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

FORM 20-F

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

OR

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

For the fiscal year ended March 31, 2022

OR

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

For the transition period from to

OR

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

Commission file number: 001-41386

OKYO Pharma Limited
(Exact name of Registrant as specified in its charter and translation of Registrant's name into English)

Guernsey
(Jurisdiction of incorporation or organization)

OKYO Pharma Limited
Martello Court
Admiral Park
St. Peter Port
Guernsey GY1 3HB
(Address of principal executive offices)

OKYO Pharma Limited
Chief Financial Officer
107 Cheapside
London EC2V 6DN
United Kingdom
+44 20 7495 2379
(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Copies to:

Ed Lukins
Orrick, Herrington & Sutcliffe (UK) LLP
107 Cheapside
London EC2V 6DN
United Kingdom

Securities registered or to be registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
American Depositary Shares, each representing 65 ordinary shares, having a nominal value of £0.00 each Ordinary share, nominal value of £0.00 each*	NASDAQ Capital Market

(*) Not for trading, but only in connection with the listing of the American Depositary Shares

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

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

Number of outstanding shares of each of the issuer's classes of capital or common stock as of July 21, 2022: 1,374,415,468 ordinary shares.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

☐ Yes ☒ No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15 (d) of the Securities Exchange Act of 1934.

☒ Yes ☐ No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files).

☒ Yes ☐ No

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

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

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

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

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

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

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

☐ Item 17 ☐ Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

☐ Yes ☒ No

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INTRODUCTION

In this Annual Report on the Form 20-F references to "OKYO," "OKYO Pharma Ltd," "the company," "we," "us" and "our" refer to OKYO Pharma Ltd and its wholly owned subsidiary, OKYO Pharma Inc.

Solely for convenience, the trademarks, service marks and trade names in this annual report 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 annual report 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 annual report, 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 "Sterling" or "£" or "pence" are to the currency of the United Kingdom.

In this annual report, 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.

PRESENTATION OF FINANCIAL INFORMATION AND OTHER DATA

This annual report includes our audited consolidated financial statements as of and for the years ended March 31, 2022 2021, and 2020, 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 United States dollars. For the convenience of the reader, in this annual report, unless otherwise indicated, translations from Pounds Sterling into U.S. dollars were made at the rate of £1.00 to $1.2183, which was the noon buying rate of the Federal Reserve Bank of New York on July 29, 2022. 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 annual report. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that preceded them.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report contains forward-looking statements that involve substantial risks and uncertainties. All statements contained in this Annual Report, 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 annual report are based upon information available to us as of the date of this annual report 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 and our ability to continue as a going concern;
- 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, United Kingdom and foreign countries.

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 annual report 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 Annual Report and the documents that we have filed as exhibits to this Annual Report 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.

PART I

ITEM 1: IDENTITY OF DIRECTORS, SENIOR MANAGEMENT AND ADVISERS

Not Applicable

ITEM 2: OFFER STATISTICS AND EXPECTED TIMETABLE

Not applicable.

ITEM 3: KEY INFORMATION

A. Selected Financial Data

The following table summarizes our consolidated financial data as of the dates and for the periods indicated. The consolidated financial statement data for the years ended March 31, 2022, 2021 and 2020 have been derived from our consolidated financial statements, as presented at the end of this Annual Report, which have been prepared in accordance with IFRS, as issued by the IASB, and audited in accordance with the standards of the Public Company Accounting Oversight Board (United States).

Our functional currency is the pound Sterling. However, for financial reporting purposes, our financial statements, which are prepared using the functional currency, have been translated into U.S. dollars. Our assets and liabilities are translated at the exchange rates at the balance sheet date, our expenses are translated at average exchange rates for the period presented 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 translation adjustment to other comprehensive loss, a component of shareholders' equity.

Foreign currency transactions in currencies different from the functional currency are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange differences resulting from the settlement of such transactions and from the translation at period-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recorded in general and administrative expense in the statement of operations and comprehensive loss.

As of March 31, 2022, 2021, and 2020, the representative exchange rates were £1.00 = $1.313896, £1.00 = $1.380167 and £1.00 = $1.239672, respectively.

Our historical results are not necessarily indicative of the results that may be expected in the future. The following selected consolidated financial data should be read in conjunction with our audited consolidated financial statements included at the end of this Annual Report and the related notes and Item 5, "Operating and Financial Review and Prospects" below.

Consolidated Statement of Operations and Comprehensive Loss Data:

	Years Ended March 31,		
	2022	2021	2020
	(in thousands except share and per share data)		
Operating expenses:			
Research and development	$ (1,301)	$ (174)	$ (518)
General and administrative	(4,916)	(3,192)	(1,017)
Total operating expenses	(6,217)	(3,366)	(1,535)
Loss from operations	(6,217)	(3,366)	(1,535)
Other income (expense)	-	(12)	(86)
Tax credit	786	25	76
Net loss attributable to ordinary shareholders	(5,431)	(3,353)	(1,544)
Other comprehensive loss:			
Foreign currency translation adjustment	(837)	346	87
Total comprehensive loss	(6,268)	(3,007)	(1,457)
Basic and diluted net loss per ordinary share	(0.01)	(0.01)	(0.00)

Consolidated Balance Sheet Data:

	Years Ended March 31,		
	2022	2021	2020
	(in thousands except share and per share data)		
Cash and cash equivalents	$ 2,701	$ 6,889	$ 235
Working capital	2,942	5,280	(144)
Total assets	4,301	7,091	599
Total shareholders' equity/(deficit)	2,947	5,319	(140)

We define working capital as current assets less current liabilities.

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Our business has significant risks. You should consider carefully the risks described below, together with the other information contained in this Annual Report, including our financial statements and the related notes. If any of the following risks occur, our business, financial condition, results of operations and future growth prospects could be materially and adversely affected. This Annual Report also contains forward-looking statements that involve risks and uncertainties. Our results could materially differ from those anticipated in these forward-looking statements, as a result of certain factors including the risks described below and elsewhere in this Annual Report and our other SEC filings. See "Cautionary Statement Regarding Forward-Looking Statements" above.

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 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 Dry Eye Disease (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 March 31, 2022, our cash and cash equivalents balance was approximately $2.7 million and our working capital was approximately $6.9 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 October 2022 raises substantial doubt about our ability to continue as a going concern. If we are unable to improve our liquidity position by October 2022, we may not be able 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, including for funding clinical studies, registration, manufacturing, marketing, sales and distribution. In order 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 U.S. 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 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 and consultancy agreements are in place including six to 12 months' notice periods for all executive officers, they may give notice to terminate their employment or services 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 feasible. 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 by any 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 ourself 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 the 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 and UK 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 Current Good Manufacturing Practice ('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 the European Union, 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 an approved BLA 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 an approved 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, the European Union 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 the European Union 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 Patient Protection and Affordable Care Act ('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 could also 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 in the US 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 the 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 and UK 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 other similar law 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 or court–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 local and foreign laws, including US federal and state 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 or court 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 1961, and other anti-corruption laws that apply in countries where we do business. The U.K. Bribery Act 2010, 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 2010, 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

The prices of the ADSs and our ordinary shares may be volatile and fluctuate substantially, which could result in substantial losses for holders of the ADSs and our ordinary shares.

The market prices of the ADSs on the Nasdaq Capital Market and of our ordinary shares on LSE may be volatile and fluctuate substantially. The stock market in general and the market for smaller pharmaceutical and biotechnology companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, holders of the ADSs and our ordinary shares may not be able to sell their ADSs or ordinary shares at or above the price at which they were purchased. The market price for the ADSs and ordinary shares may be influenced by many factors, including:

- the success of competitive products or technologies;
- results of clinical trials of OK-101, OK-201 and any other future product candidate that we develop;
- results of clinical trials of product candidates of our competitors;
- changes or developments in laws or regulations applicable to OK-101, OK-201 and any other future product candidates that we develop;
- our entry into, and the success of, any collaboration agreements with third parties;
- developments or disputes concerning patent applications, issued patents or other proprietary rights;
- the recruitment or departure of key personnel;
- the level of expenses related to any of our product candidates or clinical development programs;
- the results of our efforts to discover, develop, acquire or in-license additional product candidates, products or technologies;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- variations in our financial results or those of companies that are perceived to be similar to us;
- market conditions in the biotechnology and pharmaceutical sectors;
- general economic, industry and market conditions;
- the trading volume of ADSs on the Nasdaq Capital Market and of our ordinary shares on LSE; and
- the other factors described in this “Risk Factors” section

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 Companies Law (Guernsey) 2008, 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 a Foreign Private Issuer ('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. We are also not required to file financial statements prepared in U.S. GAAP, to comply with Regulation FD and the proxy rules. 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, risk and disclosure committee are 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, risk and disclosure committee is not subject to additional Nasdaq requirements applicable to listed U.S. companies, including an affirmative determination that all members of the audit, risk and disclosure 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 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 March 31, 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 (EGC) 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 Jumpstart Our Business Startups (JOBS) Act, 2012). 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 March 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, which is required 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.

ADS 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 not 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 ('PFIC'), 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 out ADSs will remain listed on Nasdaq or 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 authorities 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 Our Reliance on Third Parties

We rely, and expect to continue to rely, on third parties to conduct our preclinical studies and clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates.

We have relied upon and plan to continue to rely upon third parties, including independent clinical investigators and third-party CROs, to conduct our preclinical studies and clinical trials and to monitor and manage data for our ongoing preclinical and clinical programs. In engaging these third parties, we typically have to, and expect to have to, negotiate budgets and contracts, which may result in delays to our development timelines and increases costs. Additionally, there is a limited number of qualified third-party service providers that specialize or have the expertise required to achieve our business objectives, and so it may be challenging to find alternative investigators or CROs, or do so on commercially reasonable terms. We rely on these parties for execution of our preclinical studies and clinical trials, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance on these third parties does not relieve us of our regulatory responsibilities. We and our third-party contractors and CROs are required to comply with GCP requirements, which are regulations and guidelines enforced by the FDA, the Competent Authorities of the Member States of the European Economic Area and comparable foreign regulatory authorities for all of our product candidates in clinical development. Regulatory authorities enforce these GCP requirements through periodic inspections of trial sponsors, principal investigators and clinical trial sites. If we fail to exercise adequate oversight over any of our CROs or if we or any of our CROs fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or other regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon a regulatory inspection of us or our CROs or other third parties performing services in connection with our clinical trials, such regulatory authority will determine that any of our clinical trials complies with GCP regulations. In addition, our clinical trials must be conducted with product produced under applicable cGMP regulations. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process.

Further, these investigators and CROs are not our employees, and we will not be able to control, other than by contract, the amount of resources, including time, which they devote to our product candidates and clinical trials. If independent investigators or CROs fail to devote sufficient resources to the development of our product candidates, or if their performance is substandard, it may delay or compromise the prospects for approval and commercialization of our product candidates. These investigators and CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could affect their performance on our behalf. In addition, the use of third-party service providers requires us to disclose our proprietary information to these parties, which increases the risk that a competitor will discover them or that this information will be misappropriated or disclosed.

