dividends and distributions to be paid to shareholders. If any share is issued on terms providing that it shall rank for dividend or distribution as from a particular date, such share shall rank for dividend or distribution accordingly.

(b) Our directors may direct that any dividend or distribution shall be satisfied wholly or partly by the distribution of assets, and in particular of paid-up shares, debentures, or other securities of any other company.

(c) No dividend or distribution payable shall bear interest against us.

(d) A transfer of shares shall not pass the right to any dividend or distribution declared thereon before the registration of the transfer.

(e) Unless otherwise directed, any dividend or distribution may be paid by way of electronic transfer in such manner as agreed between the shareholder and us or by cheque or warrant sent through the post to the registered address of such shareholder entitled thereto, or in the case of joint holders to that one whose name stands first on our register of members in respect of the joint holding.

(f) All dividends or distribution unclaimed for a period of one year from the date on which such dividend or distribution was declared may be invested or otherwise made use of by our directors for our benefit until claimed.

(g) All dividends or distribution unclaimed for a period of six years from the date on which such dividend or distribution was declared shall, if our directors so resolve, be forfeited and shall revert to us.

(h) Subject to the Guernsey Companies Law or in the terms of issue of any share in our capital, for the purposes of making any distribution or paying any dividend, our directors may determine that those persons who are entered on the register of members at the close of business on a day determined by our directors shall be the persons who are entitled to receive such dividends or distributions.

Limitation on Owning Securities

Our Articles do not restrict in any way the ownership or voting of our shares by non-residents.

Purchase of Own Shares

Our Articles, a summary of which is provided above, do not prohibit us from purchasing our own shares.

Our Articles do not have conditions governing changes to our capital which are more stringent than those required by law.

Shareholder Rights

Certain rights granted under the Guernsey Companies Law, including the right to requisition a general meeting or require a resolution to be put to shareholders at the annual general meeting, are only available to our members. For Guernsey law purposes, our members are the persons who are registered as the owners of the legal title to the shares and whose names are recorded in our register of members. In the case of shares held in a settlement system operated by the Depository Trust Company, or DTC, the registered member will be DTC's nominee, Cede & Co. If a person who holds their ADSs in DTC wishes to exercise certain of the rights granted under the Guernsey Companies Law, they may be required to first take steps to withdraw their ADSs from the settlement system operated by DTC and become the registered holder of the shares in our register of members. A withdrawal of shares from DTC may have tax implications, for additional information on the potential tax implications of withdrawing your shares from the settlement system operated by DTC, see "Material Tax Considerations—Guernsey Taxation."

Exchange Controls and Other Limitations Affecting Security Holders

Under Guernsey law, there are currently no restrictions on the export or import of capital, including foreign exchange controls or restrictions that affect the remittance of dividends, interest or other payments to nonresidents holders of our ordinary shares.

Enforcement of Civil Liabilities

U.S. laws do not necessarily extend either to us or our officers or directors. We are incorporated under the laws of Guernsey. Some of our directors and officers reside outside of the United States. Substantially all of the assets of both us and our directors and officers are located outside the United States. As a result, it may not be possible for investors to effect service of process on either us or our officers and directors within the United States, or to enforce against these persons or us, either inside or outside the United States, a judgment obtained in a U.S. court predicated upon the civil liability provisions of the federal securities or other laws of the United States or any State in the United States.

We have appointed OKYO Pharma US, Inc., as our agent to receive service of process with respect to any action brought against us in the United States under the federal securities laws of the United States or of the laws of any state of the United States.

A judgment of a U.S. court is not directly enforceable in Guernsey, but constitutes a cause of action which may be enforced by Guernsey courts provided that:

- the applicable U.S. courts had jurisdiction over the case, as recognized under Guernsey law;
- the judgment is given on the merits and is final, conclusive and non-appealable;
- the judgment relates to the payment of a sum of money, not being taxes, fines or similar governmental penalties;
- the defendant is not immune under the principles of public international law;
- the same matters at issue in the case were not previously the subject of a judgment or disposition in a separate court;
- the judgment was not obtained by fraud; and
- the recognition and enforcement of the judgment is not contrary to public policy in Guernsey.

Guernsey courts award compensation for the loss or damage actually sustained by the plaintiff. Although punitive damages are generally unknown to the Guernsey legal system, there is no prohibition on them either by statute or customary law. Whether a particular judgment may be deemed contrary to Guernsey public policy depends on the facts of each case, though judgments found to be exorbitant, unconscionable, or excessive will generally be deemed as contrary to public policy. Moreover, certain defendants may qualify for protection under Protection of Trading Interests Act 1980, an act of the UK extended to Guernsey by the Protection of Trading Interests Act 1980 (Guernsey) Order, 1983. This Act provides that a qualifying defendant is not liable for multiple damages, in excess of that required for actual compensation. A "qualifying defendant" for these purposes is a citizen of the UK and its Colonies (as defined in the Act), a corporation or other limited liability entity organized under the laws of the UK, Guernsey or other territory for whose international relations the UK is responsible or a person conducting business in Guernsey.

Guernsey courts cannot enter into the merits of the foreign judgment and cannot act as a court of appeal or review over the foreign courts. It is doubtful that an original action based on U.S. federal or state securities laws could be brought before Guernsey courts. In addition, a plaintiff who is not resident in Guernsey may be required to provide a security bond in advance to cover the potential of the expected costs of any case initiated in Guernsey. In addition, Clarivate has been further advised by our legal counsel in Guernsey that it is uncertain as to whether the courts of Guernsey would entertain original actions or enforce judgments from U.S. courts against us or our officers and directors which originated from actions alleging civil liability under U.S. federal or state securities laws.

DESCRIPTION OF THE AMERICAN DEPOSITARY SHARES

JPMorgan Chase Bank, N.A., or JPMorgan, as depositary, will issue the ADSs. Each ADS will represent an ownership interest a designated number of ordinary shares which we will deposit with the custodian, as agent of the depositary, under the deposit agreement among ourselves, the depositary and yourself as an ADR holder. In the future, each ADS will also represent any securities, cash or other property deposited with the depositary but which they have not distributed directly to you. Unless certificated ADRs are specifically requested by you, all ADSs will be issued on the books of our depositary in book-entry form and periodic statements will be mailed to you which reflect your ownership interest in such ADSs. In our description, references to American depositary receipts, or ADRs, shall include the statements you will receive which reflect your ownership of ADSs.

The depositary's office is located at 383 Madison Avenue, Floor 11, New York, NY 10179.

You may hold ADSs either directly or indirectly through your broker or other financial institution. If you hold ADSs directly, by having an ADS registered in your name on the books of the depositary, you are an ADR holder. This description assumes you hold your ADSs directly. If you hold the ADSs through your broker or financial institution nominee, you must rely on the procedures of such broker or financial institution to assert the rights of an ADR holder described in this section. You should consult with your broker or financial institution to find out what those procedures are.

As an ADR holder, we will not treat you as a shareholder of ours and you will not have any shareholder rights. The laws of Guernsey governs shareholder rights. Because the depositary or its nominee will be the shareholder of record for the ordinary shares represented by all outstanding ADSs, shareholder rights rest with such record holder. Your rights are those of an ADR holder. Such rights derive from the terms of the deposit agreement to be entered into among us, the depositary and all registered holders from time to time of ADRs issued under the deposit agreement. The obligations of our company, the depositary and its agents are also set out in the deposit agreement. Because the depositary or its nominee will actually be the registered owner of the ordinary shares, you must rely on it to exercise the rights of a shareholder on your behalf. The deposit agreement and the ADSs are governed by New York law. Under the deposit agreement, as an ADR holder, you agree that any legal suit, action or proceeding against or involving us or the depositary, arising out of or based upon the deposit agreement, the ADSs or the transactions contemplated thereby, may only be instituted in a state or federal court in New York, New York, and you irrevocably waive any objection which you may have to the laying of venue of any such proceeding and irrevocably submit to the exclusive jurisdiction of such courts in any such suit, action or proceeding.

The following is a summary of what we believe to be the material terms of the deposit agreement. Notwithstanding this, because it is a summary, it may not contain all the information that you may otherwise deem important. For more complete information, you should read the entire deposit agreement and the form of ADR which contains the terms of your ADSs. You can read a copy of the deposit agreement which is filed as an exhibit to the registration statement of which this prospectus forms a part. You may also obtain a copy of the deposit agreement at the SEC's Public Reference Room which is located at 100 F Street, NE, Washington, DC 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-732-0330. You may also find the registration statement and the attached deposit agreement on the SEC's website at www.sec.gov.

Share Dividends and Other Distributions

How will I receive dividends and other distributions on the ordinary shares underlying my ADSs?

We may make various types of distributions with respect to our securities. The depositary has agreed that, to the extent practicable, it will pay to you the cash dividends or other distributions it or the custodian receives on ordinary shares or other deposited securities, after converting any cash received into U.S. dollars (if it determines such conversion may be made on a reasonable basis) and, in all cases, making any necessary deductions provided for in the deposit agreement. The depositary may utilize a division, branch or affiliate of JPMorgan to direct, manage and/or execute any public and/or private sale of securities under the deposit agreement. Such division, branch and/or affiliate may charge the depositary a fee in connection with such sales, which fee is considered an expense of the depositary. You will receive these distributions in proportion to the number of underlying securities that your ADSs represent.

Except as stated below, the depositary will deliver such distributions to ADR holders in proportion to their interests in the following manner:

- *Cash.* The depositary will distribute any U.S. dollars available to it resulting from a cash dividend or other cash distribution or the net proceeds of sales of any other distribution or portion thereof (to the extent applicable), on an averaged or other practicable basis, subject to (i) appropriate adjustments for taxes withheld, (ii) such distribution being impermissible or impracticable with respect to certain registered ADR holders, and (iii) deduction of the depositary's and/or its agents' expenses in (1) converting any foreign currency to U.S. dollars to the extent that it determines that such conversion may be made on a reasonable basis, (2) transferring foreign currency or U.S. dollars to the United States by such means as the depositary may determine to the extent that it determines that such transfer may be made on a reasonable basis, (3) obtaining any approval or license of any governmental authority required for such conversion or transfer, which is obtainable at a reasonable cost and within a reasonable time and (4) making any sale by public or private means in any commercially reasonable manner. *If exchange rates fluctuate during a time when the depositary cannot convert a foreign currency, you may lose some or all of the value of the distribution.*
- *Ordinary Shares.* In the case of a distribution in ordinary shares, the depositary will issue additional ADRs to evidence the number of ADSs representing such ordinary shares. Only whole ADSs will be issued. Any ordinary shares which would result in fractional ADSs will be sold and the net proceeds will be distributed in the same manner as cash to the ADR holders entitled thereto.
- *Rights to receive additional ordinary shares.* In the case of a distribution of rights to subscribe for additional ordinary shares or other rights, if we timely provide evidence satisfactory to the depositary that it may lawfully distribute such rights, the depositary will distribute warrants or other instruments in the discretion of the depositary representing rights to acquire additional ADRs. However, if we do not timely furnish such evidence, the depositary may:

(i) sell such rights if practicable and distribute the net proceeds in the same manner as cash to the ADR holders entitled thereto; or

(ii) if it is not practicable to sell such rights by reason of the non-transferability of the rights, limited markets therefor, their short duration or otherwise, do nothing and allow such rights to lapse, in which case ADR holders will receive nothing and the rights may lapse.

- *Other Distributions.* In the case of a distribution of securities or property other than those described above, the depositary may either (i) distribute such securities or property in any manner it deems equitable and practicable or (ii) to the extent the depositary deems distribution of such securities or property not to be equitable and practicable, sell such securities or property and distribute any net proceeds in the same way it distributes cash.
- *Elective Distributions.* In the case of a dividend payable at the election of our shareholders in cash or in additional ordinary shares, we will notify the depositary at least 30 days prior to the proposed distribution stating whether or not we wish such elective distribution to be made available to ADR holders. The depositary shall make such elective distribution available to ADR holders only if (i) we shall have timely requested that the elective distribution is available to ADR holders, (ii) the depositary shall have determined that such distribution is reasonably practicable and (iii) the depositary shall have received satisfactory documentation within the terms of the deposit agreement including any legal opinions of counsel that the depositary in its reasonable discretion may request. If the above conditions are not satisfied, the depositary shall, to the extent permitted by law, distribute to the ADR holders, on the basis of the same determination as is made in the local market in respect of the ordinary shares for which no election is made, either (x) cash or (y) additional ADSs representing such additional ordinary shares. If the above conditions are satisfied, the depositary shall establish procedures to enable ADR holders to elect the receipt of the proposed dividend in cash or in additional ADSs. There can be no assurance that ADR holders generally, or any ADR holder in particular, will be given the opportunity to receive elective distributions on the same terms and conditions as the holders of ordinary shares.

If the depositary determines in its discretion that any distribution described above is not practicable with respect to any specific registered ADR holder, the depositary may choose any method of distribution that it deems practicable for such ADR holder, including the distribution of foreign currency, securities or property, or it may retain such items, without paying interest on or investing them, on behalf of the ADR holder as deposited securities, in which case the ADSs will also represent the retained items.

Any U.S. dollars will be distributed by checks drawn on a bank in the United States for whole dollars and cents. Fractional cents will be withheld without liability and dealt with by the depositary in accordance with its then current practices.

The depositary is not responsible if it fails to determine that any distribution or action is lawful or reasonably practicable.

There can be no assurance that the depositary will be able to convert any currency at a specified exchange rate or sell any property, rights, shares or other securities at a specified price, nor that any of such transactions can be completed within a specified time period. All purchases and sales of securities will be handled by the Depositary in accordance with its then current policies, which are currently set forth in the "Depositary Receipt Sale and Purchase of Security" section of www.adr.com/Investors/FindOutAboutDRs, the location and contents of which the Depositary shall be solely responsible for.

Deposit, withdrawal and Cancellation

How does the depositary issue ADSs?

The depositary will issue ADSs if you or your broker deposit ordinary shares or evidence of rights to receive ordinary shares with the custodian and pay the fees and expenses owing to the depositary in connection with such issuance. In the case of the ADSs to be issued under this prospectus, we will arrange with the Selling Shareholders named herein to deposit such ordinary shares.

Ordinary shares deposited in the future with the custodian must be accompanied by certain delivery documentation and shall, at the time of such deposit, be registered in the name of the depositary, the custodian or a nominee of either.

The custodian will hold all deposited ordinary shares (including those being deposited by or on our behalf in connection with this offering to which this prospectus relates) for the account and to the order of the depositary for the benefit of registered holders of ADRs, to the extent not prohibited by law. ADR holders thus have no direct ownership interest in the ordinary shares and only have such rights as are contained in the deposit agreement. The custodian will also hold any additional securities, property and cash received on or in substitution for the deposited ordinary shares. The deposited ordinary shares and any such additional items are referred to as "deposited securities."

Upon each deposit of ordinary shares, receipt of related delivery documentation and compliance with the other provisions of the deposit agreement, including the payment of the fees and charges of the depositary and any taxes or other fees or charges owing, the depositary will issue an ADR or ADRs in the name or upon the order of the person entitled thereto evidencing the number of ADSs to which such person is entitled. All of the ADSs issued will, unless specifically requested to the contrary, be part of the depositary's direct registration system, and a registered holder will receive periodic statements from the depositary which will show the number of ADSs registered in such holder's name. An ADR holder can request that the ADSs not be held through the depositary's direct registration system and that a certificated ADR be issued.

How do ADR holders cancel an ADS and obtain deposited securities?

When you turn in your ADR certificate at the depositary's office, or when you provide proper instructions and documentation in the case of direct registration ADSs, the depositary will, upon payment of certain applicable fees, charges and taxes, deliver the underlying ordinary shares to you or upon your written order. Delivery of deposited securities in certificated form will be made at the custodian's office. At your risk, expense and request, the depositary may deliver deposited securities at such other place as you may request.

The depositary may only restrict the withdrawal of deposited securities in connection with:

- temporary delays caused by closing our transfer books or those of the depositary or the deposit of ordinary shares in connection with voting at a shareholders meeting, or the payment of dividends;
- the payment of fees, taxes and similar charges; or
- compliance with any U.S. or foreign laws or governmental regulations relating to the ADRs or to the withdrawal of deposited securities.

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

Record Dates

The depositary may, after consultation with us if practicable, fix record dates (which, to the extent applicable, shall be as near as practicable to any corresponding record dates set by us) for the determination of the registered ADR holders who will be entitled (or obligated, as the case may be):

- to receive any distribution on or in respect of deposited securities;
- to give instructions for the exercise of voting rights;
- to pay the fee assessed by the depositary for administration of the ADR program and for any expenses as provided for in the ADR;
- to receive any notice or to act in respect of other matters; or
- all subject to the provisions of the deposit agreement.

Voting Rights

How do I vote?

If you are an ADR holder and the depositary asks you to provide it with voting instructions, you may instruct the depositary how to exercise the voting rights for the ordinary shares which underlie your ADSs. Subject to the next sentence, as soon as practicable after receipt from us of notice of any meeting at which the holders of ordinary shares are entitled to vote, or of our solicitation of consents or proxies from holders of ordinary shares, the depositary shall fix the ADS record date in accordance with the provisions of the deposit agreement in respect of such meeting or solicitation of consent or proxy. The depositary shall, if we request in writing in a timely manner (the depositary having no obligation to take any further action if our request shall not have been received by the depositary at least 30 days prior to the date of such vote or meeting) and at our expense and provided no legal prohibitions exist, distribute to the registered ADR holders a notice stating such information as is contained in the voting materials received by the depositary, stating that that each registered holder of ADRs on the ADS record date will, subject to any applicable provisions of the laws of Guernsey, be entitled to instruct the depositary as to the exercise of any voting rights pertaining to ordinary shares underlying such holder's ADSs, and describing how you may instruct the depositary to exercise the voting rights for the ordinary shares which underlie your ADSs, including instructions for giving a discretionary proxy to a person designated by us. For instructions to be valid, the depositary must receive them in the manner and on or before the date specified. The depositary will try, as far as is practical, subject to the provisions of or governing the underlying ordinary shares or other deposited securities, to vote or cause to be voted the ordinary shares or other deposited securities as you instruct. The depositary will only vote or attempt to vote as you instruct. Holders are strongly encouraged to forward their voting instructions to the depositary as soon as possible. Voting instructions will not be deemed to be received until such time as the ADR department responsible for proxies and voting has received such instructions notwithstanding that such instructions may have been physically received by the depositary prior to such time. The depositary will not itself exercise any voting discretion. Furthermore, neither the depositary nor its agents are responsible for any failure to carry out any voting instructions, for the manner in which any vote is cast or for the effect of any vote. Notwithstanding anything contained in the deposit agreement or any ADR, the depositary may, to the extent not prohibited by law or regulations, or by the requirements of the stock exchange on which the ADSs are listed, in lieu of distribution of the materials provided to the depositary in connection with any meeting of, or solicitation of consents or proxies from, holders of deposited securities, distribute to the registered holders of ADRs a notice that provides such holders with, or otherwise publicizes to such holders, instructions on how to retrieve such materials or receive such materials upon request (*i.e.*, by reference to a website containing the materials for retrieval or a contact for requesting copies of the materials).

There is no guarantee that you will receive voting materials in time to instruct the depositary to vote and it is possible that you, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote.

Reports and Other Communications

Will ADR holders be able to view our reports?

The depositary will make available for inspection by ADR holders at the offices of the depositary and the custodian the deposit agreement, the provisions of or governing deposited securities, and any written communications from us which are both received by the custodian or its nominee as a holder of deposited securities and made generally available to the holders of deposited securities.

Additionally, if we make any written communications generally available to holders of our ordinary shares, and we furnish copies thereof (or English translations or summaries) to the depositary, it will distribute the same to registered ADR holders.

Fees and Expenses

What fees and expenses will I be responsible for paying?

The depositary may charge each person to whom ADSs are issued, including, without limitation, issuances against deposits of ordinary shares, issuances in respect of share distributions, rights and other distributions, issuances pursuant to a stock dividend or stock split declared by us or issuances pursuant to a merger, exchange of securities or any other transaction or event affecting the ADSs or deposited securities, and each person surrendering ADSs for withdrawal of deposited securities or whose ADSs are cancelled or reduced for any other reason, \$5.00 for each 100 ADSs (or any portion thereof) issued, delivered, reduced, cancelled or surrendered, as the case may be. The depositary may sell (by public or private sale) sufficient securities and property received in respect of a share distribution, rights and/or other distribution prior to such deposit to pay such charge.

The following additional charges shall be incurred by the ADR holders, by any party depositing or withdrawing ordinary shares or by any party surrendering ADSs and/or to whom ADSs are issued (including, without limitation, issuance pursuant to a stock dividend or stock split declared by us or an exchange of stock regarding the ADSs or the deposited securities or a distribution of ADSs), whichever is applicable:

- a fee of U.S.\$1.50 per ADR or ADRs for transfers of certificated or direct registration ADRs;
- a fee of up to U.S.\$0.05 per ADS for any cash distribution made pursuant to the deposit agreement;
- an aggregate fee of up to U.S.\$0.05 per ADS per calendar year (or portion thereof) for services performed by the depositary in administering the ADRs (which fee may be charged on a periodic basis during each calendar year and shall be assessed against holders of ADRs as of the record date or record dates set by the depositary during each calendar year and shall be payable in the manner described in the next succeeding provision);
- a fee for the reimbursement of such fees, charges and expenses as are incurred by the depositary and/or any of its agents (including, without limitation, the custodian and expenses incurred on behalf of holders in connection with compliance with foreign exchange control regulations or any law or regulation relating to foreign investment) in connection with the servicing of the ordinary shares or other deposited securities, the sale of securities (including, without limitation, deposited securities), the delivery of deposited securities or otherwise in connection with the depositary's or its custodian's compliance with applicable law, rule or regulation (which fees and charges shall be assessed on a proportionate basis against holders as of the record date or dates set by the depositary and shall be payable at the sole discretion of the depositary by billing such holders or by deducting such charge from one or more cash dividends or other cash distributions);

- a fee for the distribution of securities (or the sale of securities in connection with a distribution), such fee being in an amount equal to the \$0.05 per ADS issuance fee for the execution and delivery of ADSs which would have been charged as a result of the deposit of such securities (treating all such securities as if they were ordinary shares) but which securities or the net cash proceeds from the sale thereof are instead distributed by the depositary to those holders entitled thereto;
- stock transfer or other taxes and other governmental charges;
- SWIFT, cable, telex and facsimile transmission and delivery charges incurred at your request in connection with the deposit or delivery of ordinary shares, ADRs or deposited securities;
- transfer or registration fees for the registration or transfer of deposited securities on any applicable register in connection with the deposit or withdrawal of deposited securities;
- in connection with the conversion of foreign currency into U.S. dollars, JPMorgan shall deduct out of such foreign currency the fees, expenses and other charges charged by it and/or its agent (which may be a division, branch or affiliate) so appointed in connection with such conversion; and
- fees of any division, branch or affiliate of the depositary utilized by the depositary to direct, manage and/or execute any public and/or private sale of securities under the deposit agreement.

To facilitate the administration of various depositary receipt transactions, including disbursement of dividends or other cash distributions and other corporate actions, the depositary may engage the foreign exchange desk within JPMorgan Chase Bank, N.A., or the Bank, and/or its affiliates in order to enter into spot foreign exchange transactions to convert foreign currency into U.S. dollars. For certain currencies, foreign exchange transactions are entered into with the Bank or an affiliate, as the case may be, acting in a principal capacity. For other currencies, foreign exchange transactions are routed directly to and managed by an unaffiliated local custodian (or other third party local liquidity provider), and neither the Bank nor any of its affiliates is a party to such foreign exchange transactions. For further details see www.adr.com.

We will pay all other charges and expenses of the depositary and any agent of the depositary (except the custodian) pursuant to agreements from time to time between us and the depositary. The charges described above may be amended from time to time by agreement between us and the depositary. The right of the depositary to receive payment of fees, charges and expenses as provided above shall survive the termination of the deposit agreement.

The depositary may make available to us a set amount or a portion of the depositary fees charged in respect of the ADR program or otherwise upon such terms and conditions as we and the depositary may agree from time to time. The depositary collects its fees for issuance and cancellation 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 will generally set off the amounts owing from distributions made to holders of ADSs. If, however, no distribution exists and payment owing is not timely received by the depositary, the depositary may refuse to provide any further services to holders that have not paid those fees and expenses owing until such fees and expenses have been paid. At the discretion of the depositary, all fees and charges owing under the deposit agreement are due in advance and/or when declared owing by the depositary.

Payment of Taxes

If any taxes or other governmental charges (including any penalties and/or interest) shall become payable by or on behalf of the custodian or the depositary with respect to any ADR, any deposited securities represented by the ADSs evidenced thereby or any distribution thereon, such tax or other governmental charge shall be paid by the holder thereof to the depositary and by holding or having held an ADR the holder and all prior holders thereof, jointly and severally, agree to indemnify, defend and save harmless each of the depositary and its agents in respect thereof. If an ADR holder owes any tax or other governmental charge, the depositary may (i) deduct the amount thereof from any cash distributions, or (ii) sell deposited securities by public or private sale (after attempting by reasonable means to notify the ADR holder hereof prior to such sale) and deduct the amount owing from the net proceeds of such sale. In either case the ADR holder remains liable for any shortfall. If any tax or governmental charge is unpaid, the depositary may also refuse to affect any registration, registration of transfer, split-up or combination of deposited securities or withdrawal of deposited securities until such payment is made. If any tax or governmental charge is required to be withheld on any cash distribution, the depositary may deduct the amount required to be withheld from any cash distribution or, in the case of a non-cash distribution, sell the distributed property or securities (by public or private sale) in such amounts and in such manner as the depositary deems necessary and practicable to pay such taxes and distribute any remaining net proceeds or the balance of any such property after deduction of such taxes to the ADR holders entitled thereto.

By holding an ADR or an interest therein, you will be agreeing to indemnify us, the depositary, its custodian and any of our or their respective officers, directors, employees, agents and affiliates against, and hold each of them harmless from, any claims by any governmental authority with respect to taxes, additions to tax, penalties or interest arising out of any refund of taxes, reduced rate of withholding at source or other tax benefit obtained.

Reclassifications, Recapitalizations and Mergers

If we take certain actions that affect the deposited securities, including (i) any change in nominal value, split-up, consolidation, cancellation or other reclassification of deposited securities or (ii) any distributions of ordinary shares or other property not made to holders of ADRs or (iii) any recapitalization, reorganization, merger, consolidation, liquidation, receivership, bankruptcy or sale of all or substantially all of our assets, then the depositary may choose to, and shall if reasonably requested by us:

- (1) amend the form of ADR;
- (2) distribute additional or amended ADRs;
- (3) distribute cash, securities or other property it has received in connection with such actions;
- (4) sell any securities or property received and distribute the proceeds as cash; or
- (5) none of the above.

If the depositary does not choose any of the above options, any of the cash, securities or other property it receives will constitute part of the deposited securities and each ADS will then represent a proportionate interest in such property.

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 your consent for any reason. ADR holders must be given at least 30 days' notice of any amendment that imposes or increases any fees or charges (other than stock transfer or other taxes and other governmental charges, transfer or registration fees, SWIFT, cable, telex or facsimile transmission costs, delivery costs or other such expenses), or otherwise prejudices any substantial existing right of ADR holders. Such notice need not describe in detail the specific amendments effectuated thereby, however, it must identify to ADR holders a means to access the text of such amendment. If an ADR holder continues to hold an ADR or ADRs after being so notified, such ADR holder is deemed to agree to such amendment and to be bound by the deposit agreement as so amended. Any amendments or supplements which (i) are reasonably necessary (as agreed by us and the depositary) in order for (a) the ADSs to be registered on Form F-6 under the Securities Act or (b) the ADSs or ordinary shares to be traded solely in electronic book-entry form and (ii) do not in either such case impose or increase any fees or charges to be borne by ADR holders, shall be deemed not to prejudice any substantial rights of ADR holders. Notwithstanding the foregoing, if any governmental body or regulatory body should adopt new laws, rules or regulations which would require amendment or supplement of the deposit agreement or the form of ADR to ensure compliance therewith, we and the depositary may amend or supplement the deposit agreement and the ADR at any time in accordance with such changed laws, rules or regulations, which amendment or supplement may take effect before a notice is given or within any other period of time as required for compliance. No amendment, however, will impair your right to surrender your ADSs and receive the underlying securities, except in order to comply with mandatory provisions of applicable law.

How may the deposit agreement be terminated?

The depositary may, and shall at our written direction, terminate the deposit agreement and the ADRs by mailing notice of such termination to the registered holders of ADRs at least 30 days prior to the date fixed in such notice for such termination; provided, however, if the depositary shall have (i) resigned as depositary under the deposit agreement, notice of such termination by the depositary shall not be provided to registered holders unless a successor depositary shall not be operating under the deposit agreement within 60 days of the date of such resignation, and (ii) been removed as depositary under the deposit agreement, notice of such termination by the depositary shall not be provided to registered holders of ADRs unless a successor depositary shall not be operating under the deposit agreement on the 120th day after our notice of removal was first provided to the depositary. After termination, the depositary's only responsibility will be (i) to deliver deposited securities to ADR holders who surrender their ADRs, and (ii) to hold or sell distributions received on deposited securities. As soon as practicable after the expiration of six months from the termination date, the depositary will sell the deposited securities which remain and hold the net proceeds of such sales (as long as it may lawfully do so), without liability for interest, in trust for the ADR holders who have not yet surrendered their ADRs. After making such sale, the depositary shall have no obligations except to account for such proceeds and other cash.

Limitations on Obligations and Liability to ADR holders

Limits on our obligations and the obligations of the depositary; limits on liability to ADR holders and holders of ADSs

Prior to the issue, registration, registration of transfer, split-up, combination, or cancellation of any ADRs, or the delivery of any distribution in respect thereof, and from time to time in the case of the production of proofs as described below, we or the depositary or its custodian may require:

- payment with respect thereto of (i) any stock transfer or other tax or other governmental charge, (ii) any stock transfer or registration fees in effect for the registration of transfers of ordinary shares or other deposited securities upon any applicable register and (iii) any applicable fees and expenses described in the deposit agreement;
- the production of proof satisfactory to it of (i) the identity of any signatory and genuineness of any signature and (ii) such other information, including without limitation, information as to citizenship, residence, exchange control approval, beneficial ownership of any securities, compliance with applicable law, regulations, provisions of or governing deposited securities and terms of the deposit agreement and the ADRs, as it may deem necessary or proper; and
- compliance with such regulations as the depositary may establish consistent with the deposit agreement.

The issuance of ADRs, the acceptance of deposits of ordinary shares, the registration, registration of transfer, split-up or combination of ADRs or the withdrawal of ordinary shares, may be suspended, generally or in particular instances, when the ADR register or any register for deposited securities is closed or when any such action is deemed advisable by the depositary; provided that the ability to withdraw ordinary shares may only be limited under the following circumstances: (i) temporary delays caused by closing transfer books of the depositary or our transfer books or the deposit of ordinary shares in connection with voting at a shareholders meeting, or the payment of dividends, (ii) the payment of fees, taxes, and similar charges, and (iii) compliance with any laws or governmental regulations relating to ADRs or to the withdrawal of deposited securities.

The deposit agreement expressly limits the obligations and liability of the depositary, ourselves and each of our and the depositary's respective agents, provided, however, that no disclaimer of liability under the Securities Act or the Exchange Act, to the extent applicable, is intended by any provision of the deposit agreement. In the deposit agreement it provides that neither we nor the depositary nor any such agent will be liable to registered holders or beneficial owners of ADSs if:

- any present or future law, rule, regulation, fiat, order or decree of the United States, Guernsey, England and Wales or any other country or jurisdiction, or of any governmental or regulatory authority or securities exchange or market or automated quotation system, the provisions of or governing any deposited securities, any present or future provision of our charter, any act of God, war, terrorism, nationalization, expropriation, currency restrictions, work stoppage, strike, civil unrest, revolutions, rebellions, explosions, computer failure or circumstance beyond our, the depositary's or our respective agents' direct and immediate control shall prevent or delay, or shall cause any of them to be subject to any civil or criminal penalty in connection with, any act which the deposit agreement or the ADRs provide shall be done or performed by us, the depositary or our respective agents (including, without limitation, voting);
- it exercises or fails to exercise discretion under the deposit agreement or the ADRs including, without limitation, any failure to determine that any distribution or action may be lawful or reasonably practicable;
- it performs its obligations under the deposit agreement and ADRs without gross negligence or willful misconduct; or
- it takes any action or refrains from taking any action in reliance upon the advice of or information from legal counsel, accountants, any person presenting ordinary shares for deposit, any registered holder of ADRs, or any other person believed by it to be competent to give such advice or information.

We, the depositary and its agents may rely and shall be protected in acting upon any written notice, request, direction, instruction or document believed by them to be genuine and to have been signed, presented or given by the proper party or parties.

Neither the depositary nor its agents have any obligation to appear in, prosecute or defend any action, suit or other proceeding in respect of any deposited securities or the ADRs. We and our agents shall only be obligated to appear in, prosecute or defend any action, suit or other proceeding in respect of any deposited securities or the ADRs, which in our opinion may involve us in expense or liability, if indemnity satisfactory to us against all expense (including fees and disbursements of counsel) and liability is furnished as often as may be required. The depositary and its agents may fully respond to any and all demands or requests for information maintained by or on its behalf in connection with the deposit agreement, any registered holder or holders of ADRs, any ADRs or otherwise related to the deposit agreement or ADRs to the extent such information is requested or required by or pursuant to any lawful authority, including without limitation laws, rules, regulations, administrative or judicial process, banking, securities or other regulators. The depositary shall not be liable for the acts or omissions made by, or the insolvency of, any securities depository, clearing agency or settlement system. Furthermore, the depositary shall not be responsible for, and shall incur no liability in connection with or arising from, the insolvency of any custodian that is not a branch or affiliate of JPMorgan Chase Bank, N.A. Notwithstanding anything to the contrary contained in the deposit agreement or any ADRs, the depositary shall not be responsible for, and shall incur no liability in connection with or arising from, any act or omission to act on the part of the custodian except to the extent that any registered holder of ADRs has incurred liability directly as a result of the custodian having (i) committed fraud or willful misconduct in the provision of custodial services to the depositary or (ii) failed to use reasonable care in the provision of custodial services to the depositary as determined in accordance with the standards prevailing in the jurisdiction in which the custodian is located. The depositary shall not have any liability for the price received in connection with any sale of securities, the timing thereof or any delay in action or omission to act nor shall it be responsible for any error or delay in action, omission to act, default or negligence on the part of the party so retained in connection with any such sale or proposed sale.