If any of our relationships with these third-party CROs terminate, we may not be able to enter into arrangements with alternative CROs or to do so on commercially reasonable terms. If CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and commercial prospects would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Repeating clinical trials or switching or engaging additional CROs involves additional cost and requires our management's time and focus. In addition, there is a natural transition period when a clinical trial has to be repeated or when a new CRO commences work. As a result, delays could occur, which could materially impact our ability to meet our desired clinical development timelines.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

We have engaged CROs specializing in ophthalmic drug development, to prepare and support the IND filing, and we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our proprietary technology and confidential information or other unauthorized use or disclosure of such technology or information would impair our competitive position and may have an adverse effect on our business, financial condition, results of operations and prospects.

Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of these agreements, independent development or publication of information including our trade secrets by third parties. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business, financial condition, results of operations and prospects.

We utilize, and expect to continue to utilize, third parties to conduct our product manufacturing for the foreseeable future, and these third parties may not perform satisfactorily.

We will rely on contract manufacturing organizations (CMOs) for the manufacturing of clinical batches and intend to continue to rely on third parties to manufacture our preclinical study and clinical trial product supplies. If our current CMOs, or any future third-party manufacturers, do not successfully carry out their contractual duties, meet expected deadlines or manufacture our product candidates in accordance with regulatory requirements, or if there are disagreements between us and our CMOs or any future third-party manufacturers, we will not be able to complete, or may be delayed in completing, the preclinical studies required to support future investigational new drug, or IND, submissions and the clinical trials required for approval of our product candidates.

In addition to our current CMOs, we may rely on additional third parties to manufacture ingredients of our product candidates in the future and to perform quality testing, and reliance on these third parties entails risks to which we would not be subject if we manufactured the product candidates ourselves, including:

- reduced control for certain aspects of manufacturing activities;
- termination or nonrenewal of manufacturing and service agreements with third parties in a manner or at a time that is costly or damaging to us; and
- disruptions to the operations of our third-party manufacturers and service providers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or service provider.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval or impact our ability to successfully commercialize any of our product candidates. Some of these events could be the basis for FDA, EMA or other regulatory authority action, including injunction, recall, seizure or total or partial suspension of product manufacture.

To the extent we rely on a third-party manufacturing facility for commercial supply, that third party will be subject to significant regulatory oversight with respect to manufacturing our product candidates.

The preparation of therapeutics for clinical trials or commercial sale is subject to extensive regulation. Components of a finished therapeutic product approved for commercial sale or used in late-stage clinical trials must be manufactured in accordance with cGMP requirements. These regulations govern manufacturing processes and procedures, including record keeping, and the implementation and operation of quality systems to control and assure the quality of investigational products and products approved for sale. Poor control of production processes can lead to the introduction of outside agents or other contaminants, or to inadvertent changes in the properties or stability of a product candidate that may not be detectable in final product testing. To the extent that we utilize third-party facilities for commercial supply, the third party's facilities and quality systems must pass an inspection for compliance with the applicable regulations as a condition of regulatory approval. In addition, the regulatory authorities may, at any time, audit or inspect the third-party manufacturing facility or the associated quality systems for compliance with the regulations applicable to the activities being conducted. If, for example, these facilities do not pass a plant inspection, the FDA will not approve the applicable New Drug Application ('NDA') or biologics license application, or BLA.

We do not directly control the manufacturing of, and are completely dependent on, our CMOs for compliance with cGMP requirements. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, EMA or other regulatory authorities, they will not be able to secure and/or maintain regulatory approval for their manufacturing facilities. In addition, we have no direct control over the ability of our CMOs to maintain adequate quality control, quality assurance and qualified personnel. Furthermore, all of our CMOs are engaged with other companies to supply and/or manufacture materials or products for such companies, which exposes our CMOs to regulatory risks for the production of such materials and products. As a result, failure to meet the regulatory requirements for the production of those materials and products may generally affect the regulatory clearance of our CMOs' facilities. Our failure, or the failure of third parties, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates or products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products and product candidates.

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

ITEM 4: INFORMATION ON THE COMPANY

A. History and Development of the Company

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 standard listing of 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 annual report. Our agent for service of process in the United States is OKYO Pharma US, Inc.

The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers, such as us, that file electronically, with the SEC at www.sec.gov.

B. Business Overview

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. 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. We have not yet submitted an application to the Food and Drug Administration ("FDA") for any of our product candidates. We have however significantly advanced our ongoing Investigational New Drug ("IND) enabling work on our lead candidate OK-101 during this past year for an IND submission for OK-101 to treat dry eye and are presently on schedule to file an IND on OK-101 to treat dry eye disease in the fourth quarter of 2022. (see Figure 1 below).

Figure 1. OKYO Pipeline

**Anticipated IND Submission date Q4, 2022*
***Topical drug delivery*

The evidence from over 40 years of scientific literature suggests inflammation as the most common underlying cause 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. 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 dry eye syndrome represents a major expanding economic burden to public healthcare. According to Market Research Report, Dry Eye Syndrome, 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 essentially three major prescription drugs used to treat DED: 1) R Cyclosporine (Restasis® & Cequa®), 2) Lifitegrast (Xiidra®), and 3) Varenicline (Tyrvaya®). However, DED continues to be a major unmet medical need due to the large number of patients not well served by present-day treatments due to their lack of adequate efficacy, slow onset of action and poor side effect profile. 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 cause of DED. Consequently, development of new therapeutic agents that target inflammatory pathways is crucial in improving symptoms in DED patients. OK-101 is focused on an anti-inflammatory pathway for treating dry eye.

OK-101 is designed to target a chemokine-like receptor 1, or CMKLR1, or CHEMR23, which is a G protein-coupled receptor expressed on macrophages, neutrophils, monocytes, plasmacytoid/myeloid dendritic cells, natural killer cells and nonhemopoietic cell types, such as endothelial and epithelial cells. Activation of CMKLR1 by its endogenous peptide ligand chemerin is known to modulate inflammation, 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 (Note: technology licensed to OKYO Pharma Limited) 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. (See Figure 2).

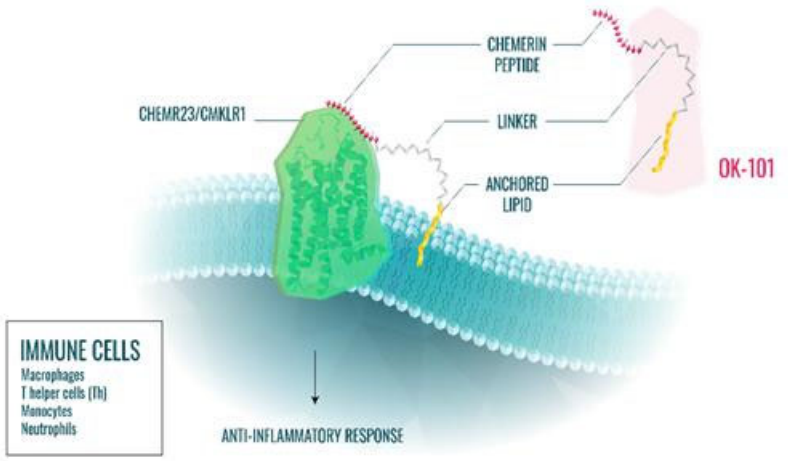


Figure 2. OK-101 binds to CHEMR23 receptor producing an anti-inflammatory response

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.

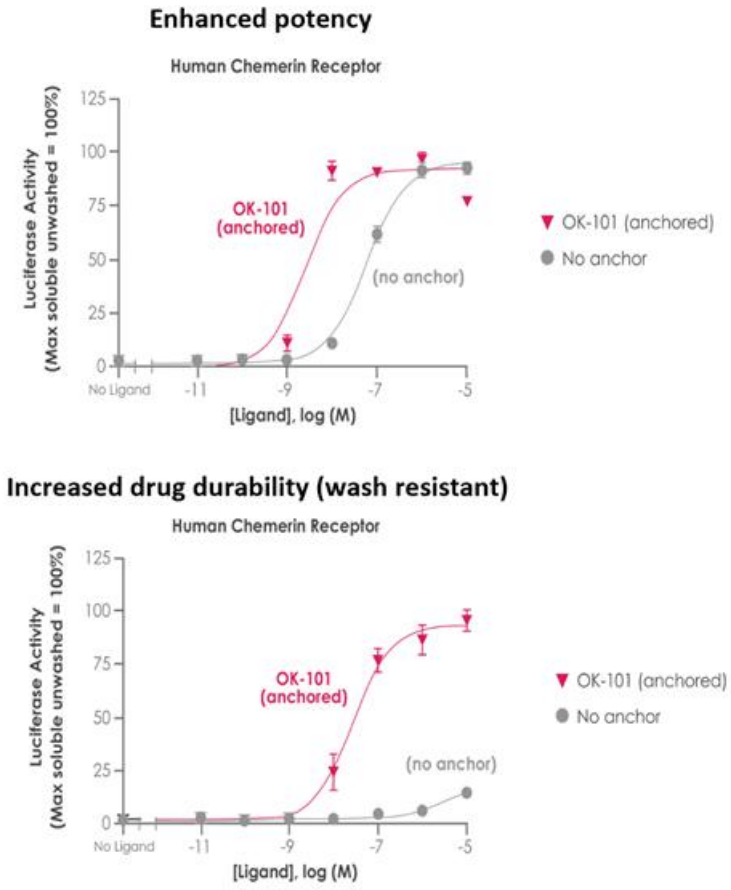


Figure 3 shows the significance of including a lipid anchor in the "chemerin" molecule on drug potency and wash resistance conducted in a series of *in vitro* studies. HEK293 cells were transiently transfected with cDNAs encoding human chemerin receptor CMKLR1. Twenty-four hours after transfection, cells 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 Standard Error. from at least three independent experiments, each performed in triplicate. The lipidated stable chemerin analog OK-101 showed a 50-fold higher potency against human chemerin receptor than the corresponding non-lipidated peptide (Figure 3 top panel). Signaling of the lipidated stable chemerin analog OK-101 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 µL 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 µL (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 EnvisionTM 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.

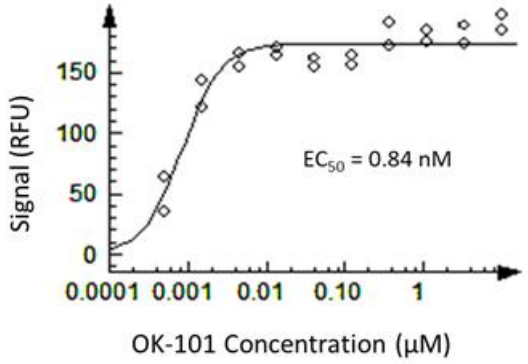


Figure 4. Agonist activity of OK-101 using PathHunter® β-Arrestin assay

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.

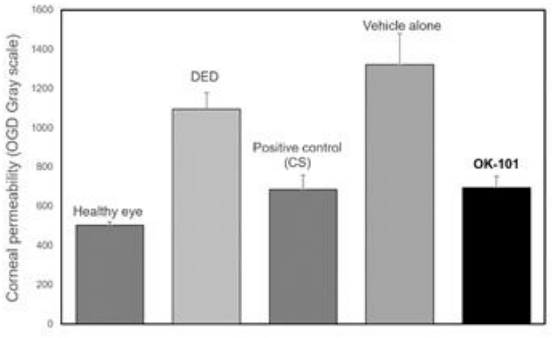


Figure 5. Effect of various treatments on mouse corneal permeability. Corneal permeability was measured using Oregon Green Dextran (OGD) staining followed by imaging. CS was positive control.

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.