The depositary has no obligation to inform ADR holders or other holders of an interest in any ADSs about the requirements of the laws of Guernsey, rules or regulations or any changes therein or thereto.

Neither the depositary nor its agents will be responsible for any failure to carry out any instructions to vote any of the deposited securities, for the manner in which any such vote is cast or for the effect of any such vote. The depositary may rely upon instructions from us or our counsel in respect of any approval or license required for any currency conversion, transfer or distribution. The depositary shall not incur any liability for the content of any information submitted to it by us or on our behalf for distribution to ADR holders or for any inaccuracy of any translation thereof, for any investment risk associated with acquiring an interest in the deposited securities, for the validity or worth of the deposited securities, for the credit-worthiness of any third party, for allowing any rights to lapse upon the terms of the deposit agreement or for the failure or timeliness of any notice from us. The depositary shall not be liable for any acts or omissions made by a successor depositary whether in connection with a previous act or omission of the depositary or in connection with any matter arising wholly after the removal or resignation of the depositary. Neither the depositary nor any of its agents shall be liable to registered holders or beneficial owners of interests in ADSs for any indirect, special, punitive or consequential damages (including, without limitation, legal fees and expenses) or lost profits, in each case of any form incurred by any person or entity, whether or not foreseeable and regardless of the type of action in which such a claim may be brought.

In the deposit agreement each party thereto (including, for avoidance of doubt, each holder and beneficial owner and/or holder of interests in ADRs) irrevocably waives, to the fullest extent permitted by applicable law, any right it may have to a trial by jury in any suit, action or proceeding against the depositary and/or us directly or indirectly arising out of or relating to the ordinary shares or other deposited securities, the ADSs or the ADRs, the deposit agreement or any transaction contemplated therein, or the breach thereof (whether based on contract, tort, common law or any other theory).

The depositary and its agents may own and deal in any class of securities of our company and our affiliates and in ADSs.

Disclosure of Interest in ADSs

To the extent that the provisions of or governing any deposited securities may require disclosure of or impose limits on beneficial or other ownership of deposited securities, other ordinary shares and other securities and may provide for blocking transfer, voting or other rights to enforce such disclosure or limits, you agree to comply with all such disclosure requirements and ownership limitations and to comply with any reasonable instructions we may provide in respect thereof. We reserve the right to instruct you to deliver your ADSs for cancellation and withdrawal of the deposited securities so as to permit us to deal with you directly as a holder of ordinary shares and, by holding an ADS or an interest therein, you will be agreeing to comply with such instructions.

Books of Depositary

The depositary or its agent will maintain a register for the registration, registration of transfer, combination and split-up of ADRs, which register shall include the depositary's direct registration system. Registered holders of ADRs may inspect such records at the depositary's office at all reasonable times, but solely for the purpose of communicating with other holders in the interest of the business of our company or a matter relating to the deposit agreement. Such register may be closed at any time or from time to time, when deemed expedient by the depositary.

The depositary will maintain facilities for the delivery and receipt of ADRs.

Pre-release of ADSs

In its capacity as depositary, the depositary shall not lend ordinary shares or ADSs; provided, however, that the depositary may (i) issue ADSs prior to the receipt of ordinary shares and (ii) deliver ordinary shares prior to the receipt of ADSs for withdrawal of deposited securities, including ADSs which were issued under (i) above but for which ordinary shares may not have been received, each such transaction a “pre-release.” The depositary may receive ADSs in lieu of ordinary shares under (i) above (which ADSs will promptly be canceled by the depositary upon receipt by the depositary) and receive ordinary shares in lieu of ADSs under (ii) above. Each such pre-release will be subject to a written agreement whereby the person/entity, or applicant to whom ADSs or ordinary shares are to be delivered (a) represents that at the time of the pre-release the applicant or its customer owns the ordinary shares or ADSs that are to be delivered by the applicant under such pre-release, (b) agrees to indicate the depositary as owner of such ordinary shares or ADSs in its records and to hold such ordinary shares or ADSs in trust for the depositary until such ordinary shares or ADSs are delivered to the depositary or the custodian, (c) unconditionally guarantees to deliver to the depositary or the custodian, as applicable, such ordinary shares or ADSs, and (d) agrees to any additional restrictions or requirements that the depositary deems appropriate. Each such pre-release will be at all times fully collateralized with cash, U.S. government securities or such other collateral as the depositary deems appropriate, terminable by the depositary on not more than five (5) business days’ notice and subject to such further indemnities and credit regulations as the depositary deems appropriate. The depositary will normally limit the number of ADSs and ordinary shares involved in such pre-release at any one time to 30% of the ADSs outstanding (without giving effect to ADSs outstanding under (i) above), provided, however, that the depositary reserves the right to change or disregard such limit from time to time as it deems appropriate. The depositary may also set limits with respect to the number of ADSs and ordinary shares involved in pre-release with any one person on a case-by-case basis as it deems appropriate. The depositary may retain for its own account any compensation received by it in conjunction with the foregoing. Collateral provided in connection with pre-release transactions, but not the earnings thereon, shall be held for the benefit of the ADR holders (other than the applicant).

Appointment

In the deposit agreement, each registered holder of ADRs and each person holding an interest in ADSs, upon acceptance of any ADSs (or any interest therein) issued in accordance with the terms and conditions of the deposit agreement will be deemed for all purposes to:

- be a party to and bound by the terms of the deposit agreement and the applicable ADR or ADRs; and
- appoint the depositary its attorney-in-fact, with full power to delegate, to act on its behalf and to take any and all actions contemplated in the deposit agreement and the applicable ADR or ADRs, to adopt any and all procedures necessary to comply with applicable laws and to take such action as the depositary in its sole discretion may deem necessary or appropriate to carry out the purposes of the deposit agreement and the applicable ADR and ADRs, the taking of such actions to be the conclusive determinant of the necessity and appropriateness thereof.

Governing Law

The deposit agreement and the ADRs shall be governed by and construed in accordance with the laws of the State of New York. In the deposit agreement, we have submitted to the jurisdiction of the courts of the State of New York and appointed OKYO Pharma US, Inc. as an agent for service of process on our behalf. Notwithstanding the foregoing, any action based on the deposit agreement or the transactions contemplated thereby may be instituted by the depositary in any competent court in Guernsey.

By holding an ADS or an interest therein, registered holders of ADRs and owners of ADSs each irrevocably agree that any legal suit, action or proceeding against or involving us or the depositary, arising out of or based upon the deposit agreement, the ADSs or the transactions contemplated thereby, may only be instituted in a state or federal court in New York, New York, and each irrevocably waives any objection which it may have to the laying of venue of any such proceeding, and irrevocably submits to the exclusive jurisdiction of such courts in any such suit, action or proceeding.

ORDINARY SHARES AND ADSs ELIGIBLE FOR FUTURE SALE

Prior to our initial public offering offering, no public market existed for our ADSs. Future sales of substantial amounts of ADSs in the public market, the availability of ADSs for future sale or the perception that such sales may occur, however, could adversely affect the market price of our ADSs and/or ordinary shares and also could adversely affect our future ability to raise capital through the sale of our ADSs and/or ordinary shares or other equity-related securities at times and prices we believe appropriate.

Based on the number of our ordinary shares outstanding as of March 10, 2023, upon the closing of the offering, we will have 4,132,092 ADSs outstanding, representing 268,585,980 ordinary shares, and 1,642,956,193 ordinary shares outstanding (including ordinary shares in the form of ADSs).

All of the ADSs sold in this offering will be freely tradable without restrictions or further registration under the Securities Act, except for any shares sold to our “affiliates,” as that term is defined under Rule 144 under the Securities Act. The outstanding ordinary shares held by existing shareholders are “restricted securities,” as that term is defined in Rule 144 under the Securities Act. Restricted securities may be sold in the public market only if the offer and sale is registered under the Securities Act or if the offer and sale of those securities qualifies for exemption from registration, including exemptions provided by Rules 144 or 701 promulgated under the Securities Act. Restricted securities may also be sold outside of the United States to non-U.S. persons in accordance with Rule 904 of Regulation S under the Securities Act.

Subject to the lock-up agreements described below and the provisions of Rule 144 or Regulation S under the Securities Act, as well as our insider trading policy, these restricted securities will be available for sale in the public market at various times beginning at least 135 days after the date of this prospectus.

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements for at least 90 days, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates, is entitled to sell such shares without complying with the manner of sale, volume limitation, or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares without complying with any of the requirements of Rule 144.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell upon expiration of the lock-up agreements described below, within any three-month period beginning 90 days after the date of this prospectus, a number of shares that does not exceed the greater of:

- 1% of the number of ADSs then outstanding, which will equal approximately shares immediately after this offering; or
- the average weekly trading volume of our ADSs during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to certain manner of sale provisions and notice requirements and to the availability of current public information about us.

Rule 701

Rule 701 generally allows a shareholder who was issued shares pursuant to a written compensatory plan or contract and who is not deemed to have been an affiliate of our company during the immediately preceding 90 days to sell these shares in reliance upon Rule 144, but without being required to comply with the public information, holding period, volume limitation or notice provisions of Rule 144. Rule 701 also permits affiliates of our company to sell their Rule 701 shares under Rule 144 without complying with the holding period requirements of Rule 144. All holders of Rule 701 shares, however, are required by that rule to wait until 90 days after the date of this prospectus before selling those shares pursuant to Rule 701.

Regulation S

Regulation S provides generally that sales made in offshore transactions are not subject to the registration or prospectus-delivery requirements of the Securities Act.

CERTAIN U.S. AND GUERNSEY TAX CONSIDERATIONS

Material U.S. Federal Income Tax Considerations for U.S. Holders

The following discussion describes the material U.S. federal income tax consequences relating to the ownership and disposition of our ADSs by U.S. Holders. This discussion applies to U.S. Holders that purchase our ADSs pursuant to this offering and hold such ADSs as capital assets for U.S. federal income tax purposes. This discussion is based on the Internal Revenue Code, U.S. Treasury regulations promulgated thereunder and administrative and judicial interpretations thereof, all as in effect on the date hereof and all of which are subject to change, possibly with retroactive effect. This discussion does not address all of the U.S. federal income tax consequences that may be relevant to specific U.S. Holders in light of their particular circumstances or to U.S. Holders subject to special treatment under U.S. federal income tax law (such as certain financial institutions, insurance companies, dealers or traders in securities or other persons that generally mark their securities to market for U.S. federal income tax purposes, tax-exempt entities or governmental organizations, retirement plans, regulated investment companies, real estate investment trusts, grantor trusts, brokers, dealers or traders in securities, commodities, currencies or notional principal contracts, certain former citizens or long-term residents of the United States, persons who hold our ADSs as part of a “straddle,” “hedge,” “conversion transaction,” “synthetic security” or integrated investment, persons that have a “functional currency” other than the U.S. dollar, persons who are subject to the tax accounting rules of Section 451(b) of the Internal Revenue Code, persons that own directly, indirectly or through attribution 10% or more (by vote or value) of our equity, corporations that accumulate earnings to avoid U.S. federal income tax, partnerships and other pass-through entities, and investors in such pass-through entities). This discussion does not address any U.S. state or local or non-U.S. tax consequences or any U.S. federal estate, gift or alternative minimum tax consequences. Except as discussed below, this discussion does not address U.S. federal income tax reporting obligations.

As used in this discussion, the term “U.S. Holder” means a beneficial owner of our ADSs that is, for U.S. federal income tax purposes, (1) an individual who is a citizen or resident of the United States, (2) a corporation (or entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof, or the District of Columbia, (3) an estate the income of which is subject to U.S. federal income tax regardless of its source or (4) a trust (x) with respect to which a court within the United States is able to exercise primary supervision over its administration and one or more United States persons have the authority to control all of its substantial decisions or (y) that has elected under applicable U.S. Treasury regulations to be treated as a domestic trust for U.S. federal income tax purposes.

If an entity treated as a partnership for U.S. federal income tax purposes holds our ADSs, the U.S. federal income tax consequences relating to an investment in such ADSs will generally depend upon the status and activities of such entity and the particular partner. Any such entity and a partner in any such entity should consult its own tax advisor regarding the U.S. federal income tax consequences applicable to it (and, as applicable, its partners) of the purchase, ownership and disposition of our ADSs.

We have not sought, nor will we seek, a ruling from the IRS with respect to the matters discussed below. There can be no assurance that the IRS will not take a different position concerning the tax consequences of the purchase, ownership or disposition of the ADSs or that any such position would not be sustained. Persons considering an investment in our ADSs should consult their own tax advisors as to the particular tax consequences applicable to them relating to the purchase, ownership and disposition of our ADSs, including the applicability of U.S. federal, state and local tax laws and non-U.S. tax laws.

Passive Foreign Investment Company Rules

In general, a corporation organized outside the United States will be treated as a PFIC for any taxable year in which either (1) at least 75% of its gross income is “passive income,” referred to as the PFIC income test, or (2) on average at least 50% of its assets, determined on a quarterly basis, are assets that produce passive income or are held for the production of passive income, referred to as the PFIC asset test. Passive income for this purpose generally includes, among other things, dividends, interest, royalties, rents, and gains from the sale or exchange of property that give rise to passive income. Assets that produce or are held for the production of passive income generally include cash, even if held as working capital or raised in a public offering, marketable securities, and other assets that may produce passive income. Generally, in determining whether a non-U.S. corporation is a PFIC, a proportionate share of the income and assets of each corporation in which it owns, directly or indirectly, at least a 25% interest (by value) is taken into account.

Although PFIC status is determined on an annual basis and generally cannot be determined until the end of the taxable year, based on the nature of our current and expected income and the current and expected value and composition of our assets, and while not free from doubt, we do not believe we were a PFIC for our 2020 tax year and we do not expect to be a PFIC for our current taxable year. Nevertheless, there can be no assurance that we will not be a PFIC in future taxable years. Furthermore, even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the IRS will agree with our conclusion and that the IRS would not successfully challenge our position. Because of the uncertainties involved in establishing our PFIC status, our U.S. counsel expresses no opinion regarding our PFIC status, and also expresses no opinion with respect to our predictions or past determinations regarding our PFIC status.

If we are a PFIC in any taxable year during which a U.S. Holder owns our ADSs, the U.S. Holder would be liable for additional taxes and interest charges under the “PFIC excess distribution regime” upon (1) a distribution paid during a taxable year that is greater than 125% of the average annual distributions paid in the three preceding taxable years, or, if shorter, the U.S. Holder’s holding period for our ADSs, and (2) any gain recognized on a sale, exchange or other disposition, including, under certain circumstances, a pledge, of our ADSs, whether or not we continue to be a PFIC. Under the PFIC excess distribution regime, the tax on such distribution or gain would be determined by allocating the distribution or gain ratably over the U.S. Holder’s holding period for our ADSs. The amount allocated to the current taxable year (*i.e.*, the year in which the distribution occurs, or the gain is recognized) and any year prior to the first taxable year in which we are a PFIC will be taxed as ordinary income earned in the current taxable year. The amount allocated to other taxable years will be taxed at the highest marginal rates in effect for individuals or corporations, as applicable, to ordinary income for each such taxable year, and an interest charge, generally applicable to underpayments of tax, will be added to the tax.

If we are a PFIC for any taxable year during which a U.S. Holder holds our ADSs and one of our non-United States subsidiaries is also a PFIC (*i.e.*, a lower-tier PFIC), such U.S. Holder would be treated as owning a proportionate amount (by value) of the shares of the lower-tier PFIC and would be taxed under the PFIC excess distribution regime on distributions by the lower-tier PFIC and on gain from the disposition of shares of the lower-tier PFIC even though such U.S. Holder would not receive the proceeds of those distributions or dispositions. Any of our non-United States subsidiaries that have elected to be disregarded as entities separate from us or as partnerships for U.S. federal income tax purposes would not be corporations under U.S. federal income tax law and accordingly, cannot be classified as lower-tier PFICs. However, a non-United States subsidiary that has not made the election may be classified as a lower-tier PFIC if we are a PFIC during your holding period and the subsidiary meets the PFIC income test or PFIC asset test.

If we are a PFIC, a U.S. Holder will not be subject to tax under the PFIC excess distribution regime on distributions or gain recognized on our ADSs if a valid “mark-to-market” election is made by the U.S. Holder for our ADSs. An electing U.S. Holder generally would take into account as ordinary income each year, the excess of the fair market value of our ADSs held at the end of such taxable year over the adjusted tax basis of such ADSs. The U.S. Holder would also take into account, as an ordinary loss each year, the excess of the adjusted tax basis of such ADSs over their fair market value at the end of the taxable year, but only to the extent of the excess of amounts previously included in income over ordinary losses deducted as a result of the mark-to-market election. The U.S. Holder’s tax basis in our ADSs would be adjusted annually to reflect any income or loss recognized as a result of the mark-to-market election. Any gain from a sale, exchange or other disposition of our ADSs in any taxable year in which we are a PFIC would be treated as ordinary income and any loss from such sale, exchange or other disposition would be treated first as ordinary loss (to the extent of any net mark-to-market gains previously included in income) and thereafter as capital loss. If, after having been a PFIC for a taxable year, we cease to be classified as a PFIC because we no longer meet the PFIC income or PFIC asset test, the U.S. Holder would not be required to take into account any latent gain or loss in the manner described above and any gain or loss recognized on the sale or exchange of the ADSs would be classified as a capital gain or loss.