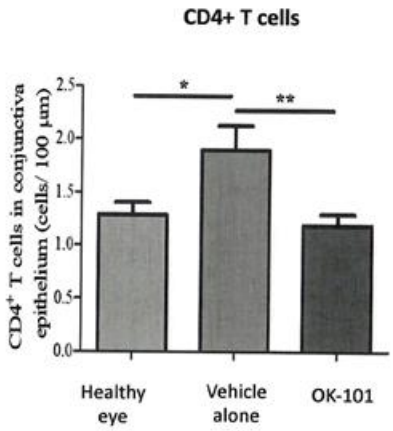


Figure 6. CD4+ T cells in the conjunctival epithelium after acute DED induction.

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.

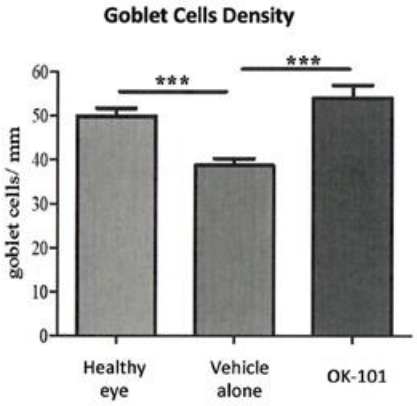


Figure 7. Goblet Cell density following acute DED induction.

In addition, in a separate set of animal model experiments, we evaluated pain-reducing activity of OK-101 in a ciliary nerve ligation mouse model of corneal neuropathic pain. Neuropathic corneal pain is a severe, chronic and debilitating disease with no FDA approved commercially available treatments currently available for this condition. In collaboration with Pedram Hamrah, MD, Professor of Ophthalmology, cornea specialist, and clinician-scientist at Tufts Medical Center, Boston, we demonstrated that OK-101 suppresses neuropathic corneal pain in a mouse model of neuropathic corneal pain 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 oral drug for neuropathic pain. 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 effect on corneal epithelial integrity compared to gabapentin or balanced salt solution.

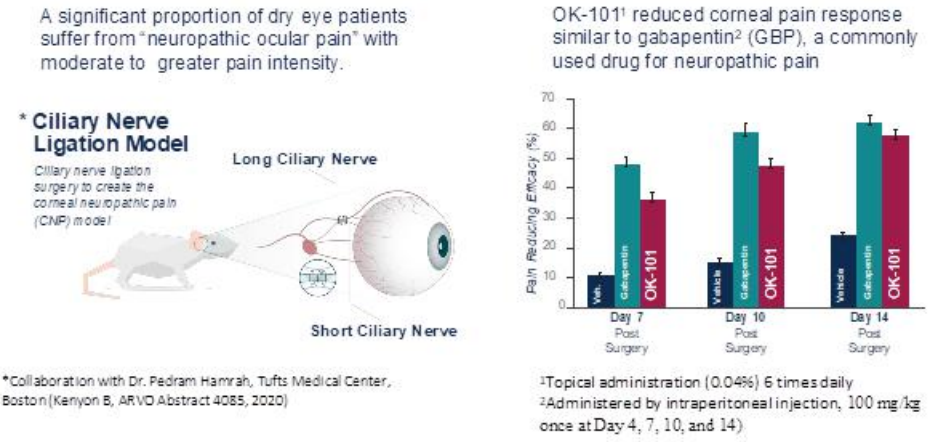


Figure 8. *OK-101 ameliorates neuropathic corneal pain in a mouse model of ciliary nerve ligation*

A separate series of experiments were 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 results from earlier DED animal model studies that have been performed with OK-101 as well as the additional animal study illuminating the potential of OK-101 to reduce corneal neuropathic pain, we are moving forward with plans to file an IND in the fourth quarter of 2022 on OK-101 to treat DED to enable us to begin clinical trials soon thereafter. During the second quarter of 2021 we successfully manufactured a 200-gram batch of OK-101 drug substance needed for the IND-enabling studies. To support the IND preparatory work, we also signed an agreement in April 2021 with Ora Inc., a major CRO specializing in ophthalmic drug development who is providing the following consulting services:

- Preparation of the OK-101 pre-IND briefing document
- Support in requesting and preparing for the OK-101 pre-IND meeting with FDA
- Support for regulatory publishing and submission of IND in Electronic Common Technical Document (eCTD) format

- Providing quality oversight for development of topical formulation for OK-101
- Providing quality oversight for development and qualification of a drug stability analysis method for OK-101 along with conducting stability studies to establish that the formulated drug product is stable for at least 90 days
- Support for completing animal toxicology studies in two animal species

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 cause 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.

During 2022 we have significantly advanced our efforts to finish all IND-enabling activities and are presently on track to file an IND on OK-101 to treat DED in the fourth quarter of 2022. These ongoing activities have included:

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

Based on recent consultations with Ora, we plan to commence the first human study with OK-101 in the first 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. Consequently, 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 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 6-8 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 decision to designate co-primary efficacy endpoints covering both a sign and a symptom of DED in the clinical protocol of the trial. The decision to designate efficacy endpoints as primary endpoints in this trial is highly significant as should this trial meet its prespecified primary endpoints, this result could accelerate the timeline to an NDA filing with the FDA.

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 DED, 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 of 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 August 10, 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

On Target Therapeutics (OTT) and Tufts Medical Centre (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 they 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 on 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 is currently expected to take effect in 2019, there will be 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 Committee for Medicinal Products for Human Use (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 adopts 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 redacted 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. 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 state 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 U.S. states have similar laws and regulations that may differ from each other and federal law in significant ways. Moreover, several U.S. 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 States 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. 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 European 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). The European Commission proposed the ePrivacy Regulation in January 2017. It was intended to take effect alongside the EU GDPR (General Data Protection Regulation) on 25 May 2018.However, the final text is still to be agreed, with the Council of the European Union and the European Parliament disagreeing about a number of issues.

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.

C. Organizational Structure

The following table sets out details of the Company's only subsidiary:

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

D. Property, Plant and Equipment

The below table contains information regarding existing or planned material tangible fixed assets owned or leased by OKYO Pharma Ltd and its 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 Avenue Suite 1402 New York, NY 10170	6 Months	CEO Office

ITEM 4A: UNRESOLVED STAFF COMMENTS

Not applicable.

ITEM 5: OPERATING AND FINANCIAL REVIEW AND PROSPECTS

You should read the following discussion and analysis of our financial condition and results of operations together with "Selected Consolidated Financial Data" and our consolidated financial statements and the related notes thereto appearing at the end of this Annual Report. We present our consolidated financial statements in U.S. dollars and in accordance with International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB.

Some information included in this discussion and analysis, including statements regarding industry outlook, our expectations regarding our future performance, liquidity and capital resources and other statements regarding our plans and strategy for our business and related financing, are forward-looking statements. These forward-looking statements are subject to numerous risks and uncertainties. You should read the "Risk Factors" section of this Annual Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

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.

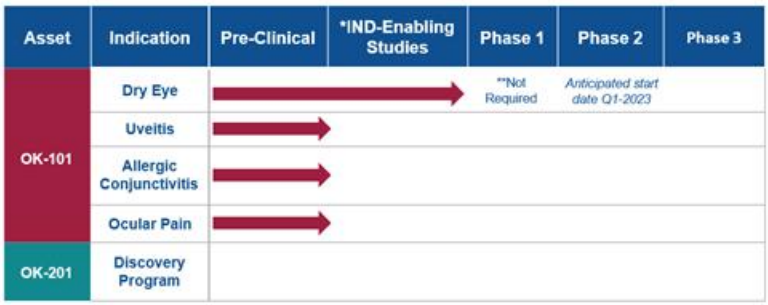
Overview

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. 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 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.

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 is a significant step for us, highlighting a careful realignment of the strategic focus of our research and development program. We believe this realignment will allow us to file IND applications on our drug candidates from with FDA in the shortest time possible. We have not yet submitted an application to the FDA for any of our product candidates. We have however significantly advanced our ongoing IND enabling work on our lead candidate OK-101 during this past year for an IND submission for OK-101 to treat dry eye and are presently on schedule to file an IND on OK-101 to treat dry eye disease in the fourth quarter of 2022. (see Figure 1 below)

Figure 1. OKYO Pipeline



**Anticipated IND Submission date Q4, 2022*
***Topical drug delivery*

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 our functional currency 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

R&D expenses consist primarily of costs incurred in connection with the R&D 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 clinical trials, preclinical studies and other scientific development services;
- manufacturing scale-up expenses and the cost of acquiring and manufacturing materials for preclinical studies and clinical trial materials;
- employee-related expenses, including salaries, related benefits, travel and share-based compensation expense for employees engaged in R&D 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 R&D 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 R&D 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 R&D 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 R&D expenses incurred by program:

	Year ended March 31,		
	2022	2021	2020
Direct research and development expense by program:			
OK-101	$ 1,300,664	$ 170,417	$ 449,580
OK-201	514	3,404	68,518
Total direct research and development expense	$ 1,301,178	$ 173,821	$ 518,098
Total research and development expense	$ 1,301,178	$ 173,821	$ 518,098

R&D 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 R&D 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 R&D 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.

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 R&D relief allows us to claim back up to 14.5% of our surrenderable losses as a tax cash credit.

A. 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 Years Ended March 31, 2022 and 2021

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

	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	$ (6,217,566)	$ (3,366,206)	$ (2,851,360)
Other Income/ (Expense)	-	(12,295)	12,295
Tax credit	786,521	24,994	761,527
Net Loss	$ (5,431,045)	$ (3,353,507)	$ (2,077,538)
Other comprehensive loss:			
Foreign currency translation adjustment	(837,152)	346,365	(1,183,517)
Total Comprehensive (Loss)	$ (6,268,197)	$ (3,007,142)	$ (3,261,055)

Research and Development Expenses

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 R&D activity after the temporary pause in R&D activity in 2020 while the Scientific Advisory Board and management team were established.

General and Administrative Expenses

Operating 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. 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.

Comparison of Years Ended March 31, 2021 and 2020

The following tables summarizes our results of operations for the years ended March 31, 2021 and 2020:

	Year Ended March 31,		
	2021	**2020**	**Change**
Operating Expenses:			
Research and development	$ (173,821)	$ (518,098)	$ 344,277
General and administrative	$ (3,192,385)	$ (1,016,548)	$ (2,175,837)
Total Operating expenses	$ (3,366,206)	$ (1,534,646)	$ (1,831,560)
Other Income/ (Expense)	(12,295)	(85,701)	73,407
Tax credit	24,994	76,289	(51,295)
Net Loss	$ (3,353,507)	$ (1,544,059)	$ (1,809,448)
Other comprehensive loss:			
Foreign currency translation adjustment	346,365	86,654	259,711
Total Comprehensive (Loss)/Profit	$ (3,007,142)	$ (1,457,405)	$ (1,549,737)

Research and Development Expenses

Research and development activities were $173,821 for the year ended March 31, 2021 compared to $518,098 for the year ended March 31, 2020. The decrease of $344,277 is due to the temporary pause in R&D activity in the year to March 31, 2021 while the Scientific Advisory Board and team were established.

General and Administrative Expenses

General and administrative expenses were $3,192,385 and $1,016,548 for the year ended March 31, 2021 and 2020. The increase of $2,175,837 is predominantly due to bonuses accrued of approximately $1,200,000, additional share-based payment charges of approximately $485,000, additional legal and audit costs of approximately $142,000 and realized foreign exchange approximately $466,000 offset by savings of approximately $103,000.