A mark-to-market election is available to a U.S. Holder only for “marketable stock.” Generally, stock will be considered marketable stock if it is “regularly traded” on a “qualified exchange” within the meaning of applicable U.S. Treasury regulations. A class of stock is regularly traded during any calendar year during which such class of stock is traded, other than in de minimis quantities, on at least 15 days during each calendar quarter.

Our ADSs will be marketable stock as long as they remain listed on Nasdaq and are regularly traded. A mark-to-market election will not apply to the ADSs for any taxable year during which we are not a PFIC, but will remain in effect with respect to any subsequent taxable year in which we become a PFIC. Such election will not apply to any of our non-U.S. subsidiaries. Accordingly, a U.S. Holder may continue to be subject to tax under the PFIC excess distribution regime with respect to any lower-tier PFICs notwithstanding the U.S. Holder’s mark-to-market election for our ADSs.

The tax consequences that would apply if we were a PFIC would also be different from those described above if a U.S. Holder were able to make a valid QEF election. As we do not expect to provide U.S. Holders with the information necessary for a U.S. Holder to make a QEF election, prospective investors should assume that a QEF election will not be available.

The U.S. federal income tax rules relating to PFICs are very complex. Prospective U.S. investors are strongly urged to consult their own tax advisors with respect to the impact of our possible PFIC status on the purchase, ownership and disposition of our ADSs, the consequences to them of an investment in a PFIC, any elections available with respect to the ADSs and the IRS information reporting obligations with respect to the purchase, ownership and disposition of ADSs of a PFIC.

Distributions

Subject to the discussion above under “— Passive Foreign Investment Company Rules,” a U.S. Holder that receives a distribution with respect to our ADSs generally will be required to include the gross amount of such distribution in gross income as a dividend when actually or constructively received by the U.S. Holder to the extent of the U.S. Holder’s pro rata share of our current and/or accumulated earnings and profits (as determined under U.S. federal income tax principles). To the extent a distribution received by a U.S. Holder is not a dividend because it exceeds the U.S. Holder’s pro rata share of our current and accumulated earnings and profits, it will be treated first as a tax-free return of capital and reduce (but not below zero) the adjusted tax basis of the U.S. Holder’s ADSs. To the extent the distribution exceeds the adjusted tax basis of the U.S. Holder’s ADSs, the remainder will be taxed as capital gain. Because we may not account for our earnings and profits in accordance with U.S. federal income tax principles, U.S. Holders should expect all distributions to be reported to them as dividends.

Distributions on our ADSs that are treated as dividends generally will constitute income from sources outside the United States for foreign tax credit purposes and generally will constitute passive category income. The amount of any dividend income paid in a currency other than the U.S. dollar will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of actual or constructive receipt, regardless of whether the payment is in fact converted into U.S. dollars at that time. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. holder should not be required to recognize foreign currency gain or loss in respect of the dividend amount. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt.

Distributions paid on our ADSs will not be eligible for the “dividends received” deduction generally allowed to corporate shareholders with respect to dividends received from U.S. corporations under the Internal Revenue Code. Dividends paid by a “qualified foreign corporation” to non-corporate U.S. Holders are eligible for taxation at a reduced capital gains rate rather than the marginal tax rates generally applicable to ordinary income provided that a holding period requirement (more than 60 days of ownership, without protection from the risk of loss, during the 121-day period beginning 60 days before the ex-dividend date) and certain other requirements are met. Each U.S. Holder is advised to consult their tax advisors regarding the availability of the reduced tax rate on dividends to their particular circumstances. However, if we are a PFIC for the taxable year in which the dividend is paid or the preceding taxable year (see discussion above under “— Passive Foreign Investment Company Rules”), we will not be treated as a qualified foreign corporation, and therefore the reduced capital gains tax rate described above will not apply.

A non-United States corporation (other than a corporation that is classified as a PFIC for the taxable year in which the dividend is paid or the preceding taxable year) generally will be considered to be a qualified foreign corporation with respect to any dividend it pays on ADSs that are readily tradable on an established securities market in the United States.

The amount of any dividend income that is paid in Pounds Sterling will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of receipt, regardless of whether the payment is in fact converted into U.S. dollars. If the dividend is converted into U.S. dollars on the date of receipt (actual or constructive), a U.S. Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt (actual or constructive).

Sale, Exchange or Other Taxable Disposition of Our ADSs

Subject to the discussion above under “— Passive Foreign Investment Company Rules,” a U.S. Holder generally will recognize capital gain or loss for U.S. federal income tax purposes upon the sale, exchange or other disposition of our ADSs in an amount equal to the difference, if any, between the amount realized (*i.e.*, the amount of cash plus the fair market value of any property received) on the sale, exchange or other disposition and such U.S. Holder’s adjusted tax basis in the ADSs. Such capital gain or loss generally will be long-term capital gain taxable at a reduced rate for non-corporate U.S. Holders or long-term capital loss if, on the date of sale, exchange or other disposition, the ADSs were held by the U.S. Holder for more than one year. Any capital gain of a non-corporate U.S. Holder that is not long-term capital gain is taxed at ordinary income rates. The deductibility of capital losses is subject to limitations. Any gain or loss recognized from the sale or other disposition of our ADSs will generally be gain or loss from sources within the United States for U.S. foreign tax credit purposes.

Medicare Tax

Certain U.S. Holders that are individuals, estates or trusts and whose income exceeds certain thresholds generally are subject to a 3.8% tax on all or a portion of their net investment income, which may include their gross dividend income and net gains from the disposition of our ADSs. If you are a U.S. Holder that is an individual, estate or trust, you are encouraged to consult your tax advisors regarding the applicability of this Medicare tax to your income and gains in respect of your investment in our ADSs.

Information Reporting and Backup Withholding

U.S. Holders may be required to file certain U.S. information reporting returns with the IRS with respect to an investment in our ADSs, including, among others, IRS Form 8938 (Statement of Specified Foreign Financial Assets). In addition, each U.S. Holder who is a shareholder of a PFIC must file an annual report containing certain information. U.S. Holders paying more than \$100,000 for our ADSs may be required to file IRS Form 926 (Return by a U.S. Transferor of Property to a Foreign Corporation) reporting this payment. Substantial penalties and other adverse circumstances may be imposed upon a U.S. Holder that fails to comply with the required information reporting.

Dividends on and proceeds from the sale or other disposition of our ADSs generally have to be reported to the IRS unless the U.S. Holder establishes a basis for exemption. Backup withholding may apply to amounts subject to reporting if the holder (1) fails to provide an accurate U.S. taxpayer identification number or otherwise establish a basis for exemption, or (2) is described in certain other categories of persons. However, U.S. Holders that are corporations generally are excluded from these information reporting and backup withholding tax rules.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules generally will be allowed as a refund or a credit against a U.S. Holder’s U.S. federal income tax liability if the required information is furnished by the U.S. Holder on a timely basis to the IRS.

U.S. Holders should consult their own tax advisors regarding the backup withholding tax and information reporting rules.

EACH PROSPECTIVE INVESTOR IS URGED TO CONSULT ITS OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO IT OF AN INVESTMENT IN OUR ADSs IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES.

Guernsey Tax Considerations

The summary below is based on current Guernsey law and published practice in Guernsey as of the date hereof, both of which are subject to change, possibly with retrospective effect. This summary is intended as a general guide of certain Guernsey tax matters related to the holders of ordinary shares of the Company (“**Shareholders**”) only and is not, is not intended to be nor should it be construed to be, legal or tax advice or a summary of all tax matters in Guernsey.

Shareholders, whether corporations or individuals, that are not residents of Guernsey for tax purposes and who do not conduct business in Guernsey through a permanent establishment situated in Guernsey, will not be subject to Guernsey income or Guernsey withholding tax. Any distributions made by the Company to non-Guernsey tax resident Shareholders will not be subject to Guernsey income or Guernsey withholding tax.

Individual Shareholders who are residents of Guernsey for tax purposes will generally be subject to Guernsey income tax at the individual standard rate of 20% on distributions received from the Company.

Corporate Shareholders that are residents of Guernsey for tax purposes (and which do not have exempt company status under the Income Tax (Exempt Bodies) (Guernsey) Ordinance, 1989, as amended) will generally be subject to Guernsey income tax at the company standard rate, which is currently 0%, on distributions received from the Company.

Guernsey does not currently levy capital gains tax (with the exception of a dwellings profit tax) and, therefore, Shareholders will not suffer capital gains tax in Guernsey.

No stamp duty is chargeable in Guernsey on the issue, acquisition, transfer, conversion or redemption or other disposition of ordinary shares of the Company (provided that it does not hold Guernsey real property).

Guernsey has implemented through domestic legislation matters related to (i) the Foreign Account Tax Compliance Act, or FATCA, contained in the United States Internal Revenue Code of 1986 and the Treasury Regulations promulgated thereunder and (ii) the Organization for Economic Co-operation and Development’s regime known as the Common Reporting Standard, or CRS. Pursuant to FATCA and CRS, disclosure and reporting of information may be required, including disclosure of certain information about Shareholders, their ultimate beneficial owners and/or controllers and their investment in the Company. You should consult your tax advisers regarding the possible implications of FATCA, CRS and other similar regimes that may be relevant to your ownership and disposition of ordinary shares of the Company.

PLAN OF DISTRIBUTION

We are offering 3,503,665 ADSs at a public offering price of \$1.50 per ADS, without any investment bank, although we reserve the right to engage a broker dealer. We may engage a placement agent for this offering in the future. This offering will terminate 45 days from the date of this prospectus, unless the offering is fully subscribed before that date or we decide to terminate the offering prior to that date. In either event, the offering may be closed without further notice to you. Any and all funds for securities purchased in the offering will be transmitted directly to us for our immediate use.

This is a self-underwritten offering. This prospectus is part of a registration statement that permits our officers and directors to sell the ADS directly to the public with no commission or other remuneration payable to him for any ADSs that are sold by him. We may also engage registered broker-dealers to offer and sell ADSs (collectively, the "Placement Agents"). We may pay any such registered persons who make such sales a commission of up to a certain percentage of the aggregate purchase price of the ADSs sold by such Placement Agent in this offering and issue to the Placement Agent a warrant to purchase such number of ADSs in an amount not to exceed certain percentage of the number of ADSs sold by such Placement Agent in this offering, subject to the compliance with the maximum allowable fees under applicable, rules and regulations including the rules of the Financial Industry Regulatory Authority ("FINRA") and the foreign equivalent agencies where the Placement Agent is regulated. However, we have not entered into any underwriting or agent agreement, arrangement or understanding for the sale of the securities being offered pursuant to this prospectus. This offering is intended to be made solely by the delivery of this prospectus and the accompanying subscription agreements to prospective investors. Any Placement Agent engaged by us for this offering would only be compensated based on the aggregate purchase price of the ADSs sold by such Placement Agent in this offering.

This offering is intended to be made solely by the delivery of this prospectus and the accompanying subscription agreement to prospective investors. We may terminate this offering prior to the expiration date. Our officers and directors will sell the ADSs and intend to offer them to friends, family members and business acquaintances. In offering the securities on our behalf, our directors and officers will rely on the safe harbor from broker dealer registration set out in Rule 3a4-1 under the Securities Exchange Act of 1934, as amended.

Rule 3a4-1 sets forth those conditions under which a person associated with an Issuer may participate in the offering of the Issuer's securities and not be deemed to be a broker-dealer. Those conditions are as follows:

- a. Our officers and directors are not subject to a statutory disqualification, as that term is defined in Section 3(a)(39) of the Securities Exchange Act, at the time of their participation; and
- b. Our officers and directors will not be compensated in connection with their participation by the payment of commissions or other remuneration based either directly or indirectly on transactions in securities; and
- c. Our officers and directors are not, nor will they be at the time of their participation in the offering, an associated person of a broker-dealer; and
- d. Our officers and directors meet the conditions of paragraph (a)(4)(ii) of Rule 3a4-1 of the Securities Exchange Act of 1934, as amended, in that they (A) primarily perform, or intend primarily to perform at the end of the offering, substantial duties for or on behalf of our Company, other than in connection with transactions in securities; and (B) are not a broker or dealer, or been associated person of a broker or dealer, within the preceding twelve months; and (C) have not participated in selling and offering securities for any Issuer more than once every twelve months other than in reliance on Paragraphs (a)(4)(i) and (a)(4)(iii).

Our officers, directors, control persons and affiliates may purchase ADSs in this offering.

Investors interested in subscribing for the ADSs in this offering must complete and deliver to the Company a completed securities purchase agreement to the address provided in the securities purchase agreement. Upon receipt of the completed securities purchase agreement, the Company will inform the investor that it has accepted the subscription and send prompt notification of this acceptance if the Company decides to accept the subscription. Then the investor should deliver the purchase price for the number of ADSs being purchased by wire transfer in immediately available funds using the wire transfer instructions provided in the securities purchase agreement. Promptly following the receipt of purchase proceeds from the investor, the Company will notify its depository to either deliver the subscribed ADSs in a book entry form or in the investor's brokerage account as requested by the investor. All funds for subscriptions in the offering will be transmitted to the Company's bank account for immediate use by the Company. The Company shall not offer and sell fractional ADSs in this Offering.

We have not arranged to place the funds from investors in an escrow, trust or similar account. All funds for subscriptions in the offering will be transmitted to the Company's bank account for immediate use by the Company. As a result, upon execution of the securities purchase agreement by the subscriber and acceptance by the Company such subscription is irrevocable.

Any Placement Agent engaged by us will only be paid a commission and/or issued warrants based on the securities sold by such Placement Agent. Because there cannot be any assurance that the maximum offering amount will be sold in this offering or how much of the amount of the securities offered will be sold by any Placement Agents, the actual total offering commissions, if any, are not presently determinable and may be substantially less than the maximum amount set forth above.

Our obligations to issue and sell the ADSs to the purchasers is subject to the conditions set forth in the securities purchase agreement, which may be waived by us at our discretion. A purchaser's obligation to purchase the ADSs is subject to the conditions set forth in the securities purchase agreement as well, which may also be waived.

We estimate the total offering expenses in this offering that will be payable by us, excluding the placement agents' fees, if any, will be approximately \$250,000, which include legal, accounting, stock issuances and printing costs.

The foregoing does not purport to be a complete statement of the terms and conditions of any placement agent agreement we may enter into and the securities purchase agreement. A form of securities purchase agreement with investors is included as an exhibit to the Registration Statement of which this prospectus forms a part.

The Placement Agents may be deemed to be underwriters within the meaning of Section 2(a)(11) of the Securities Act, of 1933, as amended, and any commissions received by them and any profit realized on the resale of the securities sold by them while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. As underwriters, the Placement Agents would be required to comply with the Securities Act and the Securities Exchange Act of 1934, as amended, including without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the Placement Agents acting as principal. Under these rules and regulations, the Placement Agents:

- 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.

EXPENSES OF THIS OFFERING

We estimate that our expenses in connection with this offering will be as follows:

	Amount
SEC registration fee	\$ 1,322
FINRA Filing Fee	2,570
Printing and engraving expenses	10,000
Legal fees and expenses	178,000
Transfer agent and registrar fees and expenses	5,000
Accounting fees and expenses	46,800
Miscellaneous costs	6,308
Total	\$ 250,000

All amounts in the table are estimates except the SEC registration fee, the listing fee, and the FINRA filing fee. We will pay all of the expenses of this offering.

LEGAL MATTERS

Certain legal matters with respect to English law and Guernsey law in connection with the validity of our ordinary shares registered hereby will be passed upon for us by Orrick, Herrington & Sutcliffe (UK) LLP, United Kingdom and Carey Olsen (Guernsey) LLP, Bailiwick of Guernsey, respectively. Certain matters of U.S. federal law will be passed upon for us by Sheppard, Mullin, Richter & Hampton LLP, New York, New York.

EXPERTS

The consolidated financial statements of OKYO Pharma Limited as of March 31, 2022, and 2021 and for each of the years then ended, included in our Form 20-F annual report for the year ended March 31, 2022 and incorporated by reference in this prospectus have been audited by Mazars LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting. The registered business address of Mazars LLP is 30 Old Bailey, London EC4M 7AU, United Kingdom.

SERVICE OF PROCESS AND ENFORCEMENT OF LIABILITIES

We are incorporated and currently existing under the laws of Guernsey. In addition, certain of our directors and officers reside outside the United States, and most of the assets of our non-U.S. subsidiaries are located outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon OKYO or those persons or to enforce against OKYO or them, either inside or outside the United States, judgments obtained in U.S. courts, or to enforce in U.S. courts, judgments obtained against them in courts in jurisdictions outside the U.S., in any action predicated upon civil liability provisions of the federal securities laws of the United States. Both in original actions and in actions for the enforcement of judgments of U.S. courts, there is doubt as to whether civil liabilities predicated solely upon the U.S. federal securities laws are enforceable in Guernsey. See “Description of Share Capital and Memorandum and Articles of Incorporation—Enforcement of Civil Liabilities.”