Income Tax Credit

Income tax credits of $24,994 and $76,288 are recognized for the years ended March 31, 2021 and 2020, respectively. The credits are obtained at a rate of 14.5% of 230% of our qualifying research and development expenditure. The decrease in the provision is due primarily to the decrease in qualifying research and development expenditure incurred in the year ending March 31, 2021.

B. 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, American Depository Shares, or ADSs, and convertible loan notes.

As of March 31, 2022, we had cash and cash equivalents of $2,700,724.

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

Cash Flows

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

	Year ended March 31,		
	2022	2021	2020
Net cash used in operating activities	$ (5,468,065)	$ (1,600,198)	$ (1,202,066)
Net cash used in investing activities	(1,669)	(18,114)	(132,668)
Net cash provided by financing activities	2,153,270	7,826,938	963,310
Effect of exchange rate changes on cash and cash equivalents	(872,141)	445,217	(20,708)
Net (decrease)/increase in cash and cash equivalents	$ (3,316,464)	$ 6,208,627	$ (371,423)

Net Cash Used in Operating Activities

Our use of cash in each of the years ended March 31, 2022, 2021 and 2020, 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.

Our use of cash in each of the years ended March 31, 2021 and 2020 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 $1,600,198 during the year ended March 31, 2021 increased by $398,132 compared to the year ended March 31, 2020. The increase in net cash used in operating activities was primarily due to increased activity.

Net Cash Used in Investing Activities

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 advances under a loan facility to West African Minerals Ltd. During the year ended March 31, 2020, $132,668 was used for the same reason.

Net Cash Provided by Financing Activities

During the years ended March 31, 2022 and 2021, net cash provided by financing activities was $1,378,387 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.

During the year ended March 31, 2021, and 2020, net cash provided by financing activities was $7,826,938 and $963,310, respectively, consisting of net cash proceeds from our sale and issuance of ordinary shares and entering into fixed term convertible loan agreements.

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 do not believe that our existing cash, will enable us to fund our operating expenses and capital expenditure requirements for the foreseeable future. We have 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 $112m , a net loss for the year ended March 31, 2022, of $5.4m and net cash used in operating activities of $5.5m.

We 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, we conclude significant doubt exists about the Group's ability to continue as a going concern. 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. See note 2 in the consolidated financial statements.

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 and other financing activities such as debt arrangements. 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.

C. Research and Development Expenses, Patents and Licenses, etc.

See “Item 4.B.—Business Overview,” and “Item 5. Operating and Financial Review and Prospects.”

D. Trend Information

See “Item 5. Operating and Financial Review and Prospects—Trend Information.”

E. Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

F. Tabular Disclosure of Contractual Obligations

The following table summarizes our contractual commitments and obligations as of March 31, 2022 and 2021.

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	$ -	-

As at March 31, 2021

(in thousands)	Total	Less than 1 Year	Between 1 and 5 Years	More than 5 Years
Borrowings	$ 8,371	-	-	8,371
Operating lease obligations	$ 107	$ 42	$ 65	-
Total	$ 8,478	$ 42	$ 65	8,371

Please refer to “Item 4 B. Business Overview” and “Item 10.C. Material Contracts” for further details.

G. Safe Harbor

This Annual Report on Form 20-F contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act and as defined in the Private Securities Litigation Reform Act of 1995. See the section titled “Cautionary Statement Regarding Forward-Looking Statements”.

ITEM 6: DIRECTORS, SENIOR MANAGEMENT AND EMPLOYEES

A. Directors and Senior Management

The following table sets forth information regarding our directors and senior management as of the date of this annual report.

Name	Age	Position
Gabriele Marco Antonio Cerrone MBA (2)	50	Non-Executive Chairman
Dr. Gary S. Jacob	75	CEO and Executive Director
Dr. Raj Patil	64	Chief Scientific Officer
Keeren Shah	46	Chief Financial Officer
Willy Simon (1) (2) (3)	70	Senior 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) Nomination Committee member
(3) Audit, risk and disclosure Committee member

Gabriele Marco Antonio Cerrone – *Non-Executive Chairman*

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, and 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 he served as its Chairman from September 2013 to November 2018. 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 Wiess 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 Finance Director 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 programs 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 Honors in Economics and is a member of the Chartered Institute of Management Accountants.

Willy Simon – *Non-Executive Director*

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 – *Non-Executive Director*

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, Cardiff Oncology, Inc. since December 2005 and Tiziana Life Sciences Limited since July 2020. Mr. Brancaccio served as a director of Synergy from July 2008 until April 2019.

Bernard Denoyer– *Non-Executive Director*

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. He is currently serving on the Board of Trustees for two not-for-profits, St. Edmunds Retreat, Inc. and Midwestern Connecticut Council on Alcoholism, Inc.

Family Relationships

There are no family relationships among any of our executive officers or directors.

B. Compensation

Total Compensation for the Non-Executive Chairman and Non-Executive Directors

The table below sets out the total remuneration received by the Non-Executive Chairman and the Non-Executive Directors for the year ended March 31, 2022.

Name	Position	Fees earned or paid in cash ($000) (1)	Options awarded ($000) (2)	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 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 6, 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.

Compensation of Executive Directors

The table below sets the remuneration of each of the 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)
Gary Jacob	Executive Director	350	75	517	942

(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.

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.

Outstanding Equity Awards at Fiscal Year-End

The following table provides information regarding all outstanding equity awards for our directors, executive officers, and non-executive directors, as of March 31, 2022:

Name	Ordinary Shares Underlying Options	Exercise Price Per Ordinary Share (£)	Grant Date	Expiration Date
Gary Jacob	40,000,000	0.05	06/01/2021	05/01/2031
	13,000,000	0.049	31/08/2021	30/08/2031
Willy Simon	2,000,000	0.045	06/07/2018	06/07/2028
John Brancaccio	450,000	0.155	20/08/2020	20/08/2030
	900,000	0.049	31/08/2021	30/08/2031
	100,000	0.08	31/01/2022	31/01/2032
Bernard Denoyer	1,000,000	0.08	31/01/2022	31/01/2032

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

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

Eligibility

All executive directors, officers and employees of the Company and any of its subsidiaries are eligible to participate in the Unapproved 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 Main Market of the London Stock Exchange, 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 Main Market of the London Stock Exchange, 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 Unapproved 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, their 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 their 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 Unapproved 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 Unapproved 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 Unapproved 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 Unapproved Share Option Plan except that (apart from minor amendments to benefit the administration of the 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 Unapproved 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 Unapproved Share Option Plan at any time, whereupon no further share options shall be granted but in all other respects the provisions of the Unapproved 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 Unapproved Share Option Plan is adopted.

C. Board Practices

Corporate Governance Practices

We are a "foreign private issuer," 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 have a compensation 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 follow the QCA code corporate governance practices in lieu of Nasdaq corporate governance requirements as follows:

- We do not follow Nasdaq Rule 5620(c) regarding quorum requirements applicable to meetings of shareholders. Such quorum requirements are not required under English law. In accordance with generally accepted business practice, our Articles of Association will provide alternative quorum requirements that are generally applicable to meetings of shareholders.

- We do not 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 a foreign private issuer 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 Articles of Association—Differences in Corporate Law."

Compliance with the Quoted Companies Alliance Corporate Governance Code

All companies with securities admitted to trading on LSE are required to include on their website details of a recognized corporate governance code that the board of directors of the company have decided to apply, how the company complies with that code, and where it departs from its chosen corporate governance code an explanation of the reasons for doing so. This information is required to be reviewed annually.

The company has decided to apply the Corporate Governance Code published by the Quoted Companies Alliance, or the QCA Code. The QCA Code sets out a standard of minimum best practice for small and midsize quoted companies.

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	2014	2022
Gary Jacob	2015	2022
Willy Simon	2016	2022
John Brancaccio	2020	2022
Bernard Denoyer	2021	2022

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, risk and disclosure committee, a remuneration committee and a nomination 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, risk and disclosure committee. The audit, risk and disclosure 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, risk and disclosure committee satisfy the "independence" requirements set forth in Rule 10A-3 under the Exchange Act. The audit, risk and disclosure committee will be governed by a charter that complies with Nasdaq rules.

The audit, risk and disclosure 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.

Nomination Committee

The nomination committee consists of Mr. Denoyer, Mr. Brancaccio and Mr. Simon. Mr. Denoyer serves as chairman of the nomination committee. The nomination 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 Okyo Pharma Ltd or our subsidiary that provide for benefits upon termination of employment.

D. Employees

As of March 31, 2022, we had 3 full time employees. Two of our employees were engaged in research and development and one employee was engaged in management, administration and finance. One is located in England and two 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 Companies (Guernsey) Law, 2008, 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 annual report.

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.

E. Share Ownership

See "Item 7. Major Shareholders and Related Party Transactions."

ITEM 7: MAJOR SHAREHOLDERS AND RELATED PARTY TRANSACTIONS

A. Major Shareholders

The following table sets forth information relating to the beneficial ownership of our ordinary shares as of July 21, 2022 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 July 21, 2022 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.

	Number of Ordinary Shares Beneficially Owned	
Name of beneficial owner	**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)]	1,807,100	*
Gary Jacob [(3)]	10,000,000	*
John Brancaccio[(4)]	112,500	*
Bernard Denoyer	-	-
All directors and executive officers as a group (5 persons)[(3)]	564,963,315	39.60

* 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 1,500,000 stock options which are currently exercisable or exercisable within 60 days of July 21, 2022

(3) Consists of 10,000,000 stock options which are currently exercisable or exercisable within 60 days of July 21, 2022

(4) Consists of 112,500 stock options which are currently exercisable or exercisable within 60 days of July 21, 2022

B. Related Party Transactions

The following is a description of related party transactions we have entered into since April 1, 2021, with the beneficial owners of 5% or more of our ordinary shares, which are our only voting securities, and senior management and members of our board of directors.

Indemnity Agreements

We have entered into deeds of indemnity with each of our directors.

Shared services Agreements

We have entered into a Shared Services agreement with Tiziana whereby we are charged for shared services such as payroll and rent.

Related Person Transaction Policy

Our board of directors has adopted a written related person transaction policy, effective as of May 10, 2022. This policy covers, 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, risk and disclosure 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.

C. Interests of Experts and Counsel

Not applicable.

ITEM 8: FINANCIAL INFORMATION

A. Consolidated Statements and Other Financial Information

See "Item 18. Financial Statements".

Legal Proceedings

Save as disclosed in this paragraph, there are no governmental, legal or arbitration proceedings (including any such proceedings which are pending or threatened of which the Company is aware), which may have, or have had during the 12 months prior to the date of this annual report, a significant effect on the Company's and/or our financial position or profitability. In addition to the proceedings set out in this section, the Company is not involved in other legal proceedings and claims in the ordinary course of business.

B. Significant Changes

See Note 25 of our consolidated financial statements at the end of this Annual Report for a description of the significant changes since March 31, 2022.

ITEM 9: THE LISTING

A. Listing Details

The principal trading market for our ordinary shares is the main market of the London Stock Exchange (LSE), where our ordinary shares have been listed since July 17, 2018. 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 London Stock Exchange for our ordinary shares in pounds Sterling. See "Exchange Rate Information" on page 4 for the exchange rates applicable to the periods set forth below.

Our ordinary shares have been trading on the Main Market of the London Stock Exchange under the symbol "OKYO" since July 17, 2018.

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 Main Market of the London Stock Exchange 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 July 29, 2022 which was £1.00 to $1.2183.

	Price Per Ordinary Share £		Price Per Ordinary Share $	
	High	**Low**	**High**	**Low**
Year Ended March 31, 2023				
First Quarter	0.065	0.026	0.079	0.032
Second Quarter (to August 3, 2022)	0.028	0.020	0.033	0.024
Year Ended March 31, 2022				
First Quarter	0.078	0.060	0.094	0.073
Second Quarter	0.065	0.040	0.079	0.049
Third Quarter	0.085	0.041	0.104	0.050
Fourth Quarter	0.083	0.048	0.101	0.058
Year Ended March 31, 2021				
First Quarter	0.055	0.017	0.067	0.021
Second Quarter	0.180	0.053	0.219	0.064
Third Quarter	0.121	0.071	0.147	0.087
Fourth Quarter	0.120	0.076	0.146	0.093
Year Ended March 31, 2020				
First Quarter	0.021	0.011	0.026	0.013
Second Quarter	0.059	0.021	0.072	0.025
Third Quarter	0.043	0.017	0.052	0.021
Fourth Quarter	0.023	0.013	0.027	0.015

On August 3, 2022 the last reported sale price of our ordinary shares on LSE was £0.019 per ordinary share ($0.023 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.

	Price Per ADS $	
	High	**Low**
Monthly:		
June 2022	2.60	1.88
July 2022	2.35	1.95
August 2022 (to August 3, 2022)	2.37	1.96

On August 3, 2022, the last reported sale price of our ADS's on the Nasdaq Capital Market was $1.96 per ADS.

B. Plan of Distribution

Not applicable.

C. Markets

Our ordinary shares are listed on LSE under the symbol "OKYO" and our ADSs are listed on the Nasdaq Global Market under the symbol "OKYO".

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

ITEM 10: ADDITIONAL INFORMATION

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

We incorporate by reference into this Annual Report the description of our amended articles of association contained in our Registration Statement on Form F-1 originally filed with the SEC on March 4, 2022, as amended.

C. Material Contracts

Except as otherwise disclosed in this Annual Report (including the exhibits hereto), we are not currently, and have not been in the last two years, party to any material contract, other than contracts entered into in the ordinary course of business.

D. Exchange Controls

There are no governmental laws, decrees, regulations or other legislation in the United Kingdom that may affect the import or export of capital, including the availability of cash and cash equivalents for use by us, or that may affect the remittance of dividends, interest, or other payments by us to non-resident holders of our ordinary shares or ADSs, other than withholding tax requirements. There is no limitation imposed by English and our Guernsey law or our articles of association on the right of non-residents to hold or participate in shareholders vote.

E. Taxation

Material U.S. Federal Income Tax Considerations for U.S. Holders

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 tax purposes. This discussion is based on the Internal Revenue Code, U.S. Treasury regulations promulgated thereunder and administrative and judicial interpretations thereof, and the income tax treaty between the United Kingdom and the United States, or the Treaty, 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.

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 (i) 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 (ii) 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 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 (PFIC) 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," or 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, or 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, we believe we were a PFIC for our 2017 tax year and we expect to be a PFIC for our current taxable year. There can be no assurance that we will not be a PFIC in future taxable years. 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 could 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 year during which a U.S. Holder holds our ADSs, we must generally continue to be treated as a PFIC by that U.S. Holder for all succeeding years during which the U.S. Holder holds such ADSs, unless we cease to meet the requirements for PFIC status and the U.S. Holder makes a "deemed sale" election with respect to our ADSs. If the election is made, the U.S. Holder will be deemed to sell our ADSs it holds at their fair market value on the last day of the last taxable year in which we qualified as a PFIC, and any gain recognized from such deemed sale would be taxed under the PFIC excess distribution regime. After the deemed sale election, the U.S. Holder's ADSs would not be treated as shares of a PFIC unless we subsequently become a PFIC.

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 are a PFIC would also be different from those described above if a U.S. Holder were able to make a valid Qualified Electing Fund (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 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 a 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. The amount of a dividend will include any amounts withheld by the company in respect of United Kingdom taxes.

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. Subject to applicable limitations, some of which vary depending upon the U.S. Holder's particular circumstances, any United Kingdom income taxes withheld from dividends on ADSs at a rate not exceeding the rate provided by the Treaty will be creditable against the U.S. Holder's U.S. federal income tax liability. The rules governing foreign tax credits are complex and U.S. Holders should consult their tax advisers regarding the creditability of foreign taxes in their particular circumstances. In lieu of claiming a foreign tax credit, U.S. Holders may, at their election, deduct foreign taxes, including any United Kingdom income tax, in computing their taxable income, subject to generally applicable limitations under U.S. law. An election to deduct foreign taxes instead of claiming foreign tax credits applies to all foreign taxes paid or accrued in the taxable year. 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 gains or losses 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 a long-term capital gain taxable at a reduced rate for non-corporate U.S. Holders or a 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 a long-term capital gain is taxed at ordinary income tax 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 a 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 THEIR OWN TAX ADVISOR ABOUT THE TAX CONSEQUENCES TO THEM OF AN INVESTMENT IN OUR ADSS IN LIGHT OF THE INVESTOR'S OWN CIRCUMSTANCES. IN ADDITION, SIGNIFICANT CHANGES IN U.S. FEDERAL INCOME TAX LAWS WERE RECENTLY ENACTED. PROSPECTIVE INVESTORS SHOULD ALSO CONSULT WITH THEIR TAX ADVISORS WITH RESPECT TO SUCH CHANGES IN U.S. TAX LAW AS WELL AS POTENTIAL CONFORMING CHANGES IN STATE TAX LAWS.

U.K. Taxation

The following is intended as a general guide to current U.K. tax law and Her Majesty's Revenue & Customs, or HMRC, published practice applying as at the date of this annual report (both of which are subject to change at any time, possibly with retrospective effect) relating to the holding of ADSs. It does not constitute legal or tax advice and does not purport to be a complete analysis of all U.K. tax considerations relating to the holding of ADSs, or all of the circumstances in which holders of ADSs may benefit from an exemption or relief from U.K. taxation. It is written on the basis that the company does not (and will not) directly or indirectly derive 75% or more of its qualifying asset value from U.K. land, and that the company is and remains solely resident in the U.K. for tax purposes and will therefore be subject to the U.K. tax regime and not the U.S. tax regime save as set out above under "U.S. Federal Income Taxation."

Except to the extent that the position of non-U.K. resident persons is expressly referred to, this guide relates only to persons who are resident (and, in the case of individuals, domiciled or deemed domiciled) for tax purposes solely in the U.K. and do not have a permanent establishment or fixed base in any other jurisdiction with which the holding of the ADSs is connected, or U.K. Holders, who are absolute beneficial owners of the ADSs (where the ADSs are not held through an Individual Savings Account or a Self-Invested Personal Pension) and who hold the ADSs as investments.

This guide may not relate to certain classes of U.K. Holders, such as (but not limited to):

- persons who are connected with the company;
- financial institutions;
- insurance companies;
- charities or tax-exempt organizations;
- collective investment schemes;
- pension schemes;
- market makers, intermediaries, brokers or dealers in securities;
- persons who have (or are deemed to have) acquired their ADSs by virtue of an office or employment or who are or have been officers or employees of the company or any of its affiliates; and
- individuals who are subject to U.K. taxation on a remittance basis.

The decision of the First-tier Tribunal (Tax Chamber) in *HSBC Holdings PLC and The Bank of New York Mellon Corporation v HMRC* (2012) cast some doubt on whether a holder of a depositary receipt is the beneficial owner of the underlying shares. However, based on published HMRC guidance we would expect that HMRC will regard a holder of ADSs as holding the beneficial interest in the underlying shares and therefore these paragraphs assume that a holder of ADSs is the beneficial owner of the underlying ordinary shares and any dividends paid in respect of the underlying ordinary shares (where the dividends are regarded for U.K. purposes as that person's own income) for U.K. direct tax purposes.

THESE PARAGRAPHS ARE A SUMMARY OF CERTAIN U.K. TAX CONSIDERATIONS AND ARE INTENDED AS A GENERAL GUIDE ONLY. IT IS RECOMMENDED THAT ALL HOLDERS OF ADSs OBTAIN ADVICE AS TO THE CONSEQUENCES OF THE ACQUISITION, OWNERSHIP AND DISPOSAL OF THE ADSs IN THEIR OWN SPECIFIC CIRCUMSTANCES FROM THEIR OWN TAX ADVISORS. IN PARTICULAR, NON-U.K. RESIDENT OR DOMICILED PERSONS ARE ADVISED TO CONSIDER THE POTENTIAL IMPACT OF ANY RELEVANT DOUBLE TAXATION AGREEMENTS.

Dividends

Withholding Tax

Dividends paid by the company will not be subject to any withholding or deduction for or on account of U.K. tax, irrespective of the residence or particular circumstances of the holders of ADSs.

Income Tax

An individual U.K. Holder may, depending on his or her particular circumstances, be subject to U.K. tax on dividends received from the company. An individual holder of ADSs who is not resident for tax purposes in the United Kingdom should not be chargeable to U.K. income tax on dividends received from the company unless he or she carries on (whether solely or in partnership) a trade, profession or vocation in the U.K. through a branch or agency to which the ADSs are attributable. There are certain exceptions for trading in the U.K. through independent agents, such as some brokers and investment managers.

All dividends received by an individual U.K. Holder from us or from other sources will form part of that U.K. Holder's total income for income tax purposes and will constitute the top slice of that income. A nil rate of income tax will apply to the first £2,000 of taxable dividend income received by the individual U.K. Holder in a tax year. Income within the nil-rate band will be taken into account in determining whether income in excess of the £2,000 tax-free allowance falls within the basic rate, higher rate or additional rate tax bands. Dividend income in excess of the tax-free allowance will (subject to the availability of any income tax personal allowance) be taxed at 7.5 per cent. to the extent that the excess amount falls within the basic rate tax band, 32.5 per cent. to the extent that the excess amount falls within the higher rate tax band and 38.1 per cent. to the extent that the excess amount falls within the additional rate tax band.

Corporation Tax

A corporate holder of ADSs who is not resident for tax purposes in the United Kingdom should not be chargeable to U.K. corporation tax on dividends received from the company unless it carries on (whether solely or in partnership) a trade in the United Kingdom through a permanent establishment to which the ADSs are attributable.

Corporate U.K. Holders should not be subject to U.K. corporation tax on any dividend received from the company so long as the dividends qualify for exemption, which should be the case, provided the dividends fall within an exempt class and certain conditions are met. If the conditions for the exemption are not satisfied, or such U.K. Holder elects for an otherwise exempt dividend to be taxable, U.K. corporation tax will be chargeable on the amount of any dividends (at the current rate of 19%).

Chargeable Gains

A disposal or deemed disposal of ADSs by a U.K. Holder may, depending on the U.K. Holder's circumstances and subject to any available exemptions or reliefs (such as the annual exemption), give rise to a chargeable gain or an allowable loss for the purposes of U.K. capital gains tax and corporation tax on chargeable gains.

If an individual U.K. Holder who is subject to U.K. income tax at either the higher or the additional rate is liable to U.K. capital gains tax on the disposal of ADSs, the current applicable rate will be 20%. For an individual U.K. Holder who is subject to U.K. income tax at the basic rate and liable to capital gains tax on such disposal, the current applicable rate would be 10%, save to the extent that any capital gains when aggregated with the U.K. Holder's other taxable income and gains in the relevant tax year exceed the unused basic rate tax band. In that case, the rate currently applicable to the excess would be 20%.