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement (including amendments and exhibits to the registration statement) on Form F-1 under the Securities Act. This prospectus, which is part of the registration statement, does not contain all of the information in the registration statement and its exhibits. For further information with respect to us and the ADSs offered by this prospectus, we refer you to the registration statement and the exhibits and schedules to the registration statement. Statements contained in this prospectus as to the contents of any contract or any other document referred to are not necessarily complete, and in each instance, we refer you to the copy of the contract or other document filed as an exhibit to the registration statement. Each of these statements is qualified in all respects by the filed exhibits.

You may review a copy of the registration statement, including exhibits and any schedule filed therewith, and obtain copies of such materials at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet website (www.sec.gov) that contains reports, proxy and information statements and other information regarding issuers, like us, that file electronically with the SEC.

We are currently subject to the information reporting requirements of the Exchange Act applicable to FPIs. Accordingly, we will be required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K. Those reports may be inspected without charge at the locations described above. As an FPI, we will be exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act.

We also maintain a website at www.okyopharma.com contained in, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is an inactive textual reference.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

OKYO PHARMA LIMITED

Report of Independent Registered Public Accounting Firm PCAOB ID: 1401	F-2
Consolidated Balance Sheets	F-3
Consolidated Statements of Comprehensive Income	F-4
Consolidated Statements of Changes in Shareholders' Equity	F-5
Consolidated Statement of Cash Flows	F-6
Notes to Consolidated Financial Statements	F-7

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Shareholders and Board of Directors of OKYO Pharma Limited

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of OKYO Pharma Limited and its subsidiary (the Group) as of March 31, 2022 and 2021, together with the related consolidated statements of operations and comprehensive loss, consolidated statements of shareholders' equity, and consolidated statements of cash flows for each of the two years in the period ended March 31, 2022 and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Group as of March 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended March 31, 2022, in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Group will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the Group are pre-revenue, and its business model requires significant ongoing expenditure on research and development. The forecast prepared by management indicates that the current cash held will be exhausted by October 2022 without additional financing facilities in place. The Group is in the final stages of its Investigational New Drug (IND) application for OK101, due to be filed with the U.S. Food and Drug Administration (FDA) in mid-November 2022 after which there is a 30 day period for the FDA to raise questions or issue a clinical hold. On completion of the IND application process, management intends to raise sufficient funds to enable the Group to complete Phase II clinical trials for OK101. As management's forecasts indicate current cash held is not sufficient to complete the IND application process and cover working capital requirements until further funds are raised for the Phase II clinical trials, to meet the short-term need, the Group has secured a \$2 million short-term credit facility with a related party, Tiziana Life Sciences Limited, which must be repaid six months after the initial draw-down. After taking this facility into consideration the available cash position will be extended to approximately April 2023. If further funds for the Phase II clinical trials are not raised before then, to continue operating, the Group will need to raise additional funds sufficient to meet its ongoing working capital requirements as well as to repay the \$2 million short-term credit facility. These conditions raise substantial doubt about the Group's ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Group's management. Our responsibility is to express an opinion on these consolidated 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 Group in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB. The Group is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, 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 Group's internal control over financial reporting. Accordingly, we express no such opinion.

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 consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

Mazars LLP

We have served as the Group's auditor since 2019.

London, England

August 15, 2022

OKYO Pharma Limited
Consolidated Balance Sheets

	Six months ended September 30, 2022 (unaudited)	Year ended March 31, 2022	2021
	\$	\$	\$
ASSETS			
Current assets:			
Cash and cash equivalents	705,046	2,700,724	6,889,329
Related party receivables	-	-	27,664
Current taxation receivable	492,619	781,688	26,322
Other receivables	564,790	812,956	43,371
Total current assets	1,762,455	4,295,368	6,986,686
Property and Equipment, net	5,601	5,225	6,057
Right of use asset	-	-	98,579
Total non-current assets	5,601	5,225	104,636
Total assets	1,768,056	4,300,593	7,091,322
LIABILITIES AND SHAREHOLDERS' EQUITY			
Liabilities:			
Current liabilities:			
Trade and other payables	1,987,528	1,306,150	1,673,154
Related party payable	125,113	47,041	-
Lease liabilities - current	-	-	34,148
Total current liabilities	2,112,641	1,353,191	1,707,302
Lease liabilities - non current	-	-	64,612
Total liabilities	2,112,641	1,353,191	1,771,914
Shareholders' Equity:			
Share capital	125,830,402	123,976,510	111,629,173
Share options reserve	3,023,280	2,355,040	636,313
Warrants reserve	72,215	53,413	861,214
Convertible Loan Note reserve	-	-	8,370,836
Foreign currency translation reserve	(11,300,059)	(11,011,527)	(10,174,375)
Retained deficit	(117,970,423)	(112,426,034)	(106,003,753)
Total shareholders' equity	(344,585)	2,947,402	5,319,408
Total liabilities and shareholders' equity	1,768,056	4,300,593	7,091,322

OKYO Pharma Limited
Consolidated Statements of Operations and Comprehensive Loss

	Six months ended September 30,		Year ended March 31,	
	2021		2021	
	2022 (unaudited)	(unaudited)	2022	2021
	\$	\$	\$	\$
Operating expenses:				
Research and development	(2,607,675)	(479,700)	(1,301,178)	(173,821)
Operating Expenses	<u>(2,936,714)</u>	<u>(2,254,393)</u>	<u>(4,916,388)</u>	<u>(3,192,385)</u>
Total operating expenses	<u>(5,544,389)</u>	<u>(2,734,093)</u>	<u>(6,217,566)</u>	<u>(3,366,206)</u>
Other income/(expense):				
Finance Income	-	-	-	-
Finance (expense)	-	(1,021)	-	(1,123)
Impairment of loan	-	-	-	(11,172)
Loss from operations before income taxes	<u>(5,544,389)</u>	<u>(2,735,114)</u>	<u>(6,217,566)</u>	<u>(3,378,501)</u>
Income tax provision	-	188,761	786,521	24,994
Loss for the year	<u>(5,544,389)</u>	<u>(2,546,353)</u>	<u>(5,431,045)</u>	<u>(3,353,507)</u>
Other Comprehensive loss:				
Exchange differences on translating foreign operations	<u>(62,581)</u>	<u>37,845</u>	<u>(837,152)</u>	<u>346,365</u>
Comprehensive loss	<u>(5,606,970)</u>	<u>(2,508,508)</u>	<u>(6,268,197)</u>	<u>(3,007,142)</u>
Basic and diluted loss per share attributable to common shareholders	\$ (0.00)	\$ (0.00)	\$ (0.01)	\$ (0.01)

OKYO Pharma Limited
Consolidated Statements of Shareholders' Equity

	<u>No. of Shares</u>	<u>Share Capital</u> \$	<u>Options reserve</u> \$	<u>Warrant reserve</u> \$	<u>Convertible Loan Note reserve</u> \$	<u>Retained Deficit</u> \$	<u>Translation Reserve</u> \$	<u>Total Equity</u> \$
Balance at 31 March 2020	636,297,049	112,079,984	93,441	639,903	—	(102,432,702)	(10,520,740)	(140,114)
Issue of share capital	36,269,253	230,019	—	—	—	—	—	230,019
Options charge	—	—	550,138	—	—	—	—	550,138
Options exercised	250,000	15,870	(1,515)	—	—	1,515	—	15,870
Options forfeiture	—	—	(5,751)	—	—	—	—	(5,751)
Warrants charge	—	(138,305)	—	221,311	—	—	—	83,006
Convertible loan note issued	—	(558,395)	—	—	8,151,777	—	—	7,593,382
Convertible loan note interest	—	—	—	—	219,059	(219,059)	—	—
Total transactions	—	(450,811)	542,872	221,311	8,370,836	(217,544)	—	8,466,664
<u>Comprehensive income</u>								
Loss for the period	—	—	—	—	—	(3,353,507)	—	(3,353,507)
Currency translation	—	—	—	—	—	—	346,365	346,365
Total comprehensive income	—	—	—	—	—	(3,353,507)	346,365	(3,007,142)
Balance at 31 March 2021	672,816,302	111,629,173	636,313	861,214	8,370,836	(106,003,753)	(10,174,375)	5,319,408
Options charge	—	—	1,737,876	—	—	—	—	1,737,876
Options forfeiture	—	—	(19,149)	—	—	—	—	(19,149)
Warrants charge	—	—	—	61,721	—	—	—	61,721
Warrants Exercised	386,512,756	3,470,940	—	(2,010,030)	—	—	—	1,460,910
Convertible loan note conversion	315,086,410	8,876,397	—	—	(8,876,397)	—	—	—
Convertible loan note and warrant interest	—	—	—	546,318	444,918	(991,236)	—	—
Currency translation on Convertible Loan note conversion	—	—	—	—	654,833	—	—	654,833
Transfer between equity reserves	—	—	—	594,190	(594,190)	—	—	—
Total transactions	701,599,166	12,347,337	1,718,727	(807,801)	(8,370,836)	(991,236)	—	3,896,191
<u>Comprehensive income</u>								
Loss for the period	—	—	—	—	—	(5,431,045)	—	(5,431,045)
Currency translation	—	—	—	—	—	—	(837,152)	(837,152)
Total comprehensive income	—	—	—	—	—	(5,431,045)	(837,152)	(6,268,197)
Balance at 31 March 2022	1,374,415,468	123,976,510	2,355,040	53,413	—	(112,426,034)	(11,011,527)	2,947,402
Options charge	—	—	668,240	—	—	—	—	668,240
Warrants charge	—	—	—	18,802	—	—	—	18,802
Issue of shares (IPO Fundraise)	40,625,000	2,500,000	—	—	—	—	—	2,500,000
IPO Expenses	—	(646,108)	—	—	—	—	—	(646,108)
Total transactions	40,625,000	1,853,892	668,240	18,802	—	—	—	2,540,934
<u>Comprehensive income</u>								
Loss for the period	—	—	—	—	—	(5,544,389)	—	(5,544,389)
Currency translation	—	—	—	—	—	—	(288,532)	(288,532)
	—	—	—	—	—	(5,544,389)	(288,532)	(5,832,921)

Total comprehensive income								
Balance at 30 September 2022 (unaudited)	1,415,040,468	125,830,402	3,023,280	72,215	—	(117,970,423)	(11,300,059)	(344,585)
				F-5				

OKYO Pharma Limited
Consolidated Statements of Cash Flows

	Six months ended September 30,		Year ended March 31,	
	2022 (unaudited)	2021 (unaudited)	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES:				
Loss from operations before income taxes	\$ (5,544,389)	\$ (2,735,114)	\$ (6,217,566)	\$ (3,378,501)
Adjustments to reconcile net loss to net cash used in operating activities:				
Share option charge	668,240	831,903	1,737,876	550,138
Warrant charge	18,802	34,970	61,721	83,006
Forfeiture of options	-	(19,149)	(19,149)	(5,751)
Depreciation of fixed assets	1,524	1,079	2,331	1,510
Amortization of right of use asset	-	14,997	-	11,601
(Gain)/Loss on foreign exchange	(62,581)	(15,263)	(9,230)	4,056
Impairment of loan to West African Minerals Ltd	-	-	-	11,171
Gain on disposal of right of use asset	-	-	(179)	(818)
Net decrease/ (increase) in related party receivables	-	27,807	27,376	(3,862)
Net increase/(decrease) in related party payables	93,272	28,748	48,900	(46,311)
Net decrease/(increase) in operating assets/other receivables	135,291	(106,322)	(802,154)	208,931
Net increase/(decrease) in trade and other payables	964,037	(1,108,328)	(297,991)	886,093
Cash inflow from taxation	185,267	-	-	78,540
Net cash used in operating activities	(3,540,537)	(3,044,672)	(5,468,065)	(1,600,198)
CASH FLOWS FROM INVESTING ACTIVITIES				
Acquisition of property, plant and equipment	(2,699)	-	(1,669)	(6,943)
Loan to West African Minerals Ltd	-	-	-	(11,171)
Net cash used in investing activities	(2,699)	-	(1,669)	(18,114)
CASH FLOWS FROM FINANCING ACTIVITIES:				
Proceeds from issuance of ordinary shares	2,500,000	-	-	230,019
Proceeds from issuance of convertible loan notes	-	-	-	7,593,380
Proceeds from options exercised	-	-	-	15,870
Proceeds from warrants exercised	-	1,460,910	2,153,270	-
Repayment of leasing liabilities	-	(14,575)	-	(12,331)
Fundraising costs	(646,108)	-	-	-
Net cash provided by financing activities	1,853,892	1,446,335	2,153,270	7,826,938
Net (decrease)/increase in cash and cash equivalents	(1,689,344)	(1,598,337)	(3,316,464)	6,208,627
Cash and cash equivalent, beginning of period	2,700,724	6,889,329	6,889,329	235,485
Exchange difference	(306,334)	(106,844)	(872,141)	445,217
Cash and cash equivalent, end of period	705,046	5,184,149	2,700,724	6,889,329

1. Reporting Entity

OKYO Pharma Limited (the “Company” or “OKYO”) is a company domiciled in Guernsey and listed with a standard listing on the main market of the London Stock Exchange (LSE) and on the NASDAQ Capital Market (LSE: OKYO, NASDAQ: OKYO).

The Company is developing next-generation therapeutics to improve the lives of patients with inflammatory eye diseases and chronic pain. Our goal is to develop first in class drug candidates that prevent the disease instead of controlling it, and we achieve this through our collaboration with pioneer scientists in the field.

The ultimate parent of the group is Panetta Partners Limited, incorporated in the British Virgin Islands.

2. ACCOUNTING POLICIES

The principal accounting policies applied in the preparation of these consolidated financial statements are set out below. These policies have been applied consistently to all the years presented unless otherwise stated.

Basis of preparation

The consolidated financial statements of the Group and Company have been prepared in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB), IFRIC interpretations and the Companies (Guernsey) Law 2008 as applicable to companies reporting under IFRS.

Basis of measurement

Going Concern

The Group has experienced net losses and significant cash outflows from cash used in operating activities over the past years, and as of March 31, 2022, had an accumulated deficit of £76.8m (£64m of this accumulated loss relates to a discontinued business prior to the reorganization in 2018), a net loss for the year ended March 31, 2022, of £4.0m and net cash used in operating activities of £4.0m.

The Directors have prepared cash flow projections that include the costs associated with the continued clinical trials and additional investment to fund that operation. On the basis of those projections, the directors conclude that the company will not be able to meet its liabilities as they fall due within the next 12 months from the date when these financial statements are issued. The cash balance as at 1 August 2022 is approximately £1.5m, with current liabilities of £978k. The cash burn rate until from the beginning of August to the end of December 2022 is projected at £2.4m, and the company projects that without additional financing facilities it will run out of cash in October 2022. Consequently, in the opinion of the directors there is a material uncertainty that may cause significant doubt about the Group’s ability to continue as a going concern.

The Directors are however aware, through their own extensive experience in the sector, that this position is not uncommon in the context of a pre-revenue life sciences company principally involved in cash consuming research and development activity. The Directors took strategic advantage of the opportunity to dual list the Company on NASDAQ in May 2022 in order to be able to access potential liquidity in the US, which is generally a more favorable environment for life sciences companies to raise money and where there are more specialist investors focused on early-stage opportunities. The Directors are also confident that the nature of the OK101 clinical program is such that various inflection points arise over a relatively short period of time which should provide financing opportunities, for example the FDA approval of the IND in December 2022 for OK101 in dry-eye and the return of headline data from the Phase II registration trial to be held between July and December 2023; these pivotal events in the primary clinical program for OK101 have the benefit of being near term events (which is unusual in the context of the normal timeframes for Phase II clinical programs to deliver meaningful data points. The Directors have also consulted the Company’s investment bankers with a view to planning a number of alternative financing strategies to ensure the Company has access to sufficient capital to finance its planned research and development activity in the coming 18 months.

To meet the Company’s short-term liquidity needs, the Company has secured a \$2m short-term credit facility with a related party in order to bridge any delays in the occurrence of the anticipated clinical milestones for the OK-101 program. The loan is available for a period of 6 months upon first draw-down and carries an interest rate of 16% per annum, with additional default interest of 4% if the loan is not repaid after the 6-month period. The loan will extend the Company’s fixed cost cash burn to April 2023 without the need to raise additional funds. The Directors believe that this facility together with additional working capital management measures will be sufficient to complete the IND application. The Directors also considered any risks to the short-term cash position of the company such as delay in IND filing, and they identified that the risk would be highly unlikely and could be managed within the current cash resources and the additional financing strategies already disclosed.

On completion of the IND application the company will be in a position to raise funds on the market, via the financing strategies being discussed with the Company's investment bankers. The necessary steps are being taken to affect such a fundraise.