If a corporate U.K. Holder becomes liable to U.K. corporation tax on the disposal (or deemed disposal) of ADSs, the main rate of U.K. corporation tax (currently 19%) would apply. Indexation allowance is not available in respect of disposals of ADSs acquired on or after January 1, 2018 (and only covers the movement in the retail prices index up until 31 March 2017, in respect of assets acquired prior to that date). A holder of ADSs which is not resident for tax purposes in the United Kingdom should not normally be liable to U.K. capital gains tax or corporation tax on chargeable gains on a disposal (or deemed disposal) of ADSs unless the person is carrying on (whether solely or in partnership) a trade, profession or vocation in the United Kingdom through a branch or agency (or, in the case of a corporate holder of ADSs, through a permanent establishment) to which the ADSs are attributable. However, an individual holder of ADSs who is treated as resident outside the United Kingdom for the purposes of a double tax treaty, or who has ceased to be resident for tax purposes in the United Kingdom for a period of less than five years and who disposes of ADSs during that period may be liable on his or her return to the United Kingdom to U.K. tax on any capital gain realized (subject to any available exemption or relief).

Stamp Duty and Stamp Duty Reserve Tax

The discussion below relates to the holders of our ordinary shares or ADSs wherever resident, however it should be noted that special rules may apply to certain persons such as market makers, brokers, dealers or intermediaries.

Issue of Shares

No U.K. stamp duty or stamp duty reserve tax, or SDRT, is payable on the issue of the underlying ordinary shares in the company.

Transfers of Shares

Transfers of the ordinary shares (including instruments transferring ordinary shares and agreements to transfer ordinary shares) are subject to stamp duty or SDRT at a rate of 0.5% on the value of the transfer.:

- the ordinary shares are admitted to trading on LSE, but are not listed on any market (with the term "listed" being construed in accordance with section 99A of the Finance Act 1986), and this has been certified to Euroclear;

In the event that either of the above requirements is not met, stamp duty or SDRT will generally apply to transfers of, or agreements to transfer, ordinary shares. Where applicable, the purchaser normally pays the stamp duty or SDRT.

Issue and Transfers of ADSs

U.K. stamp duty or SDRT is payable on the issue or transfer of (including an agreement to transfer) ADSs in the company at a rate of 0.5%.

F. Dividends and Paying Agents

Not applicable.

G. Statements by Experts

Not applicable.

H. Documents on Display

We are subject to the informational requirements of the Exchange Act. Accordingly, we are required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K. You may inspect and copy reports and other information filed with the SEC at the public reference facilities of the SEC located at 100 F Street, N.E., Washington, D.C. 20549. You may also obtain copies of the documents at prescribed rates by writing to the Public Reference Section of the SEC at 100 F Street, N.E., Washington, DC 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room. The SEC also maintains a website at http://www.sec.gov from which certain filings may be accessed.

We also make available on our website, free of charge, our Annual Report and the text of our reports on Form 6-K, including any amendments to these reports, as well as certain other SEC filings, as soon as reasonably practicable after they are electronically filed with or furnished to the SEC. Our website address is www.okyopharma.com. The information contained on our website is not incorporated by reference in this Annual Report.

I. Subsidiary Information

For information on our subsidiaries, see "Item 4C. Organizational Structure."

ITEM 11: 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.

ITEM 12: DESCRIPTION OF SECURITIES OTHER THAN EQUITY SECURITIES

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

Fees and Expenses

JPMorgan Chase Bank, N.A., or JPMorgan, as depositary, registers and delivers the American Depositary Shares, also referred to as ADSs. Each ADS represents an ownership interest in a designated number of ordinary shares that are on deposit with the custodian, as agent of the depositary, under the deposit agreement among ourselves, the depositary and the ADS holders. Each ADS will also represent any securities, cash or other property deposited with the depositary but which they have not distributed directly to the ADS holders. The depositary's office is located at 4 New York Plaza, Floor 12, New York, NY, 10004. A copy of the deposit agreement is incorporated by reference as an exhibit to this Annual Report on Form 20-F.

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 American Depository Receipt (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 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 Chase Bank, N.A. ("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.

J.P. Morgan, and/or its agent may act as principal for such conversion of foreign currency. For further details see https://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 on 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.

PART II

ITEM 13: DEFAULTS, DIVIDEND ARREARAGES AN DELINQUENCIES

None.

ITEM 14: MATERIAL MODIFICATIONS TO THE RIGHTS OF SECURITY HOLDERS AND USE OF PROCEEDS

None.

ITEM 15: CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Disclosure Controls and Procedures

The Company's management, with the participation of the Company's Chief Executive Officer and Chief Financial Officer, have evaluated the effectiveness of the Company's disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of March 31, 2022. Based on that evaluation, the Company's Chief Executive Officer and the Company's Chief Financial Officer have concluded that as of March 31, 2022, due to the existence of the material weaknesses in the Company's internal control over financial reporting described below, the Company's disclosure controls and procedures were not effective.

Management's Annual Report on Internal Control over Financial Reporting

The Company's management is responsible for establishing and maintaining adequate internal controls over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act. The Company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with International Financial Reporting Standards (IFRS) as issued by the International Accounting Standards Board (IASB), and IFRIC interpretations as applicable to companies reporting under IFRS.

Because of their inherent limitations, internal controls over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Under the supervision and with the participation of management, the Company's Chief Executive Officer and the Company's Chief Financial Officer, the Company conducted an informal evaluation, based on regular verbal discussions between management and the audit committee, of the effectiveness of its internal control over financial reporting based on the framework described in Internal Control-Integrated Framework issued by the Commission of Sponsoring Organizations of the Treadway Commission, as revised in 2013. Based on that evaluation, management has concluded that the Company did not maintain effective internal control over financial reporting as of the period ended March 31, 2022 due to the existence of the material weaknesses in internal control over financial reporting described below.

Material Weaknesses

A deficiency in internal control over financial reporting exists when the design or operation of a control does not allow management or employees, in the normal course of performing their assigned functions, to prevent or detect misstatements on a timely basis. A material weakness is a deficiency, or a combination of deficiencies, in internal controls over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

The Board and management have determined that the Company did not maintain effective internal control over financial reporting as of the period ended March 31, 2022 due to the existence of the following material weaknesses identified by management. A consequence of the material weaknesses identified below did result in material errors , but these were identified during the audit phase and adjusted for in the consolidated financial statements. Management therefore believes that our consolidated financial statements present fairly the consolidated financial position, results of operations and cash flows for the periods covered. However, management recognizes that the failure of the internal control over financial reporting to operate effectively as described below could result in a material misstatement which may not have been detected by our controls:

Lack of Accounting Resources

Due to the limited financial resources available for expenditure other than research and development, the Company had a lack of accounting resources resulting in over reliance on key staff, professional opinions, a weakness in monitoring controls and other oversight procedures, which resulted in corrected misstatements.

Remediation efforts

Management intends to remediate this item in the following manner:

i. Additional funds have been made available to enable the Company to address its lack of accounting resources and additional resources have been hired and formalized review controls have been implemented.

ii. Periodic assessments will be performed to evaluate the sufficiency of the Company's accounting resources and needs for recruiting additional personnel, in addition to providing our accounting personnel with regular training over applicable IFRS accounting standards, complex accounting and financial reporting subject matters, and SEC reporting.

We intend to complete the remediation of the material weaknesses discussed above as soon as practicable, but we can give no assurance that we will be able to do so. Designing and implementing effective disclosure controls and procedures is a continuous effort that requires us to anticipate and react to changes in our business and the economic and regulatory environments and to devote significant resources to maintain a financial reporting system that adequately satisfies our reporting obligations. The remedial measures that we have taken and intend to take may not fully address the material weaknesses that we have identified, and material weaknesses in our disclosure controls and procedures may be identified in the future. Should we discover such conditions, we intend to remediate them as soon as practicable. We are committed to taking appropriate steps for remediation, as needed.

ITEM 16A: AUDIT COMMITTEE FINANCIAL EXPERT

The members of our audit, risk and disclosure committee are Mr John Brancaccio, Mr Bernard Denoyer and Mr. Willy Simon. Mr. John Brancaccio is the chair of the audit, risk and disclosure committee. Each of our audit, risk and disclosure committee members satisfies the independence requirements of Rule 5605(a)(2) of the Nasdaq Stock Market Marketplace Rules and the independence requirements of Rule 10A-3(b)(1) under the Exchange Act. Our board of directors has determined that Mr. John Brancaccio is an "audit committee financial expert" as defined in Item 16A of Form 20-F.

ITEM 16B: CODE OF 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 Annual Report, and you should not consider information on our website to be part of this Annual Report.

ITEM 16C: PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table sets forth, for each of the years indicated, the aggregate fees billed to us for services rendered by Mazars LLP, our independent registered public accounting firm.

	Year Ending March 31,	
	2022	**2021**
	(in thousands)	
Audit fees	201	59
Other assurance services[(1)]	149	73
Total	**350**	**132**

(1) Other assurance services include interim reviews and audit opinions required for other filings

ITEM 16D: EXEMPTIONS FROM THE LISTING STANDARDS FOR AUDIT COMMITTEES

Not applicable.

ITEM 16E: PURCHASES OF EQUITY SECURITIES BY THE ISSUER AND AFFILIATED PURCHASERS

None.

ITEM 16F: CHANGE IN REGISTRANTS CERTIFYING ACCOUNTANT

None.

ITEM 16G: CORPORATE GOVERNANCE

The Sarbanes-Oxley Act of 2002, as well as related rules subsequently implemented by the SEC, requires foreign private issuers, including our company, to comply with various corporate governance practices. In addition, Nasdaq rules provide that foreign private issuers may follow home country practices in lieu of the Nasdaq corporate governance standards, subject to certain exceptions and except to the extent that such exemptions would be contrary to U.S. federal securities laws. The home country practices followed by our company in lieu of Nasdaq rules are described below:

- We do not follow Nasdaq's quorum requirements applicable to meetings of shareholders. Such quorum requirements are not required under Guernsey law. In accordance with generally accepted business practice, our articles of association provide alternative quorum requirements that are generally applicable to meetings of shareholders.

- We do not follow Nasdaq's requirements that non-management directors meet on a regular basis without management present. Our board of directors may choose to meet in executive session at their discretion.

- We do not follow Nasdaq's requirements to seek shareholder approval for the implementation of certain equity compensation plans, the issuances of ordinary shares under such plans, or in connection with certain private placements of equity securities. In accordance with Guernsey law, we are not required to seek shareholder approval to allot ordinary shares in connection with applicable employee equity compensation plans. We will follow Guernsey law with respect to any requirement to obtain shareholder approval prior to any private placements of equity securities.

We intend to take all actions necessary for us to maintain compliance as a foreign private issuer under the applicable corporate governance requirements of the Sarbanes-Oxley Act of 2002, the rules adopted by the SEC and Nasdaq's listing standards.

Because we are a foreign private issuer, our directors and senior management are not subject to short-swing profit and insider trading reporting obligations under Section 16 of the U.S. Securities Exchange Act of 1934, as amended, or Exchange Act. They are, however, subject to the obligations to report changes in share ownership under Section 13 of the Exchange Act and related SEC rules.

ITEM 16H: MINE SAFETY DISCLOSURE

Not applicable.

ITEM 16L: DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 17: FINANCIAL STATEMENTS

We have elected to furnish financial statements and related information specified in Item 18.