Until and unless the Group and Company secures sufficient investment to fund their clinical pipeline, there is a significant doubt on the Group and Company's ability to continue as a going concern, and therefore, that it may be unable to realize its assets and discharge its liabilities in the normal course of business. Despite this significant doubt, the Directors conclude that it is appropriate to continue to adopt the going concern basis of accounting as the Directors are confident, based on the previous fund-raising history as well as additional measures already put in place and being planned, that sufficient funds will be forthcoming and accordingly they have prepared these financial statements on a going concern basis.

New and Revised Standards

Standards in effect in 2022

There are no new IFRS standards, amendments to standards or interpretations that are mandatory for the financial year beginning on April 1, 2021 and April 1, 2022, that are relevant to the Group or that have had any material impact in the year to March 31, 2022 or the six months to September 30, 2022. New standards, amendments to standards and interpretations that are not yet effective, have been deemed by the Group as currently not relevant, and not likely to have a material impact on the Group, and hence are not listed here.

Basis of consolidation

Subsidiary undertakings are all entities over which the Group exercises control. The Group has control when it can demonstrate all of the following: (a) power over the investee; (b) exposure, or rights, to variable returns from its involvement with the investee; and (c) the ability to use its power over the investee to affect the amount of the investor's return.

The existence and effect of both current voting rights and potential voting rights that are currently exercisable or convertible are considered when assessing whether control of an entity is exercised. Subsidiaries are consolidated from the date at which the Group obtains control and are de-consolidated from the date at which control ceases.

Inter-company transactions, balances and unrealized gains on transactions between group companies are eliminated upon consolidation. Unrealized losses are also eliminated. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group.

Segment reporting

Operating segments are reported in a manner consistent with the internal reporting provided to the Board. The Board allocates resources to and assess the performance of the segments. The Board considers there to be only one operating segment being the research and development of biotechnological and pharmaceutical products.

Taxation

The tax credit for the year represents the total of current taxation and deferred taxation. The credit in respect of current taxation is based on the estimated taxable loss for the year. Taxable profit or loss for the year is based on the profit or loss as shown in the statement of comprehensive income, as adjusted for items of income or expenditure which are not deductible or chargeable for tax purposes. The current tax asset for the year is calculated using tax rates which have either been enacted or substantively enacted at the balance sheet date.

Deferred tax is provided in full, using the liability method, on temporary differences arising between the tax bases of assets and liabilities and their carrying amounts in the consolidated financial statements. Deferred tax is determined using tax rates (and laws) that have been enacted or substantially enacted by the balance sheet date and expected to apply when the related deferred tax is realised, or the deferred liability is settled. Deferred tax assets are recognized to the extent that it is probable that the future taxable profit will be available against which the temporary differences can be utilized.

Research and Development tax credits are provided for in the year that the costs are incurred. These are estimated based on eligible research and development expenditure. Any difference rebated are recognized when the cash is received from the UK tax authorities.

Foreign currency translation

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates (the functional currency), which is Pounds sterling.

The consolidated financial statements are presented in US dollars, which is the Group's presentation currency.

Foreign currency transactions are translated into the functional currency using exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of foreign currency transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in the income statement.

The financial statements of overseas subsidiary undertakings are translated into US dollars on the following basis:

- Assets and liabilities at the rate of exchange ruling at the year-end date.
- Profit and loss account items at the average rate of exchange for the year.

Exchange differences arising from the translation of the net investment in foreign entities, borrowings and other currency instruments designated as hedges of such investments, are taken to equity (and recognized in the statement of comprehensive income) on consolidation.

License fees

Payments related to the acquisition of rights to a product or technology are capitalized as intangible assets if it is probable that future economic benefits from the asset will flow to the Group and the cost of the asset can be reliably measured.

Payments made which provide the right to perform research are carefully evaluated to determine whether such payments are to fund research or acquire an asset. License fees expenses are recognized as incurred.

Research and development

All on-going research and development expenditure is currently expensed in the period in which it is incurred. Due to the regulatory environment inherent in the development of the Group's products, the criteria for development costs to be recognized as an asset, as set out in IAS 38 'Intangible Assets', are not met until a product has been granted regulatory approval and it is probable that future economic benefit will flow to the Group. The Group currently has no such qualifying expenditure.

Financial instruments

The Group classifies a financial instrument, or its component parts, as a financial liability, a financial asset or an equity instrument in accordance with the substance of the contractual arrangement and the definitions of a financial liability, a financial asset and an equity instrument.

The Group evaluates the terms of the financial instrument to determine whether it contains an asset, a liability or an equity component. Such components shall be classified separately as financial assets, financial liabilities or equity instruments.

A financial instrument is any contract that gives rise to a financial asset of one entity and a financial liability or equity instrument of another entity.

(a) Financial assets, initial recognition and measurement and subsequent measurement

At initial recognition financial assets are measured at their fair value. Subsequent measurement depends on their classification. Financial assets such as receivables, cash and cash equivalents and deposits are subsequently measured at amortized cost using the effective interest method, less loss allowance.

The Group does not hold any financial assets at fair value through profit or loss or fair value through other comprehensive income.

The Group does not hold any financial assets at fair value through profit or loss or fair value through other comprehensive income.

(b) Financial liabilities, initial recognition and measurement and subsequent measurement

At initial recognition, financial liabilities are measured at their fair value minus, if appropriate, any transaction costs that are directly attributable to the issue of the financial liability. All financial liabilities are subsequently measured at amortized cost using the effective interest method. Interest expense and foreign exchange gains and losses are recognized in profit or loss. Any gain or loss on derecognition is also recognized in profit or loss.

The Group's financial liabilities include trade and other payables.

Cash and cash equivalents

Cash and cash equivalents comprise cash on hand.

Impairment

Impairment of financial assets measured at amortized cost

At each reporting date the Group recognizes a loss allowance for expected credit losses on financial assets measured at amortized cost.

In establishing the appropriate amount of loss allowance to be recognized, the Group applies either the general approach or the simplified approach, depending on the nature of the underlying group of financial assets.

General approach

The general approach is applied to the impairment assessment of refundable lease deposits and other refundable lease contributions, restricted cash and cash and cash equivalents.

Under the general approach the Group recognizes a loss allowance for a financial asset at an amount equal to the 12-month expected credit losses, unless the credit risk on the financial asset has increased significantly since initial recognition, in which case a loss allowance is recognized at an amount equal to the lifetime expected credit losses.

Simplified approach

The simplified approach is applied to the impairment assessment of trade receivables.

Under the simplified approach the Group always recognizes a loss allowance for a financial asset at an amount equal to the lifetime expected credit losses.

Impairment of non-financial assets

- i. Non-financial assets are tested for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable.
- ii. Non-financial assets are impaired when their carrying amount exceed its recoverable amount. The recoverable amount is measured as the higher of fair value less cost of disposal and value in use. The value in use is calculated as being net projected cash flows based on financial forecasts discounted back to present value.

Share capital

Ordinary shares of the Company are classified as equity.

Property, plant and equipment

(i) Recognition and measurement

Items of property, plant and equipment are measured at cost less accumulated depreciation and accumulated impairment losses. Costs include expenditures that are directly attributable to the acquisition of the asset. Purchased software that is integral to the functionality of the related equipment is capitalized as part of that equipment.

When parts of an item of property, plant and equipment have different useful lives, they are accounted for as separate items (major components) of property, plant and equipment.

Gains and losses on disposal of an item of property, IT and equipment are determined by comparing the proceeds from disposal with the carrying amount of property, IT and equipment, and are recognized in profit or loss. When revalued assets are sold, the amounts included in the revaluation reserve are transferred to retained earnings.

(ii) Depreciation

Depreciation is calculated on the depreciable amount, which is the cost of an asset, less its residual value.

Depreciation is recognized in profit or loss on a straight-line basis over the estimated useful life of each part of an item of property, plant and equipment.

The estimated useful lives for the current period and the comparative period are as follows:

Fixtures and fittings	5 years
IT and equipment	3 years

Depreciation methods, useful lives and residual values are reviewed at each reporting date. Depreciation is allocated to the operating expenses line of the statement of comprehensive income.

Leases

All leases are accounted for by recognizing a right-of-use asset and a lease liability except for:

- Leases of low value assets; and
- Leases with a duration of 12 months or less

The Group has leases for its offices. Each lease is reflected on the balance sheet as a right-of-use asset and a lease liability. The Group does not have any leases of low value assets. Variable lease payments which do not depend on an index or a rate (such as lease payments based on a percentage of Group sales) are excluded from the initial measurement of the lease liability and asset. The Group classifies its right-of-use assets in a consistent manner to its property, plant and equipment (see Note 10).

At lease commencement date, the Group recognizes a right-of-use asset and a lease liability in its consolidated statement of financial position. The right-of-use asset is measured at cost, which is made up of the initial measurement of the lease liability, any initial direct costs incurred by the Group, an estimate of any costs to dismantle and remove the asset at the end of the lease, and any lease payments made in advance of the lease commencement date (net of any incentives received).

The Group depreciates the right-of-use asset on a straight-line basis from the lease commencement date to the earlier of the end of the useful life of the right-of-use asset or the end of the lease term. The Group also assesses the right-of-use asset for impairment when such indicators exist.

At the commencement date, the Group measures the lease liability at the present value of the lease payments unpaid at that date, discounted using the Group's incremental borrowing rate because as the lease contracts are negotiated with third parties it is not possible to determine the interest rate that is implicit in the lease. The incremental borrowing rate is the estimated rate that the Group would have to pay to borrow the same amount over a similar term, and with similar security to obtain an asset of equivalent value. This rate is adjusted should the lessee entity have a different risk profile to that of the Group.

Lease payments included in the measurement of the lease liability are made up of fixed payments (including in substance fixed), variable payments based on an index or rate, amounts expected to be payable under a residual value guarantee and payments arising from options reasonably certain to be exercised.

Subsequent to initial measurement, the liability will be reduced by lease payments that are allocated between repayments of principal and finance costs. The finance cost is the amount that produces a constant periodic rate of interest on the remaining balance of the lease liability.

Short term leases exempt from IFRS 16 are classified as operating leases. Payments made under operating leases are recognized in profit and loss on a straight-line basis over the term of the lease.

Fair Value Measurement

Management have assessed the categorization of the fair value measurements using the IFRS 13 fair value hierarchy. Categorization within the hierarchy has been determined on the basis of the lowest level of input that is significant to the fair value measurement of the relevant asset as follows:

Level 1 - valued using quoted prices in active markets for identical assets;

Level 2 - valued by reference to valuation techniques using observable inputs other than quoted prices included within Level 1;

Level 3 - valued by reference to valuation techniques using inputs that are not based on observable market data.

Share based payments

The calculation of the fair value of equity-settled share based awards and the resulting charge to the statement of comprehensive income requires assumptions to be made regarding future events and market conditions. These assumptions include the future volatility of the Company's share price. These assumptions are then applied to a recognized valuation model in order to calculate the fair value of the awards.

Where employees, Directors or advisers are rewarded using share based payments, the fair value of the employees', Directors' or advisers' services are determined by reference to the fair value of the share options/warrants awarded. Their value is appraised at the date of grant and excludes the impact of any nonmarket vesting conditions (for example, profitability and sales growth targets).

In accordance with IFRS 2, a charge is made to the statement of comprehensive income for all share-based payments including share options based upon the fair value of the instrument used and warrants issued in return for services. A corresponding credit is made to a share based payment reserve – options, in the case of options awarded to employees, Directors, advisers and other consultants. A corresponding credit is made to a share based payment reserve – warrants, in the case of warrants issued in return for services.

Warrants

Warrants are issued by the Group in return for services and as part of a financing transaction.

Warrants issued in return for services.

Warrants issued in return for services fall within scope of IFRS 2 and are classified as a share-based payment. The share-based payment is measured at fair value and charged to the Statement of comprehensive income. There is no remeasurement of fair value.

Warrants issued as part of a financing transaction.

Warrants issued as part of a financing transaction fall outside the scope of IFRS 2. These are classified as equity instruments because a fixed amount of cash is exchanged for a fixed amount of equity. The relative fair value is recognized within equity and is not remeasured.

Classification of these instruments is governed by the so-called 'fixed' test for non-derivatives, and the 'fixed for fixed' test for derivatives. Under the fixed test, a non-derivative contract will qualify for equity classification only where there is no contractual obligation for the issuer to deliver a variable number of its own equity instruments. Under the fixed for fixed test, a derivative will qualify for equity classification only where it will be settled by the issuer exchanging a fixed amount of cash or another financial asset for a fixed number of its own equity instruments.

Warrants issued by the Company as part of a financing transaction, are classified as equity instruments because a fixed amount of cash is exchanged for a fixed amount of equity of the Company. No other features exist that would result in financial liability classification.

Convertible loan notes

The Group issues Convertible loan notes which can be classified as equity or a liability depending on whether the fixed for fixed condition is met or not.

Where the fixed for fixed condition is met

The Group classifies convertible loan notes that meet the fixed for fixed condition as equity instruments and records the principal of the loan note as equity in a Convertible loan note reserve as it is convertible into equity. The accrued interest on the principal amount is also recorded in the Convertible loan note reserve. Upon redemption of the instrument and the issue of share capital, the amount is reclassified from the convertible loan note reserve to share capital and share premium.

3. CRITICAL ACCOUNTING JUDGEMENTS AND KEY SOURCES OF ESTIMATION UNCERTAINTY

The preparation of financial information in accordance with generally accepted accounting practice, in the case of the Group being IFRS as issued by the IASB, requires the directors to make estimates and judgements that affect the reported amount of assets, liabilities, income and expenditure and the disclosures made in the financial statements. Such estimates and judgements must be continually evaluated based on historical experience and other factors, including expectations of future events.

The following are considered to be the key sources of estimation uncertainty:

Share-based payments

The Group accounts for share-based payment transactions for employees in accordance with IFRS 2 Share-based Payment, which requires the measurement of the cost of employee services received in exchange for the options on our ordinary shares, based on the fair value of the award on the grant date.

The Directors selected the Black-Scholes-Merton option pricing model as the most appropriate method for determining the estimated fair value of our share-based awards without market conditions. For performance-based options that include vesting conditions relating to the market performance of our ordinary shares, a Monte Carlo pricing model was used in order to reflect the valuation impact of price hurdles that have to be met as conditions to vesting.

The Group makes estimates as to the useful life of an option award, the expected price volatility of the underlying share, risk free interest rate for the term of the award and correlations and volatilities of the shares of peer group companies. The Group also makes estimates as to the vesting period for awards that have performance-based criteria.

The resulting cost of an equity incentive award is recognized as expense over the requisite service period of the award, which is usually the vesting period. Compensation expense is recognized over the vesting period using the straight-line method.

The assumptions used for estimating fair value for share-based payment transactions are disclosed in note 27 to our consolidated financial statements.

4. OPERATING EXPENSES

Operating expenses are stated after charging:

<u>Group</u>	Six months ended September 30,		Year Ended March 31,	
	2022 (unaudited) \$	2021 (unaudited) \$	2022 \$	2021 \$
Director fees including bonus (excluding Chairman's bonus)	445,112	395,185	707,385	278,224
Chairman's bonus *	150,000	-	-	1,160,347
Auditor's Remuneration (refer to Note 20)**	303,776	33,295	349,665	131,511
Legal and Professional fees	600,601	-	1,143,300	343,422
(Gain)/Loss on disposal of leases	-	-	(179)	-
FX Gains and losses	(17,520)	-	(13,577)	200,061
Depreciation	1,524	1,165	2,423	1,512

* On May 19, 2022, the Remuneration committee awarded the Non-Executive Chairman a bonus of \$150,000. The committee noted that in order to support the NASDAQ offering on May 19, 2022, the Non-Executive Chairman made a late subscription for ADSs totaling \$150,000. It was noted that the offering may have failed without this subscription, so it was agreed to compensate Mr. Cerrone for the successful dual listing of the Company and funds raised (unaudited).

** This has been restated for presentational purposes only to include audit-related assurance services in addition to fees payable to the company's auditors for the audit of the parent company (being OKYO Pharma Limited) and consolidated financial statements. Refer to note 20 where details of auditor's remuneration has been disclosed. This has no impact on the primary financial statements.

5. SEGMENTAL REPORTING

During the year under review management identified the Group's only operating segment as the research and development of biotechnological and pharmaceutical products. This one segment is monitored, and strategic decisions are made based upon it and other non-financial data collated from industry intelligence. The form of financial reporting reported to the Board is consistent with those presented in the annual financial statements.

6. EMPLOYEES INCLUDING OFFICERS

<u>Group</u>	Year ended March 31,	
	2022 \$	2021 \$
Staff costs comprised:		
Directors' salaries	707,385	1,438,571
Wages and salaries	323,186	121,702
Social security costs	84,449	9,543
Recruitment Costs	14,259	12,922
	1,129,279	1,582,739
The average monthly number of employees, including directors, employed by the group during the years ending March 31, 2022, and March 31, 2021 were:		
Research and Development	2	1
Corporate and administration	5	5
	7	6

The Group and Company made \$2,622 of payments to a defined contribution pension schemes on behalf of Directors or employees during the year ending March 31, 2022 (March 31, 2021: \$2,904).

7. REMUNERATION OF KEY MANAGEMENT PERSONNEL

Directors of the Group and Company received the following remuneration during the years ending March 31 2022 and 2021:

	Year ended March 31,							
	2022		2021		2022		2021	
	Directors' fees	Bonus	Salary	Share based payment expenses	Directors' fees	Bonus	Salary	Share based payment expenses
G. Cerrone (1)	164	-	-	-	35	1,160	-	-
G Jacob (2)	-	75	350	1,579	-	41	85	468
W Simon	44	-	-	1	42	-	-	2
K. Shailubhai (6)	18	-	-	(15)	37	-	-	17
J Brancaccio (3)	42	-	-	20	31	-	-	16
G Macrae (4)	-	-	-	-	13	-	-	-
B Denoyer (5)	15	-	-	4	-	-	-	-
	<u>283</u>	<u>75</u>	<u>350</u>	<u>1,589</u>	<u>158</u>	<u>1,201</u>	<u>85</u>	<u>503</u>

- (1) Gabriele Cerrone's bonus awarded for \$1,160k was awarded on the basis of the co-invention of the use of Chemerin in the COVID-19 indication when he was not a director or employee of the Company (now the subject of a patent application); work carried out in procuring, backing and completing the refinancing the Company in 2020 and actions taken to make new executive appointments and scientific advisory appointments to the Board with the result that the Company now has a clear and accelerated path to the clinic.
- (2) Gary Jacob became an employee and Director of the Company on 7 January 2021
- (3) John Brancaccio was appointed as Director on 10 June 2020
- (4) Gregor Macrae was appointed as Director on 18 December 2019 and resigned on 10 June 2020
- (5) Bernard Denoyer was appointed as Director on 24 November 2021
- (6) K Shailubhai resigned as Director on 17 June 2021

The following share options were granted to Directors in the year:

	2022 Number of options	2021 Number of options
J Brancaccio	325,000	450,000
G Jacob	3,250,000	40,000,000
B Denoyer	1,000,000	-
	<u>4,575,000</u>	<u>40,450,000</u>

No director has yet benefitted from any increase in the value of share capital since issuance of the options and no director exercised share options in the year.

The Key Management Personnel of the Group are members of the leadership team who have the authority and responsibility for planning, directing and controlling the activities of the Group either directly or indirectly. They include all Directors of the Board (executive and non-executive). Key Management Personnel compensation is set out below.

	2022	2021
	\$'000	\$'000
Short-term employee benefits	1,026	1,455
Share based payments	1,815	515
	<u>2,841</u>	<u>1,970</u>

8. TAXATION

	Year ended March 31,	
	2022	2021
	\$	\$
Group		
Current year tax (credit)	(509,282)	(24,952)
Adjustments in respect of prior periods	(277,239)	(42)
Deferred tax		
Origination and reversal of timing differences	-	-
Total tax (credit) for the period	<u>(786,521)</u>	<u>(24,994)</u>
The tax charge for the year is different from the standard rate of corporation tax in the United Kingdom of 19%. The difference can be reconciled as follows:		
Loss before taxation	(6,045,372)	(3,378,501)
Loss charged at standard rate of corporation tax 19%	(1,181,337)	(641,915)
Tax losses arising in the year not recognized	524,870	660,594
Tax losses surrendered for Research and Development	667,335	-
Expenses not deductible for taxation	370,306	-
Tax increase from effect of capital allowances and depreciation	(3)	(334)
Research and Development tax claim	(509,282)	(43,432)
Research and Development enhanced expenditure	(377,187)	-
Research and Development tax credits claimed in respect of previous periods	(277,240)	(42)
Consolidation adjustment in relation to foreign exchange movements	(3,983)	135
Loans written off	-	-
Total tax (credit) for the period	<u>(786,521)</u>	<u>(24,994)</u>

No deferred tax asset has been recognized in respect of trading losses carried forward because of uncertainty as to when these losses will be recoverable.

The Group has tax losses of \$15,870,525 (2021: \$9,411,521) to carry forward for use against future profits.

9. FINANCE INCOME AND COSTS

	Year ended March 31,	
	2022 \$	2021 \$
Finance Income		
Interest income	-	-
Total finance income	-	-
Finance Expenses		
Interest expense on lease liabilities	-	(1,122)
Total finance expenses	-	(1,123)

10. PROPERTY, PLANT AND EQUIPMENT

Details of the Group's property, plant and equipment are as follows:

\$	IT equipment	Total
Cost		
At 1 April 2022	9,779	9,779
Additions	2,699	2,699
Foreign exchange	(1,243)	(1,243)
At 30 September 2022 (Unaudited)	11,235	11,235
Depreciation		
At 1 April 2022	4,554	4,554
Charge in year	1,524	1,524
Foreign exchange	(444)	(444)
At 30 September 2022 (Unaudited)	5,634	5,634
Net Book Value as at 30 September 2022 (Unaudited)	5,601	5,601
\$	IT equipment	Total
Cost		
At 1 April 2021	8,343	8,343
Additions	1,669	1,669
Disposals	-	-
Foreign exchange	(233)	(233)
At 31 March 2022	9,779	9,779
Depreciation		
At 1 April 2021	2,286	2,286
Charge in year	2,331	2,331
Foreign exchange	(63)	(63)
At 31 March 2022	4,554	4,554
Net Book Value as at 31 March 2022	5,225	5,225
\$	IT equipment	Total
Cost		
At 1 April 2020	1,257	1,257
Additions	6,944	6,944
Disposals	-	-
Foreign exchange	142	142
At 31 March 2021	8,343	8,343
Depreciation		
At 1 April 2020	622	622
Charge in year	1,593	1,593
Foreign exchange	71	71
At 31 March 2021	2,286	2,286
Net Book Value as at 31 March 2021	6,057	6,057

The Group's property, plant and equipment is located in the following operating segments:

Group	Net Book Value March 31 2022 \$
UK	2,937
US	2,289
Total	<u>5,225</u>

11. OTHER RECEIVABLES

\$	Six months ended September 30, 2022 (unaudited)	Year ended March 31,	
		2022	2021
Other receivables	4,500	19,130	4,499
VAT receivable	45,749	82,617	17,799
Prepayments	514,541	711,209	21,072
	564,790	812,956	43,370

There are no differences between the carrying amount and fair value of any of the trade and other receivables above.

Prepayments include \$639,635 of prepaid invoices relating to the OK-101 project.

12. TRADE AND OTHER PAYABLES

\$000	Six months ended September 30, 2022 (unaudited)	Year ended March 31,	
		2022	2021
Trade payable	1,517,803	741,807	210,992
Accruals	469,725	457,773	71,093
Bonus accrual	-	106,571	1,391,069
	1,987,528	1,306,150	1,673,154

13. CAPITAL AND RESERVES

Capital Management

For the purpose of the Company's capital management, capital includes called up share capital, share premium, share based payments for options, share based payments for warrants and all other equity reserves attributable to the equity holders of the parent as reflected in the statement of financial position.

The Company's objectives when managing capital are to safeguard the Group's ability to continue as a going concern and to maximize shareholder value through the optimization of the debt and equity balance.

The Company manages its capital to maximize the return to the shareholders through the optimization of equity. The capital structure of the Company as at 31 March 2022 consists of equity attributable to equity holders of the Company, comprising issued capital, reserves and retained deficit as disclosed.

The Company manages its capital structure and makes adjustments to it, in light of economic conditions and the strategy approved by shareholders. To maintain or adjust the capital structure, the Group may adjust the dividend payment to shareholders, return capital to shareholders or issue new shares and release the Company's share premium account. No changes were made in the objectives, policies or processes during the year ended 31 March 2022 and 31 March 2021.

Share capital and premium

The Company is authorized to issue an unlimited number of nil par value shares of a single class. The Company may issue fractional shares and a fractional share shall have the corresponding fractional rights, obligations and liabilities of a whole share of the same class or series of shares. Shares may be issued in one or more series of shares as the Directors may by resolution determine from time to time.

Each share in the Company confers upon the shareholder:

- the right to one vote at a meeting of the shareholders or on any resolution of shareholders;
- the right to an equal share in any dividend paid by the Company; and
- the right to an equal share in the distribution of the surplus assets of the Company on its liquidation.

The Company may by resolution of the Directors redeem, purchase or otherwise acquire all or any of the shares in the Company subject to regulations set out in the Company's Articles of Incorporation.

Authorized

The Company is authorized to issue an unlimited number of nil par value shares of a single class.

	Shares Number	Share capital \$
Issued ordinary shares of US\$0.00 each		
At 31 March 2020	636,297,049	112,079,984
Shares issued - private placement	36,269,253	230,019
Relative Fair value charge for warrants issued in conjunction with private placement		(138,305)
CLNs issued in lieu of fundraising commission		(558,395)
Options exercised	250,000	15,870
At 31 March 2021	672,816,302	111,629,173
Exercise of warrants	386,512,756	3,470,940
Conversion of CLN	315,086,410	8,876,397
At 31 March 2022	1,374,415,468	123,976,510
Issue of shares (IPO Fundraise)	40,625,000	2,500,000
IPO Expenses	-	(646,108)
At 30 September 2022	1,415,040,468	125,830,402

Issuance of ordinary shares

In June 2020, 36,269,253 ordinary shares were issued at an issue price of 0.005p per ordinary share by way of a placing of ordinary shares to raise finance.

In March 2021, 250,000 ordinary shares were issued in relation to an exercise of options at an issue price of 0.045p per ordinary share.

In May 2021, 36,363,636 ordinary shares were issued in relation to an exercise of warrants at an issue price of 0.0135p per ordinary share.

In May 2021, 72,000,000 ordinary shares were issued in relation to an exercise of warrants at an issue price of 0.0055p per ordinary share.

In May 2021, 76,605,760 ordinary shares were issued in relation to a conversion of loan notes at an issue price of 0.004p per ordinary share.

In May 2021, 73,304,650 ordinary shares were issued in relation to a conversion of loan notes at an issue price of 0.085p per ordinary share.

In May 2021, 39,605,760 ordinary shares were issued in relation to an exercise of warrants at an issue price of 0.004p per ordinary share.

In February 2022, 165,176,000 ordinary shares were issued in relation to a conversion of loan notes at an issue price of 0.004p per ordinary share.

In February 2022, 238,543,360 ordinary shares were issued in relation to a cashless exercise of warrants.

In May 2022, 40,625,000 ordinary shares were issued in relation to a fundraise and IPO onto the NASDAQ market (unaudited).

Share options reserve

The share-based payment reserve for options represents the cost to issue share-based compensation, primarily share options, based on their grant date fair value.

Share warrants reserve

The share-based payment reserve for warrants represent the cost to issue warrants based on their grant date fair value.

Convertible Loan Note reserve

The convertible loan note reserve represents the proceeds received on issuance of convertible loan notes classified as equity instruments, accrued interest and any relative fair value adjustments. .

Retained Deficit reserve

Retained deficit represent the cumulative profits/(losses) of the entity which have not been distributed to shareholders.

Translation reserve

The translation reserve represents the unrealised gains or losses from the foreign currency translation of Companies within the Group.

Dividends

The Directors paid no dividend during the year to 31 March 2022 and 31 March 2021.

Transfer between equity reserves

The company affected a transfer between reserves in equity in order to align the values of the equity reserves on a relative fair value basis. The total amount recorded in equity remains unaltered.

14. SHARE OPTIONS AND WARRANTS

Options

The Company operates share-based payment arrangements to remunerate Directors and key employees in the form of a share option scheme. It also issues options in lieu of fees to key suppliers and collaborators. The exercise price of the option is normally equal to the market price of an ordinary share in the Company at the date of grant.

	2022		2021	
	Weighted Average exercise price (cents)	Options	Weighted Average exercise price (cents)	Options
Outstanding at 1 April	6.90	60,750,000	5.58	19,500,000
Granted	8.41	28,150,000	7.31	42,250,000
Forfeited	(5.91)	(16,500,000)	(6.21)	(750,000)
Exercised	-	-	(6.21)	(250,000)
Outstanding at 31 March	7.49	72,400,000	6.90	60,750,000
Exercisable at 31 March	7.36	14,437,500	6.21	9,250,000
	2022 (unaudited)		2021 (unaudited)	
	Weighted Average exercise price (cents)	Options	Weighted Average exercise price (cents)	Options
Outstanding at 1 April	7.49	72,400,000	6.90	19,500,000
Granted	5.79	4,420,000	7.68	750,000
Forfeited	-	-	(6.06)	(750,000)
Outstanding at 30 September	6.34	76,820,000	7.27	19,500,000
Exercisable at 30 September	6.12	18,037,500	8.35	9,500,000

No options were exercised during the six months ended 30 September 2022 (unaudited), the six months ended 30 September 2021 and the year ended 31 March 2022. During the year ending 31 March 2021, 250,000 options were exercised.

The total outstanding fair value charge at 30 September 2022 of the share option instruments is deemed to be approximately \$1,194,195 (unaudited) (March 2022 \$2,072,515, March 2021: \$2,682,050). A share-based payment charge for the six-month period ended September 30, 2022 of \$617,793 (unaudited) (September 2021: \$831,903, March 2022: \$1,718,727, March 2021: \$550,138) has been expensed in the statement of comprehensive income. The share-based payment charge in the year to March 31, 2022 includes a forfeiture of \$19,149.

The weighted average contractual life of options outstanding at September 30, 2022 is 7.13 years (unaudited). (March 31, 2022: 7.77 years, March 2021: 8.97 years).

Share options outstanding at 30 September 2022 have the following expiry dates and exercise prices:

Grant Date	Expiry Date	Exercise Price	Share Options as at 30 September 2022 ('000)
6 July 2018	6 July 2025	4.5p	2,000
20 August 2020	19 August 2028	15.5p	750
6 January 2021	5 January 2031	5p	40,000
12 January 2021	11 January 2031	7.9p	1,500
15 April 2021	15 April 2031	7.88p	5,000
31 August 2021	31 August 2031	4.9p	14,400
31 January 2022	30 January 2032	8.0p	8,750
1 August 2022 (unaudited)	31 July 202	5p	2,600
20 September 2022 (unaudited)	19 September 2027	5p	1,820
Total			76,820

Share options outstanding at 31 March 2022 have the following expiry dates and exercise prices:

Grant Date	Expiry Date	Exercise Price	Share Options as at 31 March 2022 ('000)
6 July 2018	6 July 2025	4.5p	2,000
20 August 2020	19 August 2028	15.5p	750
6 January 2021	5 January 2031	5p	40,000
12 January 2021	11 January 2031	7.9p	1,500
15 April 2021	15 April 2031	7.88p	5,000
31 August 2021	31 August 2031	4.9p	14,400
31 January 2022	30 January 2032	8.0p	8,750
Total			72,400

Fair value of options granted

The Directors have used the Black-Scholes option pricing model to estimate the fair value of most of the options applying the assumptions below.

Historical volatility relies in part on the historical volatility of a group of peer companies that management believes is generally comparable to the Company.

The Company has not paid any dividends on share capital since its inception and does not anticipate paying dividends on its share capital in the foreseeable future.

The Company has estimated a forfeiture rate of zero.

The model inputs for options granted during the year ended 31 March 2022 valued under the Black Scholes Valuation model are:

	15 April 2021	31 August 2021	31 January 2022
Grant date share price	7.7p	4.9p	4.8p
Exercise share price	7.9p	4.9p	8.0p
Vesting periods	25% each year	25% each year	1.25m options vest 33% each year and 7.5m options have developmental milestone performance conditions
Risk free rate	0.35%	0.30%	0.97%
Expected volatility	80.20%	77.7%	83.0%
Option life	5 years	5 years	5 years

The model inputs for options granted during the year ended 31 March 2021 valued under the Black Scholes Valuation model included:

	20 August 2020	6 January 2021	12 January 2021
Grant date share price	15.5p	0.8p	0.79p
Exercise share price	15.5p	0.5p	0.79p
Vesting periods	25% each year	25% each year	33% in 6 months and 67% in 1 year
Risk free rate	0.15%	-0.01%	0.4%, 0.6%
Expected volatility	77.4%	77.5%	66.7%, 83.7%
Expected option life	5 years	5 years	6 months to 1 year

Warrants

As part of the acquisition of the OK-101 project, the underlying scientific founders of the OK-101 Project (inukshuk Holdings), who will continue to be involved in the development of the Project, received 35,000,000 warrants as consideration. The warrants are exercisable at a price of 4.5 pence each and are split into four distinct tranches and each tranche becomes exercisable upon satisfaction of a specific developmental milestone. The warrants are exercisable until 17 July 2023.

In May 2019, warrants were granted over 36,363,636 shares at an exercise price of 1.35p per share in connection with a private placement. These warrants were exercised in May 2021.

In March 2020, warrants were granted over 40,000,000 shares at an exercise price of 0.55p per share in connection with a private placement. These warrants were exercised on a cashless basis in February 2022 (post a price reduction offer to 0.012p), resulting in the issuance of 39,400,000 shares.

In March 2020, warrants were granted over 35,825,130 shares at an exercise price of 0.55p per share in connection with a private placement. These warrants were exercised in May 2021.

In April 2020, warrants were granted over 36,174,870 shares at an exercise price of 0.55p per share in connection with a private placement. These warrants were exercised in May 2021.

In May 2020, warrants were granted over 909,090 shares at an exercise price of 2.75p per share in lieu of professional fees. The warrants are exercisable until 21 May 2023.