ITEM 18: FINANCIAL STATEMENTS

See the Financial Statements beginning on page F-1.

ITEM 19: EXHIBITS

Exhibit No.	Description
3.1**	Memorandum and Articles of Incorporation of OKYO Pharma Limited
2.1	Form of Deposit Agreement. (Incorporated by reference to Exhibit 4.1 to Amendment No. 6 to Form F-1 filed on May 13, 2022).
2.2	Form of American Depositary Receipt (included in Exhibit 2.1).
8.1	List of Subsidiaries. (Incorporated by reference to Exhibit 4.1 to Amendment No. 6 to Form F-1 filed on May 13, 2022).
10.1**	OKYO Pharma Limited Share Option Plan With Non-Employee Sub-Plan And US Sub-Plan (Incorporated by reference to Exhibit 4.1 to Amendment No. 6 to Form F-1 filed on May 13, 2022).
10.2**	Executive Employment Agreement dated December 21, 2020 between Gary S. Jacob and OKYO Pharma Limited as amended on January 19, 2021. (Incorporated by reference to Exhibit 4.1 to Amendment No. 6 to Form F-1 filed on May 13, 2022).
10.3**	Collaboration Agreement between On Target Therapeutics, LLC and OKYO Pharma Limited dated June 4, 2018 (Incorporated by reference to Exhibit 4.1 to Amendment No. 6 to Form F-1 filed on May 13, 2022).
10.4**	Amendment to Collaboration Agreement between On Target Therapeutics, LLC and OKYO Pharma Limited dated October 22, 2018 (Incorporated by reference to Exhibit 4.1 to Amendment No. 6 to Form F-1 filed on May 13, 2022).
10.5**	License Agreement dated as of May 1, 2018 by and between Tufts Medical Center, Inc. and OKYO Pharma Limited (Incorporated by reference to Exhibit 4.1 to Amendment No. 6 to Form F-1 filed on May 13, 2022).
10.6**	Shared Services Agreement dated as of January 1, 2018 by and between OKYO Pharma Limited and Tiziana Life Sciences plc (Incorporated by reference to Exhibit 4.1 to Amendment No. 6 to Form F-1 filed on May 13, 2022).
10.7**	License and Sublicense Agreement dated May 22, 2017 by and between On Target Therapeutics, LLC and OKYO Pharma Limited (Incorporated by reference to Exhibit 4.1 to Amendment No. 6 to Form F-1 filed on May 13, 2022).
10.8**	First Amendment to the License and Sublicense Agreement dated March 25, 2021 by and between On Target Therapeutics, LLC and OKYO Pharma Limited. (Incorporated by reference to Exhibit 4.1 to Amendment No. 6 to Form F-1 filed on May 13, 2022).
10.9**	Collaboration Agreement dated August 6, 2019 between Tufts Medical Center, Inc. and OKYO Pharma Limited. (Incorporated by reference to Exhibit 4.1 to Amendment No. 6 to Form F-1 filed on May 13, 2022).
12.1*	Certification by the Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
12.2*	Certification by the Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
13.1*	Certification by the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
13.2*	Certification by the Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
15.1*	Consent of Mazars LLP.
101.INS	XBRL Instance Document.
101.SCH	XBRL Taxonomy Extension Schema Document.
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed Herewith

SIGNATURES

The Registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

OKYO PHARMA LTD

By: */s/ Gary Jacob*
Gary Jacob
Chief Executive Officer

Date: August xx, 2022

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

OKYO PHARMA LIMITED

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To 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 three 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 three 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

	Year ended March 31,	
	2022	**2021**
	$	$
ASSETS		
Current assets:		
Cash and cash equivalents	2,700,724	6,889,329
Related party receivables	-	27,664
Current taxation receivable	781,688	26,322
Other receivables	812,956	43,371
Total current assets	4,295,368	6,986,686
Property and Equipment, net	5,225	6,057
Right of use asset	-	98,579
Total non-current assets	5,225	104,636
Total assets	4,300,593	7,091,322
LIABILITIES AND SHAREHOLDERS' EQUITY		
Liabilities:		
Current liabilities:		
Trade and other payables	1,306,150	1,673,154
Related party payable	47,041	-
Lease liabilities - current	-	34,148
Total current liabilities	1,353,191	1,707,302
Lease liabilities - non current	-	64,612
Total liabilities	1,353,191	1,771,914
Shareholders' Equity:		
Share premium	123,976,510	111,629,173
Share options reserve	2,355,040	636,313
Warrants reserve	53,413	861,214
Convertible Loan Note reserve	-	8,370,836
Foreign currency translation reserve	(11,011,527)	(10,174,375)
Retained deficit	(112,426,034)	(106,003,753)
Total shareholders' equity	2,947,402	5,319,408
Total liabilities and shareholders' equity	4,300,593	7,091,322

OKYO Pharma Limited
Consolidated Statements of Operations and Comprehensive Loss

	Year ended March 31,		
	2022	**2021**	**2020**
	$	$	$
Operating expenses:			
Research and development	(1,301,178)	(173,821)	(518,098)
Operating Expenses	(4,916,388)	(3,192,385)	(1,016,548)
Total operating expenses	(6,217,566)	(3,366,206)	(1,534,646)
Other income/(expense):			
Finance Income	-	-	48,125
Finance (expense)	-	(1,123)	(1,158)
Impairment of loan	-	(11,172)	(132,668)
Loss from operations before income taxes	(6,217,566)	(3,378,501)	(1,620,347)
Income tax provision	786,521	24,994	76,288
Loss for the year	(5,431,045)	(3,353,507)	(1,544,059)
Other Comprehensive loss:			
Exchange differences on translating foreign operations	(837,152)	346,365	86,654
Comprehensive loss	(6,268,197)	(3,007,142)	(1,457,405)
Basic and diluted loss per share attributable to common shareholders	$ (0.01)	$ (0.01)	$ (0.00)

OKYO Pharma Limited
Consolidated Statements of Shareholders' Equity

	No. of Shares	Share Capital	Options reserve	Warrant reserve	Convertible Loan Note reserve	Retained Earnings	Translation Reserve	Total Equity
		$	$	$	$	$	$	$
Balance at 31 March 2019	524,108,283	**111,741,860**	**57,101**	**30,242**	**—**	**(100,888,643)**	**(10,607,394)**	**333,166**
Issue of share capital	112,188,766	965,171	—	—	—	—	—	965,171
Options charge		—	36,340	—	—	—	—	36,340
Warrants charge		(627,047)	—	609,661	—	—	—	(17,386)
Total transactions		338,124	36,340	609,661	—	—	—	984,125
Comprehensive income					—			
Loss for the period		—	—	—	—	(1,544,059)	—	(1,544,059)
Currency translation		—	—	—	—	—	86,654	86,654
Total comprehensive income		—	—	—	—	(1,544,059)	86,654	(1,457,405)
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	—	(558,396)	—	—	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
Comprehensive income					—			
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**
Convertible loan note and warrant interest	—	—	—	546,318	444,918	(991,236)	—	—
Convertible loan note conversion	315,086,410	8,876,397	—	—	(8,876,397)	—	—	—
Currency translation on Convertible Loan note conversion	—	—	—	—	654,833	—	—	654,833
Transfer between equity reserves		—	—	594,190	(594,190)	—	—	—
Options charge	—	—	1,737,876	—	—	—	—	1,737,876
Options forfeiture			(19,149)					(19,149)
Warrants Exercised	386,512,756	3,470,940	—	(2,010,030)	—	—	—	1,460,910
Warrants charge	—	—	—	61,721	—	—	—	61,721
Total transactions	701,599,166	12,347,337	1,718,727	(807,801)	(8,370,836)	(991,236)	—	3,896,191
Comprehensive income								
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**

OKYO Pharma Limited
Consolidated Statements of Cash Flows

	Year ended March 31,		
	2022	**2021**	**2020**
CASH FLOWS FROM OPERATING ACTIVITIES:			
Loss from operations before income taxes	$ (6,217,566)	$ (3,378,501)	$ (1,620,347)
Adjustments to reconcile net loss to net cash used in operating activities:			
Share option charge	1,737,876	550,138	36,340
Warrant charge	61,721	83,006	42,846
Forfeiture of options	(19,149)	(5,751)	-
Depreciation of fixed assets	2,331	1,510	426
Amortization of right of use asset	-	11,601	5,553
(Gain)/Loss on foreign exchange	(9,230)	4,056	13,915
Impairment of loan to West African Minerals Ltd	-	11,171	132,668
Gain on disposal of right of use asset	(179)	(818)	-
Net decrease/(increase) in related party receivables	27,376	(3,862)	(543)
Net increase/(decrease) in related party payables	48,900	(46,311)	38,049
Net (increase)/decrease in operating assets/other receivables	(802,154)	208,931	(122,190)
Net (decrease)/increase in trade and other payables	(297,991)	886,093	271,218
Cash inflow from taxation	-	78,540	-
Net cash used in operating activities	(5,468,065)	(1,600,198)	(1,202,066)
CASH FLOWS FROM INVESTING ACTIVITIES			
Acquisition of property, plant and equipment	(1,669)	(6,943)	-
Loan to West African Minerals Ltd	-	(11,171)	(132,668)
Net cash used in investing activities	(1,669)	(18,114)	(132,668)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of ordinary shares	-	230,019	990,639
Proceeds from issuance of convertible loan notes	-	7,593,380	-
Processed from options exercised	-	15,870	-
Processed from warrants exercised	2,153,270	-	-
Loan to related party	-	-	(518,000)
Loan repayment from related party	-	-	496,810
Repayment of leasing liabilities	-	(12,331)	(6,139)
Net cash provided by financing activities	2,153,270	7,826,938	963,310
Net (decrease)/increase in cash and cash equivalents	(3,316,464)	6,208,627	(371,423)
Cash and cash equivalent, beginning of period	6,889,329	235,485	627,616
Exchange difference	(872,141)	445,217	(20,708)
Cash and cash equivalent, end of period	2,700,724	6,889,329	235,485

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 reorganisation 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 R&D 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, that are relevant to the Group or that have had any material impact in the year to March 31, 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 unrealised gains on transactions between group companies are eliminated upon consolidation. Unrealised 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 recognised to the extent that it is probable that the future taxable profit will be available against which the temporary differences can be utilised.

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 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 capitalised 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. Licence fees expenses are recognised 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 recognised 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.

(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 amortised cost

At each reporting date the Group recognises a loss allowance for expected credit losses on financial assets measured at amortised cost.

In establishing the appropriate amount of loss allowance to be recognised, 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 recognises 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 recognised 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 recognises 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 exceeds the 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 capitalised 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 recognised 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 recognising 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 recognises 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 recognised in profit and loss on a straight-line basis over the term of the lease.

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 recognised 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. The accrued interest on the principal amount is also recorded in the Convertible loan note reserve as it is convertible into equity. 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.

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.

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 recognised as expense over the requisite service period of the award, which is usually the vesting period. Compensation expense is recognised 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:

	Year Ended March 31,		
	2022	**2021**	**2020**
Group	**$**	**$**	**$**
Director fees including bonus (excluding Chairman's bonus)	707,385	278,224	122,101
Chairman's bonus	-	1,160,347	-
Auditor's Remuneration (refer to Note 20) *	349,665	131,511	53,402
Legal and Professional fees	1,143,300	343,422	195,433
(Gain)/Loss on disposal of leases	(179)	-	-
FX Gains and losses	(13,577)	200,061	200,061
Depreciation	2,423	1,512	212

* 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

	Year ended March 31,		
	2022 $	2021 $	2020 $
Group			
Staff costs comprised:			
Directors' salaries	707,385	1,438,571	122,101
Wages and salaries	323,186	121,702	229,347
Social security costs	84,449	9,543	68,740
Recruitment Costs	14,259	12,922	-
	1,129,279	1,582,739	420,188
The average monthly number of employees, including directors, employed by the group during the years ending March 31, 2021, and March 31, 2020 were:			
Research and Development	2	1	1
Corporate and administration	5	5	3
	7	6	4

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, March 31 2020: $2,774)

7. REMUNERATION OF KEY MANAGEMENT PERSONNEL

Directors of the Group and Company received the following remuneration during the years ending March 31 2021 and 2020:

	Year ended March 31,							
	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	-	-	-	-
	283	**75**	**350**	**1,589**	**158**	**1,201**	**85**	**503**

$'000	Year ended March 31, 2020			
	Directors fees	Bonus	Salary	Share based payment expenses
W Simon	41	-	-	4
K. Shailubhai (6)	38	-	-	31
G Macrae (4)	8	-	-	-
L Zambeletti (7)	36	-	-	6
	122	**-**	**-**	**41**

(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

(7) Leopoldo Zambeletti resigned as Director on 18 December 2019

The following share options were granted to Directors in the year:

	2022 Number of options	2021 Number of options	2020 Number of options
J Brancaccio	325,000	450,000	-
G Jacob	3,250,000	40,000,000	-
B Denoyer	1,000,000	-	-
	4,575,000	**40,450,000**	**-**

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 $'000	2021 $'000	2020 $'000
Short-term employee benefits	1,026	1,455	351
Share based payments	1,815	515	41
	2,841	1,970	392

8. TAXATION

	Year ended March 31,		
	2022 $	**2021 $**	**2020 $**
Group			
Current year tax (credit)	(509,282)	(24,952)	-
Adjustments in respect of prior periods	(277,239)	(42)	(76,289)
Deferred tax			
Origination and reversal of timing differences	-	-	-
Total tax (credit) for the period	(786,521)	(24,994)	(76,289)
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)	(1,620,347)
Loss charged at standard rate of corporation tax 19%	(1,181,337)	(641,915)	(307,866)
Tax losses arising in the year not recognized	524,870	660,594	340,114
Tax losses surrendered for Research and Development	667,335	-	-
Expenses not deductible for taxation	370,306	-	145
Tax increase from effect of capital allowances and depreciation	(3)	(334)	81
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)	(76,289)
Consolidation adjustment in relation to foreign exchange movements	(3,983)	135	(32,504)
Loans written off	-	-	-
Total tax (credit) for the period	(786,521)	(24,994)	(76,289)

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, 2020: $4,421,886) to carry forward for use against future profits.

9. FINANCE INCOME AND COSTS

	Year ended March 31,		
	2022 $	2021 $	2020 $
Finance Income			
Interest income	-	-	48,125
Total finance income	-	-	48,125
Finance Expenses			
Interest expense on lease liabilities	-	(1,122)	(1,158)
Total finance expenses	-	(1,123)	(1,158)

10. PROPERTY, PLANT AND EQUIPMENT

Details of the Group's property, plant and equipment are as follows:

$	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	5,225

11. OTHER RECEIVABLES

	Year ended March 31,	
$	**2022**	**2021**
Group		
Other receivables	19,130	4,499
VAT receivable	82,617	17,799
Prepayments	711,209	21,072
	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

	Year ended March 31,	
$000	**2022**	**2021**
Group		
Trade payable	741,807	210,992
Accruals	457,773	71,093
Bonus accrual	106,570	1,391,069
	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 Company's ability to continue as a going concern and to maximise shareholder value through the optimisation of the debt and equity balance.

The Company manages its capital to maximise the return to the shareholders through the optimisation 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.

Issued ordinary shares of US$0.00 each	Shares Number	Share capital $
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

Issuance of ordinary shares

In May 2019, 36,363,636 ordinary shares were issued at an issue price of 1.1p per ordinary share by way of a placing of ordinary shares to raise finance.

In March 2020, 75,825,130 ordinary shares were issued at an issue price of 1.1p per ordinary share by way of a further placing of ordinary shares to raise finance.

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.

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	
	Options	Weighted Average exercise price (cents)	Options	Weighted Average exercise price (cents)
Outstanding at 1 April	60,750,000	6.90	19,500,000	5.58
Granted	28,150,000	8.41	42,250,000	7.31
Forfeited	(16,500,000)	5.91	(750,000)	6.21
Exercised	-	-	(250,000)	6.21
Outstanding at 31 March	72,400,000	7.49	60,750,000	6.90
Exercisable at 31 March	14,437,500	7.36	9,250,000	6.21

	2020	
	Weighted Average exercise price (cents)	Options
Outstanding at 1 April	5.58	23,000,000
Granted	-	-
Forfeited	(5.58)	(3,500,000)
Exercised	-	-
Outstanding at 31 March	5.58	19,500,000
Exercisable at 31 March	5.58	4,875,000

During the year ending 31 March 2022, no options were exercised. During the year ending 31 March 2021, 250,000 options were exercised.

The total outstanding fair value charge of the share option instruments is deemed to be approximately $2,072,515 (2021: $2,682,050). A share-based payment charge for the year of $1,718,727 (2021: $545,582) 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 March 31, 2022 is 7.77 years. (2021: 8.07 years).

Share options outstanding at the end of the year 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:

	Grant Date		
	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 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 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, 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 (cents)	Warrants	Weighted Average exercise price (cents)
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

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 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 $43,348 (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 of $61,721 (2021: $81,914) has been expensed in the statement of comprehensive income.

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	● 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	● 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	● 2.15% coupon per annum Conversion price of 8.5p	4,506,446
17 August 2020	● 2.15% coupon per annum ● Conversion price of 8.5p	1,882,641
3 September 2020	● 2.15% coupon per annum ● Conversion price of 8.5p	663,055
Fees relating to all other equity fundraise issued as CLN	● 2.15% coupon per annum ● Conversion price of 8.5p	525,922
		8,151,777

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
	696,665	92,186	788,851

Group	2021		
$	Less than 3 months	3 to 12 months	Total
Trade and other payables	110,179	100,813	210,992
Related party payables	-	-	-
	110,179	100,813	210,992

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 monitor 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 PLC. 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.

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.

	Year ended March 31,	
	2022	**2021**
(Loss) attributable to equity holders of the company ($)	(6,268,197)	(3,353,507)
Weighted average number of ordinary shares in issue	979,212,888	672,767,629
Basic and dilutive loss per share (cents per share)	(0.01)	(0.01)

	Year ended March 31, 2020
(Loss) attributable to equity holders of the company ($)	(1,544,059)
Weighted average number of ordinary shares in issue	595,474,039
Basic and dilutive loss per share (cents per share)	(0.00)

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 recognising 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 agreement on its existing office. The new leases has 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
Depreciation of early terminated lease	(4,060)
Early Termination write off	(27,069)
Impact of Foreign exchange	1,030
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)
	-	98,760

Lease liabilities are presented in the statement of financial position as follows:

	31 March 2022 $	31 March 2021 $
Current	-	34,148
Non-current	-	64,612
	-	98,760

Operating leases

At March 31, 2022 and March 31, 2021, the company had annual commitments under non-cancellable operating leases:

Operating leases which expire:	31 March 2022 $	31 March 2021 $
Within one year	18,713	-
	18,713	-

20. Auditor's Remuneration

During the period, the group obtained the following services from the company's auditors:

	31 March 2022	31 March 2021
	$	$
Fees payable to the company's auditors for the audit of the parent company and consolidated financial statements	200,773	58,874
Fees payable to the company's auditors for other services:		
Audit-related assurance services	148,892	72,637
	349,665	131,511

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
	2,700,724	6,889,329

22. Commitments 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 commercialisation 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 Depository 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.

Exhibit 12.1

CERTIFICATION

I, Gary Jacob, certify that:

1. I have reviewed this annual report on Form 20-F of OKYO Pharma Ltd;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: August 15, 2022

/s/ Gary Jacob
Gary Jacob
Chief Executive Officer

Exhibit 12.2

CERTIFICATION

I, Keeren Shah, certify that:

1. I have reviewed this annual report on Form 20-F of OKYO Pharma Ltd;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: August 15, 2022

/s/ Keeren Shah
Keeren Shah
Chief Financial Officer

Exhibit 13.1

CERTIFICATION

The certification set forth below is being submitted in connection with OKYO Pharma Ltd's Annual Report on Form 20-F for the fiscal year ended March 31, 2022 (the "Report") for the purpose of complying with Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code.

Gary Jacob, Chief Executive Officer of OKYO Pharma Ltd, certifies that, to the best of his knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of OKYO Pharma Ltd

Date: August 15, 2022

/s/ Gary Jacob
Name: Gary Jacob
Chief Executive Officer

Exhibit 13.2

CERTIFICATION

The certification set forth below is being submitted in connection with OKYO Pharma Ltd's Annual Report on Form 20-F for the fiscal year ended March 31, 2022 (the "Report") for the purpose of complying with Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code.

Keeren Shah, Chief Financial Officer of OKYO Pharma Ltd, certifies that, to the best of his knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of OKYO Pharma Ltd

Date: August 15, 2022

/s/ Keeren Shah
Name: Keeren Shah
Chief Financial Officer

Exhibit 12.1

CERTIFICATION

I, Gary Jacob, certify that:

1. I have reviewed this annual report on Form 20-F of OKYO Pharma Ltd;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15 (f)) for the company and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: August 15, 2022

/s/ Gary Jacob
Gary Jacob
Chief Executive Officer

Exhibit 12.2

CERTIFICATION

I, Keeren Shah, certify that:

1. I have reviewed this annual report on Form 20-F of OKYO Pharma Ltd;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15 (f)) for the company and have:

   a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c. Evaluated the effectiveness of the company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d. Disclosed in this report any change in the company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the company's internal control over financial reporting; and

5. The company's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

   a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

   b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: August 15, 2022

/s/ Keeren Shah
Keeren Shah
Chief Financial Officer

Exhibit 13.1

CERTIFICATION

The certification set forth below is being submitted in connection with OKYO Pharma Ltd's Annual Report on Form 20-F for the fiscal year ended March 31, 2022 (the "Report") for the purpose of complying with Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code.

Gary Jacob, Chief Executive Officer of OKYO Pharma Ltd, certifies that, to the best of his knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of OKYO Pharma Ltd

Date: August 15, 2022

/s/ Gary Jacob
Name: Gary Jacob
Chief Executive Officer

Exhibit 13.2

CERTIFICATION

The certification set forth below is being submitted in connection with OKYO Pharma Ltd's Annual Report on Form 20-F for the fiscal year ended March 31, 2022 (the "Report") for the purpose of complying with Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934 (the "Exchange Act") and Section 1350 of Chapter 63 of Title 18 of the United States Code.

Keeren Shah, Chief Financial Officer of OKYO Pharma Ltd, certifies that, to the best of his knowledge:

1. the Report fully complies with the requirements of Section 13(a) or 15(d) of the Exchange Act; and

2. the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of OKYO Pharma Ltd

Date: August 15, 2022

/s/ Keeren Shah
Name: Keeren Shah
Chief Financial Officer