In July 2020, warrants were granted over 750,000 shares at an exercise price of 14p per share in lieu of broker fees. The warrants are exercisable until 20 July 2022.

In May 2021, warrants were granted over 76,605,760 shares at an exercise price of 0.4p per share in connection with the conversion of convertible loan notes. 39,605,760 were exercised immediately and the remaining 37,000,000 were exercised on a cashless basis in February 2022, (post a price reduction offer to 0.012p), resulting in the issuance of 36,445,000 shares.

In February 2022, warrants were granted over 165,176,000 shares at an exercise price of 0.4p per share in connection with the conversion of convertible loan notes. 165,176,000 were exercised on a cashless basis in February 2022 (post a price reduction offer to 0.012p), resulting in the issuance of 162,698,360 shares.

In summary, during the year ended March 31, 2022, 147,969,396 warrants were exercised for proceeds of £1,045,332, resulting in the issuance of 147,969,396 shares. 242,716,000 warrants were also exercised on a cashless basis resulting in the issuance of 238,543,360 shares.

	31 March 2022		31 March 2021	
	Warrants	Weighted Average exercise price (cent)	Warrants	Weighted Average exercise price (cent)
Outstanding at 1 April	185,022,726	2.1	147,188,766	2.1
Granted	241,781,760	0.5	37,833,960	1.2
Exercised	(390,145,396)	(0.7)	-	-
Outstanding at 31 March	36,659,090	6.11	185,022,726	2.1
Exercisable at 31 March	1,659,090	10.30	149,568,181	1.1

	2022 (unaudited)		2021 (unaudited)	
	Weighted Average exercise price (cents)	Warrants	Weighted Average exercise price (cents)	Warrants
Outstanding at 1 April	6.11	36,659,090	2.07	185,022,726
Granted	-	-	0.78	76,605,760
Exercised	-	-	(0.96)	(147,969,396)
Forfeited	16.13	(750,000)	-	-
Outstanding at 30 September	4.96	35,909,090	2.45	113,659,090
Exercisable at 30 September	3.06	909,090	0.85	78,659,090

The Directors have estimated the fair value of the warrants in services provided using the Black-Scholes valuation model based on the assumptions below.

The model inputs for warrants granted during the six months ended 30 September 2021 valued under the Black Scholes Valuation model included:

(unaudited)	7 May 2021
Grant date share price	7.25p
Exercise share price	0.4p
Vesting periods	Vesting market performance conditions
Risk free rate	0.36%
Expected volatility	80.6%
Expected life	3 years

The model inputs for warrants granted during the year ended 31 March 2022 valued under the Black Scholes Valuation model included:

	29 May 2020
Grant date share price	1.75p
Exercise share price	0.4p
Risk free rate	0.25%
Expected volatility	79.6%
Expected life	3 years

The Directors have estimated the fair value of the warrants in services provided during the year ending 31 March 2021 using the Black-Scholes valuation model based on the assumptions below.

	July 2020	May 2020	April 2020
Grant date share price	8.3p	2.8p	1.8p
Exercise share price	14p	2.8p	0.5p
Vesting periods	Fully vested	50% of these warrants shall only vest if the 5-day VWAP of the Company exceeds a 100% premium to the Exercise Price, and the remainder shall only vest if the 5-day VWAP of the Company exceeds a 200% premium to the Exercise Price (conditions have been met)	Fully vested
Risk free rate	0.68%	0.95%	0.22%
Expected volatility	88.1%	79.6%	82.4%
Expected life	2 years	3 years	5 years

The remaining fair value of the warrant instruments is deemed to be approximately \$19,516 as at 30 September 2022 (unaudited) and \$43,348 as at 31 March 2022 (2021: \$108,873). For the consideration warrants, the charge has been expensed over the vesting period. For all other warrants, the charge has been expensed over the service period. A share-based payment charge for the year to 31 March 2022 of \$61,721 (2021: \$81,914) has been expensed in the statement of comprehensive income. A share-based payment charge for the 6 months to 30 September 2022 of \$18,802 (2021: 34,970) has been expensed in the statement of comprehensive income (unaudited).

15. CONVERTIBLE INSTRUMENTS CLASSIFIED AS EQUITY

The Company has raised convertible equity finance via the issuance of convertible loan notes as per the table below. All notes are not convertible into cash and are convertible on the fourth anniversary of the date of issue of the Notes, or at the election of the noteholder on completion of the next non-qualifying equity financing or on the making of a takeover offer for the Company (as defined in the City Code on Takeovers and Mergers), and such election may be made on an immediate basis or conditional on any such takeover offer being declared, or becoming, unconditional.

Date	Terms	Amount \$
29 May 2020	<ul style="list-style-type: none"> • 20% coupon per annum • Conversion price of 0.4p • Upon conversion the shares will be issued with a warrant attached at an exercise price of 0.4p with a maximum life of 5 years from the date of the conversion of the loan note 	541,239
Fees relating to equity fundraise 29 May 2020 issued as CLN	<ul style="list-style-type: none"> • 20% coupon per annum • Conversion price of 0.4p • Upon conversion the shares will be issued with a warrant attached at an exercise price of 0.4p with a maximum life of 5 years from the date of the conversion of the loan note 	32,474
27 July 2020	<ul style="list-style-type: none"> • 2.15% coupon per annum • Conversion price of 8.5p 	4,506,446
17 August 2020	<ul style="list-style-type: none"> • 2.15% coupon per annum • Conversion price of 8.5p 	1,882,641
3 September 2020	<ul style="list-style-type: none"> • 2.15% coupon per annum • Conversion price of 8.5p 	663,055
Fees relating to all other equity fundraise issued as CLN	<ul style="list-style-type: none"> • 2.15% coupon per annum • Conversion price of 8.5p 	525,922
		<u>8,151,777</u>

All noteholders were offered the option to convert during the year and any conversions took place on May 7, 2021 and February 21, 2022. Loan note holders were offered conversions including the full interest that would have been accrued had the note reached its full term

16. FINANCIAL INSTRUMENTS

The main risks arising from the Group's financial instruments are liquidity risk, interest rate risk and credit risk. The Directors regularly review and agree policies for managing each of these risks which are summarized below.

Liquidity risk

The Group's policy is to regularly monitor current and expected liquidity requirements to ensure that it maintains sufficient reserves of cash to meet its liquidity requirements in the short and long term. The Group ordinarily finances its activities through cash generated from by private and public offerings of equity and debt securities.

The table below summarizes the maturity profile of the Group's financial liabilities based on contractual undiscounted payments:

Group	2022		
	Less than 3 months	3 to 12 months	Total
\$			
Trade and other payables	649,624	92,186	741,810
Related party payables	47,041	-	47,041
	<u>696,665</u>	<u>92,186</u>	<u>788,851</u>
Group	2021		
	Less than 3 months	3 to 12 months	Total
\$			
Trade and other payables	110,179	100,813	210,992
Related party payables	-	-	-
	<u>110,179</u>	<u>100,813</u>	<u>210,992</u>

Credit risk

Credit risk is managed on a Group basis. Credit risk arises principally from cash and cash equivalents and deposits with banks and financial institutions, as well as outstanding receivables. The Group reviews its banking arrangements carefully to minimize such risks and currently has no customers and therefore this risk is viewed as minimal. Management monitors loans between members of the Group as part of their internal reporting and assess outstanding receivables for ability to be repaid.

Interest rate risk

The Group has limited exposure to interest-rate risk arising from its bank deposits and convertible loan note instruments. These deposit accounts are held at variable interest rates based on Barclays bank & Penn base rates.

The Directors do not consider the impact of possible interest rate changes based on current market conditions to be material to the net result for the year or the equity position at the year-end for either the year ended 31 March 2022 or 31 March 2021.

17. RELATED PARTY TRANSACTIONS

All related party transactions occurred in the normal course of operations.

West African Minerals Limited (“WAML”)

In 2018, the Group disposed of its Cameroon operations by way of an in-specie distribution of all of its shares in West African Minerals Limited (formerly Ferrum Resources Limited) to shareholders. As part of this transaction, the Group had agreed to a deed of release with WAML whereby it agreed to write off \$17,056,070 of loans in exchange for shares in WAML to be distributed as part of the in-specie distribution. A remaining amount of \$3,400,000 was outstanding from WAML, however, after careful consideration of the operations of WAML and its subsidiaries, the Group decided to impair this receivable down to \$nil in 2018 as it did not expect to recover any of this outstanding debt. In addition to the \$3,400,000 outstanding was a working capital loan advance of \$600,000 which was also impaired as the Group does not expect to recover any of this outstanding debt. During the year ended March 31, 2022, the Group had funded \$0 (2021: \$11,172) towards this \$600,000 loan facility and as at the year-end no further amounts were payable under this facility. The amounts funded in the year have been immediately written off as the Group has no reasonable expectation of recovering the contractual cash flows of the loan in its entirety.

Tiziana Life Sciences Ltd

Tiziana Life Sciences Ltd is a related party as the entity is controlled by a person that has significant influence over the Group. The Company shares premises and other resources with Tiziana Life Sciences Ltd and there is a shared services agreement in place between the Company and Tiziana Life Sciences Ltd. As at 31st March 2022, the Company had incurred \$107,132 (2021: \$86,567) worth of costs in relation to this agreement and at 31 March 2022 \$47,041 was due to Tiziana Life Sciences Ltd. At 31 March 2021, \$27,664 was receivable from Tiziana Life Sciences Ltd. As at 30 September 2022, the Company had incurred \$67,562 (30 September 2021: \$58,80) worth of costs in relation to his agreement and at 30 September 2021, \$125,113 (30 September 2021: \$28,748) was due to Tiziana Life Sciences Ltd (unaudited).

In August 2022, the Group secured a short-term credit facility from Tiziana Life Sciences, a related party, for \$2m in order to support short term liquidity. The credit facility is available for a period of 6 months upon first draw-down and carries an interest rate of 16% per annum, with additional default interest of 4% if the credit facility is not repaid after the 6-month period. At 30 September 2022, no funds had been drawn down from the credit facility (unaudited).

18. BASIC AND DILUTED LOSS PER SHARE

Basic loss per share is calculated by dividing the loss attributable to equity holders of the Group by the weighted average number of ordinary shares in issue during the year.

	Six months ended September 30		Year ended March 31,	
	2022 (unaudited)	2021 (unaudited)	2022	2021
(Loss) attributable to equity holders of the company (\$)	(5,544,389)	(2,546,353)	(6,268,197)	(3,353,507)
Weighted average number of ordinary shares in issue	1,406,826,670	910,469,043	979,212,888	672,767,629
Basic and diluted loss per share (cents per share)	(0.00)	(0.00)	(0.01)	(0.01)

As the Group is reporting a loss from continuing operations for the year then, in accordance with IAS 33, the share options are not considered dilutive because the exercise of the share options would have an anti-dilutive effect. The basic and diluted earnings per share as presented on the face of the Statement of comprehensive income are therefore identical.

19. Leases

The Group is a lessee and does not have any leases as a lessor.

All leases are accounted for by recognizing a right-of-use asset and a lease liability except for:

- Leases of low value assets; and
- Leases with a duration of 12 months or less.

The Group has leases for its offices. Each lease is reflected on the balance sheet as a right-of-use asset and a lease liability. The Group does not have leases of low value assets. Variable lease payments which do not depend on an index or a rate (such as lease payments based on a percentage of Group sales) are excluded from the initial measurement of the lease liability and asset. The Group classifies its right-of-use assets in a consistent manner to its property, plant and equipment.

For leases over office buildings and factory premises the Group must keep those properties in a good state of repair and return the properties in their original condition at the end of the lease.

During the year to March 31, 2022, the Group entered into new lease agreements on its existing office. The new leases all have a term shorter than 12 months, so the Group has applied the exemption allowed by paragraph 5a in IFRS 16 in respect of short-term leases.

During the year to March 31, 2021, the group terminated from its lease early resulting in the right of use asset of \$27,069 and lease liability of \$27,887 being written off to the profit and loss. A new lease was subsequently entered into in January 2021. The initial recognition resulted in a right of use asset and a lease liability of \$104,377 respectively.

Right-of-use assets

	Property
	\$
At 1 April 2021	98,579
Derecognition of right of use asset	(97,553)
Impact of Foreign exchange	(1,026)
At 31 March 2022	-
	\$
At 1 April 2020	30,099
Impact of Foreign exchange	1,030
Depreciation of early terminated lease	(4,060)
Early Termination write off	(27,069)
Additions	104,377
Depreciation of new lease	(5,799)
At 31 March 2021	98,579

Lease Liabilities	31 March 2022	31 March 2021
	\$	\$
At 1 April	98,760	31,689
Interest expense		740
Lease payments	-	(4,542)
Impact of foreign exchange	(1,207)	-
Derecognition of lease liability	(97,553)	-
Early Termination write off	-	(27,887)
Additions	-	104,378
Interest expense	-	382
Lease payments	-	(6,000)
	<u>-</u>	<u>98,760</u>

Lease liabilities are presented in the statement of financial position as follows:

	30 September 2022 (unaudited)	31 March 2022	31 March 2021
	\$	\$	\$
Current	-	-	34,148
Non-current	-	-	64,612
	<u>-</u>	<u>-</u>	<u>98,760</u>

Operating leases

At September 30, 2022, March 31, 2022 and March 31, 2021, the company had annual commitments under non-cancellable operating leases:

Operating leases which expire:	30 September 2022 (unaudited)	31 March 2022	31 March 2021
	\$	\$	\$
Within one year	<u>15,245</u>	<u>18,713</u>	<u>-</u>
	<u>15,245</u>	<u>18,713</u>	<u>-</u>

20. Auditor's Remuneration

During the period, the group obtained the following services from the company's auditors:

	30 September 2022 (unaudited)	30 September 2021 (unaudited)	31 March 2022	31 March 2021
	\$	\$	\$	\$
Fees payable to the company's auditors for the audit of the parent company and consolidated financial statements				
Audit fees payable to Mazars LLP	100,341	-	200,773	58,874
Audit fees payable to PKF Littlejohn LLP	60,854	-	-	-
Fees payable to the company's auditors for other services:				
Audit-related assurance services payable to Mazars LLP	<u>142,581</u>	<u>33,295</u>	<u>148,892</u>	<u>72,637</u>
	<u>303,776</u>	<u>33,295</u>	<u>349,665</u>	<u>131,511</u>

21. Cash and Cash Equivalents

Cash and cash equivalents consist of the following:

	31 March 2022 \$	31 March 2021 \$
Cash at bank and in hand:		
GBP	2,400,817	4,344,740
USD	299,907	2,544,589
	<u>2,700,724</u>	<u>6,889,329</u>

22. Comments and Contingencies

The Group's main financial commitments relate to the contractual payments in respect of its licensing agreements. Due to the uncertain nature of scientific research and development and the length of time required to reach commercialization of the products of this research and development, pre-clinical, clinical and commercial milestone obligations are not detailed until there is a reasonable certainty that the obligation will become payable. Contractual commitments are detailed where amounts are known and certain.

- OK-101 – We are obligated to pay to On Target Therapeutics the following additional amounts in respect of the first licensed product or service which achieves the stated development milestones:

(a) First Patient Enrolled in a Phase I Human Clinical trial	\$	300,000
(b) First Patient Enrolled in a Phase II Human Clinical trial	\$	600,000
(c) First Patient Enrolled in a Phase III Human Clinical trial	\$	1,500,000

- BAM8 – The Group are committed to paying an annual license maintenance fee until the first commercial sale. The annual license maintenance fee is \$15,000 until May 2021, and \$10,000 thereafter.

23. Post Balance Sheet Events

On May 19, 2022 OKYO announced the closing of its underwritten public offering of 625,000 American Depositary Shares (the “ADSs”) at a public offering price of \$4.00 per ADS, for gross proceeds of \$2.5 million, before deducting underwriting discounts and offering expenses. As a result, the Company is now listed on the NASDAQ stock exchange and is therefore a dual listed Company with its existing listing on the London Stock Exchange.

On May 19, 2022, the Remuneration committee awarded the Non-Executive Chairman a bonus of \$150,000. The committee noted that in order to support the offering the Non-Executive Chairman participated in the offering. It was noted that the offering may have failed without this subscription, so it was agreed to compensate Mr. Cerrone for this transaction.

In August 2022, the Group secured a short-term credit facility from Tiziana Life Sciences, a related party, for \$2m in order to support short term liquidity. The loan is available for a period of 6 months upon first draw-down and carries an interest rate of 16% per annum, with additional default interest of 4% if the loan is not repaid after the 6-month period.

During November 2022, the Group drew down \$1m against the loan from Tiziana Life Sciences Ltd (unaudited).

On 21 November 2022 the Group announced the filing of the IND on OK-101 with FDA to treat DED patients. On December 18, 2022, having received no comments from FDA, the Group became authorized to commence its clinical program (unaudited).

During December 2022, the Group announced that it had filed a registration statement on Form F-1 with the U.S. Securities and Exchange Commission relating to a secondary public offering of its American Depositary Shares, each of which will represent 65 of the Company's ordinary shares of no par value each in the United States (unaudited).

3,503,665 American Depositary Shares Representing 227,738,225 Ordinary Shares



OKYO Pharma Limited

PROSPECTUS

March 13, 2023
